



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, 441, 447

[CMS-2442-F]

RIN 0938-AU68

Medicaid Program; Ensuring Access to Medicaid Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule takes a comprehensive approach to improving access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across fee-for-service (FFS), managed care delivery systems, and in home and community-based services (HCBS) programs. These improvements increase transparency and accountability, standardize data and monitoring, and create opportunities for States to promote active beneficiary engagement in their Medicaid programs, with the goal of improving access to care.

DATES: These regulations are effective on July 9, 2024.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

Title XIX of the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals, including

many with low incomes. Under the Medicaid program, each State that chooses to participate in the program and receive Federal financial participation (FFP) for program expenditures must establish eligibility standards, benefits packages, and payment rates, and undertake program administration in accordance with Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the Medicaid “State plan” and, as applicable, related authorities, such as demonstration projects and waivers of State plan requirements. Among other responsibilities, CMS approves State plans, State plan amendments (SPAs), demonstration projects authorized under section 1115 of the Act, and waivers authorized under section 1915 of the Act; and reviews expenditures for compliance with Federal Medicaid law, including the requirements of section 1902(a)(30)(A) of the Act relating to efficiency, economy, quality of care, and access to ensure that all applicable Federal requirements are met.

The Medicaid program provides essential health coverage to tens of millions of people, covering a broad array of health benefits and services critical to underserved populations,¹ including low-income adults, children, parents, pregnant individuals, older adults, and people with disabilities. For example, Medicaid pays for approximately 41 percent of all births in the U.S.² and is the largest payer of long-term services and supports (LTSS),³ the largest, single payer of services to treat substance use disorders,⁴ and services to prevent and treat the Human Immunodeficiency Virus.⁵

On January 28, 2021, the President signed Executive Order (EO) 14009,⁶ “Strengthening Medicaid and the Affordable Care Act,” which established the policy objective to protect and

¹ Executive Order 13985: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

² National Center for Health Statistics. Key Birth Statistics. Accessed at <https://www.cdc.gov/nchs/nvss/births.htm>.

³ Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated September 2023. Accessed at <https://crsreports.congress.gov/product/pdf/IF/IF10343>.

⁴ Soni, Anita. Health Care Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019. Statistical Brief #539, pg 12. February 2022. Agency for Healthcare Research and Quality, Rockville, MD. Accessed at https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf.

⁵ Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at <https://www.kff.org/hiv/aids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/>.

⁶ Executive Order 14009: <https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act>.

strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American. The EO also directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy. On April 5, 2022, EO 14070,⁷ “Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage,” directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. Consistent with CMS’ authorities under the Act, this final rule implements EOs 14009 and 14070 by helping States to strengthen Medicaid and improve access to and quality of care provided.

Ensuring that beneficiaries can access covered services is necessary to the basic operation of the Medicaid program. Depending on the State and its Medicaid program structure, beneficiaries access their health care services using a variety of care delivery systems (for example, FFS, fully-capitated managed care, partially capitated managed care, etc.), including through demonstrations and waiver programs. The volume of Medicaid beneficiaries enrolled in a managed care program in Medicaid has grown from 81 percent in 2016 to 85 percent in 2021, with 74.6 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations.^{8,9} The remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

Current access regulations are neither comprehensive nor consistent across delivery systems or coverage authority (for example, State plan and demonstration authority). For

⁷ Executive Order 14070: <https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage>.

⁸ Medicaid Managed Care Enrollment Report. <https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html>.

⁹ Throughout this document, the use of the term “managed care plan” includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) [as defined in 42 CFR 438.2] and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or primary care case management entities (PCCM entities).

example, regulations at 42 CFR 447.203 and 447.204 relating to access to care, service payment rates, and Medicaid provider participation in rate setting apply only to Medicaid FFS delivery systems and focus on ensuring that payment rates are consistent with the statutory requirements in section 1902(a)(30)(A) of the Act. The regulations do not apply to services delivered under managed care. These regulations are also largely procedural in nature and rely heavily on States to form an analysis and reach conclusions on the sufficiency of their own payment rates.

With a program as large and complex as Medicaid, access regulations need to be multi-factorial to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

In the spring of 2022, we released a request for information (RFI)¹⁰ to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and Children's Health Insurance Program (CHIP) payments are sufficient to enlist enough providers.

Some of the most common feedback we received through the RFI related to ways that we can promote health equity through cultural competency. Commenters shared the importance that

¹⁰ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

cultural competency plays in how beneficiaries access health care and in the quality of health services received by beneficiaries. The RFI respondents shared examples of actions that we could take, including collecting and analyzing health outcomes data by sociodemographic categories; establishing minimum standards for how States serve communities in ways that address cultural competency and language preferences; and reducing barriers to enrollment and retention for racial and ethnic minority groups.

In addition to the topic of cultural competency, commenters also commonly shared that they viewed reimbursement rates as a key driver of provider participation in Medicaid and CHIP programs. Further, commenters noted that aligning payment approaches and setting minimum standards for payment regulations and compliance across Medicaid and CHIP delivery systems, services, and benefits could help ensure that beneficiaries' access to services is as similar as possible across beneficiary groups, delivery systems, and programs.

As mentioned previously in this final rule, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary know if they are or may be eligible for Medicaid, be aware of Medicaid coverage options, and be able to easily apply for and enroll in coverage. The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program initially. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Exchange coverage, or Medicare, when they are no longer eligible for Medicaid coverage but have become eligible for other health coverage programs. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, Enrollment, and Renewal Processes* to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP) (87 FR 54760). This proposed rule was finalized in two parts, the

Streamlining Medicaid; Medicare Savings Program Eligibility Determination and Enrollment Final Rule (88 FR 65230) and the *Streamlining Eligibility & Enrollment final rule* (89 FR 22780).

The third dimension, which is the focus of this final rule, is access to services and supports. This rule addresses additional critical elements of access: (1) potential access, which refers to a beneficiary's access to providers and services, whether or not the providers or services are used; (2) beneficiary utilization, which refers to beneficiaries' actual use of the providers and services available to them; and (3) beneficiaries' perceptions and experiences with the care they did or were not able to receive. These terms and definitions build upon previous efforts to examine how best to monitor access.¹¹

We completed an array of regulatory activities, including three rules: the aforementioned *Streamlining Eligibility & Enrollment* final rules and a final rule entitled *Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality* (as published elsewhere in this issue of the **Federal Register**, *Managed Care* final rule), on managed care including matters of access, and this final rule on access. Additionally, we are taking non-regulatory actions to improve beneficiary access to care (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems.

As noted earlier, we issued the *Streamlining Eligibility & Enrollment* final rules to address the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through those final rules, we streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants/enrollees toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals.

¹¹ Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. "Proposed Medicaid Access Measurement and Monitoring Plan." Washington, D.C.: The Urban Institute. August 2016. Accessed at https://www.urban.org/sites/default/files/publication/88081/2001143-medicaid-access-measurement-and-monitoring-plan_0.pdf.

The Managed Care final rule improves access to care and quality outcomes for Medicaid and CHIP beneficiaries enrolled in managed care by: creating standards for timely access to care and States’ monitoring and enforcement efforts; reducing burden for some State directed payments and certain quality reporting requirements; adding new standards that will apply when States use in lieu of services and settings (ILOSs) to promote effective utilization, and specifying the scope and nature of ILOS; specifying medical loss ratio (MLR) requirements, and establishing a quality rating system for Medicaid and CHIP managed care plans.

Through the Managed Care final rule and this final rule (Ensuring Access to Medicaid Services), we finalize additional requirements to address the third dimension of the health care access continuum: access to services. The requirements outlined later in this section focus on improving access to services in Medicaid by utilizing tools such as FFS rate transparency, standardized reporting for HCBS, and improving the process for interested parties, especially Medicaid beneficiaries, to provide feedback to State Medicaid agencies and for Medicaid agencies to respond to the feedback (also known as a feedback loop).

Through a combination of these four final rules, we address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems. FFP will be available for expenditures that are necessary to implement the activities States will need to undertake to comply with the provisions of these final rules.

Finally, we also believe it is important to acknowledge the role of health equity within this final rule. Medicaid plays a disproportionately large role in covering health care for people from underserved communities in this country.¹² Consistent with EO 13985 on “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),”¹³ which calls for advancing equity for underserved populations, we are working to ensure our programs consistently provide high-quality care to all beneficiaries, and

¹² Guth, M and Artiga, S. Medicaid and Racial Health Equity March 2022. Accessed at <https://www.kff.org/medicaid/issue-brief/medicaid-and-racial-health-equity/>.

¹³ Executive Order 13985: <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

thus advance health equity, consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022-2032¹⁴ and the HHS Equity Action Plan.¹⁵ That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable coverage and care.

We recognize that each State faces a unique set of challenges related to the resumption of its normal program activities after the end of the COVID-19 public health emergency (PHE). More specifically, the expiration of the Medicaid continuous enrollment condition authorized by the Families First Coronavirus Response Act (FFCRA) presents the single largest health coverage transition event since the first open enrollment period of the Affordable Care Act. As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, States were required to maintain enrollment of nearly all Medicaid enrollees. This continuous enrollment condition expired on March 31, 2023, after which States began completing renewals for all individuals enrolled in Medicaid, CHIP, and the BHP. Additionally, many other temporary authorities adopted by States during the COVID-19 PHE expired at the end of the PHE, and States are returning to regular operations across their programs. The resumption of normal Medicaid operations is generally referred to as “unwinding” and the period for States to initiate all outstanding eligibility actions that were delayed because of the FFCRA continuous enrollment condition is called the “unwinding period.” We considered States’ unwinding responsibilities when finalizing the dates for States to begin complying with the requirements being finalized in this rule, but, as noted in the Ensuring Access to Medicaid Services proposed rule, we solicited State feedback on whether our proposals struck the correct balance.

We considered adopting an effective date of 60 days following publication of this final rule and separate compliance dates for various provisions, which we note where relevant in our

¹⁴ CMS Framework for Health Equity 2022–2032: <https://www.cms.gov/files/document/cms-framework-health-equity.pdf>.

¹⁵ HHS Equity Action Plan. April 2022. Accessed at <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf>.

discussion of specific proposals in this final rule. We solicited comment on whether an effective date of 60 days following publication would be appropriate when combined with later dates for compliance for some provisions.

We also solicited comment on the timeframe that would be most achievable and appropriate for compliance with each proposed provision and whether the compliance date should vary by provision.

B. Medical Care Advisory Committees (MCAC)

We obtained feedback during various public engagement activities conducted with States and other interested parties, which supports research findings that the beneficiary perspective and lived Medicaid experience¹⁶ should be considered when making policy decisions related to Medicaid programs.^{17,18} A 2022 report from the HHS Assistant Secretary of Planning and Evaluation (ASPE) noted that including people with lived experience in the policy-making process can lead to a deeper understanding of the conditions affecting certain populations, facilitate identification of possible solutions, and avoid unintended consequences of potential policy or program changes that could negatively impact the people the program aims to serve.¹⁹ We have concluded that beneficiary perspectives need to be central to operating a high-quality health coverage program that consistently meets the needs of all its beneficiaries.

However, effective community engagement is not as simple as planning a meeting and requesting feedback. To create opportunities that facilitate true engagement, it is important to

¹⁶ Lived experience refers to “representation and understanding of an individual’s human experiences, choices, and options and how those factors influence one’s perception of knowledge” based on one’s own life. In this context, we refer to people who have been enrolled in Medicaid currently or in the past. Accessed at <https://aspe.hhs.gov/lived-experience#:~:text=In%20the%20context%20of%20ASPE%E2%80%99s%20research%2C%20people%20with,programs%20th at%20aim%20to%20address%20the%20issue%20%28s%29>.

¹⁷ Zhu JM, Rowland R, Gunn R, Gollust S, Grande DT. Engaging Consumers in Medicaid Program Design: Strategies from the States. *Milbank Q*. 2021 Mar;99(1):99-125. doi: 10.1111/1468-0009.12492. Epub 2020 Dec 15. PMID: 33320389; PMCID: PMC7984666. Accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984666/>.

¹⁸ Key Findings from the Medicaid MCO Learning Hub Discussion Group Series and Roundtable – Focus on Member Engagement and the Consumer Voice. NORC at the University of Chicago. Jan 2021. Accessed at https://www.norc.org/PDFs/Medicaid%20Managed%20Care%20Organization%20Learning%20Hub/MMCOLearningHub_MemberEngagement.pdf.

¹⁹ Syreeta Skelton-Wilson et al., “Methods and Emerging Strategies to Engage People with Lived Experience,” Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, January 4, 2022, <https://aspe.hhs.gov/reports/lived-experience-brief>.

understand and honor strengths and assets that exist within communities; recognize and solicit the inclusion of diverse voices; dedicate resources to ensuring that engagement is done in culturally meaningful ways; ensure timelines, planning processes, and resources that support equitable participation; and follow up with communities to let them know how their input was utilized. Ensuring optimal health outcomes for all beneficiaries served by a program through the design, implementation, and operationalization of policies and programs requires intentional and continuous effort to engage people who have historically been excluded from the process.

Section 1902(a)(4) of the Act is a longstanding statutory provision that, as implemented in part in regulations currently codified at 42 CFR 431.12,²⁰ requires States to have a Medical Care Advisory Committee (MCAC) in place to advise the State Medicaid agency about health and medical care services. Under section 1903(a)(7) of the Act, expenditures made by the State agency to operate the MCAC are eligible for Federal administrative match.

The current MCAC regulations at § 431.12 require States to establish such a committee and describe high-level requirements related to the composition of the committee, the scope of topics to be discussed, and the support the Committee can receive from the State in its administration. Due to the lack of specificity in the current regulations, these regulations have not been consistently implemented across States. For example, there is no mention of how States should approach meeting periodicity or meeting structure in ways that are conducive to including a variety of Medicaid interested parties. There is also no mention in the regulations about how States can build accountability through transparency with their interested parties by publicly sharing meeting dates, membership lists, and the outcomes of these meetings. The regulations also limit the required MCAC discussions to topics about health and medical care services – which in turn limits the benefits of using the MCAC as a vehicle that can provide States with varied ideas, suggestions, and experiences on a range of issues related to the effective administration of the Medicaid program.

²⁰ The regulatory provision was originally established in 36 FR 3793 at 3870.

As such, we have determined the requirements governing MCACs need to be more robust to ensure all States are using these committees optimally to realize a more effective and efficient Medicaid program that is informed by the experiences of beneficiaries, their caretakers, and other interested parties. The current regulations have been in place without change for over 40 years.²¹ Over the last four decades, we have learned that the current MCAC requirements are insufficient in ensuring that the beneficiary perspective is meaningfully represented on the MCAC. Recent research regarding soliciting input from individuals with lived experience, including our recent discussions with States about their MCAC, provide a unique opportunity to re-examine the purpose of this committee and update the policies to reflect four decades of program experience.

In 2022, we gathered feedback from various public engagement activities conducted with States, other interested parties, and directly from a subset of State Medicaid agencies that described a wide variation in how States are operating MCACs today. The feedback suggested that some MCACs operate simply to meet the broad Federal requirements. As discussed previously in this section, we have discovered that our current regulations do not further the statutory goal of meaningfully engaging Medicaid beneficiaries and other low-income people in matters related to the operation of the Medicaid program. Meaningful engagement can help develop relationships and establish trust between the communities served and the Medicaid agency to ensure States receive important information concerning how to best provide health coverage to their beneficiary populations. The current MCAC regulations establish the importance of broad feedback from interested parties, but they lack the specificity that can ensure States use MCACs in ways that facilitate that feedback.

The current regulations require that MCACs must include Medicaid beneficiaries as committee members. However, the regulations do not mention or account for the reality that other interested parties can stifle beneficiary contribution in a group setting. For example, when

²¹ 43 FR 45091 at 45189.

there are a small number of beneficiary representatives in large committees with providers, health plans, and professional advocates, it can be uncomfortable and intimidating for beneficiaries to share their perspective and experience. Based on these reasons, several States already use beneficiary-only groups that feed into larger MCACs.

Improvements to the MCACs are critical to ensuring a robust and accurate understanding of beneficiaries' challenges to health care access. The current regulations value State Medicaid agencies having a way to get feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how MCACs can be used to benefit the Medicaid program more expressly by more fully promoting the beneficiary voice. MCACs need to provide a forum for beneficiaries and people with lived experience with the Medicaid program to share their experiences and challenges with accessing health care, and to assist States in understanding and better addressing those challenges. These committees also represent unique opportunities for States to include representation by members that reflect the demographics of their Medicaid program to ensure that the program is best serving the needs of all beneficiaries, but not all States are utilizing that opportunity.

This final rule strikes a balance that reflects how States currently use advisory committees (such as MCACs or standalone beneficiary groups). We know that some States approach these committees as a way to meet a Federal requirement while other States are using them in much more innovative ways. As a middle ground, this final rule seeks to: (1) address the gaps in the current regulations described previously in this section; and (2) establish requirements to implement more effective advisory committees. States will select members in a way that reflects a wide range of Medicaid interested parties (covering a diverse set of populations and interests relevant to the Medicaid program), place a special emphasis on the inclusion of the beneficiary perspective, and create a meeting environment where each voice is empowered to participate equally.

The changes we are making in this rule are rooted in best practices learned from States' experiences implementing the existing MCAC provisions and from other State examples of community engagement that support getting the type of feedback and experiences from beneficiaries, their caretakers, providers, and other interested parties that can then be used to positively impact care delivered through the Medicaid program.

Accordingly, this final rule includes changes that will support the implementation of the principles of bi-directional feedback, transparency, and accountability. We are making changes to the features of the new committee that can most effectively ensure member engagement, including the staff and logistical support that is required for beneficiaries and individuals representing beneficiaries to meaningfully participate in these committees. We are also making changes to expand the scope of topics to be addressed by the committee, address committee membership composition, prescribe the features of administration of the committee, establish requirements of an annual report, and underscore the importance of beneficiary engagement through the addition of a related beneficiary-only group.

C. Home and Community-Based Services (HCBS)

While Medicaid programs are required to provide medically necessary nursing facility services for most eligible individuals age 21 or older, coverage for HCBS is a State option.²² As a result of this “institutional bias” in the statute, Medicaid reimbursement for LTSS was primarily spent on institutional care, historically, with very little spending for HCBS.²³ However, over the past several decades, States have used several Medicaid authorities,²⁴ as well

²² Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. “Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019.” Chicago, IL: Mathematica, December 2021. Accessed at <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-expenditures2019.pdf>.

²³ Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf>.

²⁴ These authorities include Medicaid State plan personal care services and Social Security Act (the Act) section 1915(c) waivers, section 1915(i) State plan HCBS, section 1915(j) self-directed personal assistant services, and section 1915(k) Community First Choice. See <https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/index.html> for more information on these authorities. Some States also use demonstration authority under section 1115(a) of the Act to cover and test home and community-based service strategies. See <https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html> for more information.

as CMS-funded grant programs,²⁵ to develop a broad range of HCBS to provide alternatives to institutionalization for eligible Medicaid beneficiaries and to advance person-centered care. Consistent with many beneficiaries' preferences for where they would like to receive their care, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people with disabilities that spans efforts across the Federal government. In fact, total Medicaid HCBS expenditures surpassed the long-standing benchmark of 50 percent of LTSS expenditures in FY 2013 and has remained higher than 50 percent since then, reaching 55.4 percent in FY 2017 and 62.5 percent in FY 2020.²⁶ A total of 35 States spent at least 50 percent of Medicaid LTSS expenditures on HCBS in FY 2020.

Furthermore, HCBS play an important role in States' efforts to achieve compliance with Title II of the Americans with Disabilities Act (ADA) of 1990, section 504 of the Rehabilitation Act of 1973 (section 504),²⁷ section 1557 of the Affordable Care Act, and the Supreme Court's decision in *Olmstead v. L.C.*,²⁸ in which the Court held that unjustified segregation of persons with disabilities is a form of unlawful discrimination under the ADA²⁹ and States must ensure that persons with disabilities are served in the most integrated setting appropriate to their needs.³⁰ Section 9817 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117-2) recently made a historic investment in Medicaid HCBS by providing qualifying States with a temporary 10 percentage point increase to the FMAP for certain Medicaid expenditures for HCBS that

²⁵ Federally funded grant programs include the Money Follows the Person (MFP) demonstration program, which was initially authorized by the Deficit Reduction Act of 2005 (Pub. L. 109-171). The MFP program was recently extended under the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), which allowed new States to join the demonstration and made statutory changes affecting MFP participant eligibility criteria, allowing grantees to provide community transition services under MFP earlier in an eligible individual's inpatient stay.

²⁶ Murray, Caitlin, Michelle Eckstein, Debra Lipson, and Andrea Wysocki. "Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2020." Chicago, IL: Mathematica, December 9, 2021. Accessed at <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2020.pdf>.

²⁷ HHS interprets section 504 and Title II of the ADA similarly regarding the integration mandate and the Department of Justice generally interprets the requirements under section 504 consistently with those under Title II of the ADA.

²⁸ 527 U.S. 581 (1999).

²⁹ Medicaid and the Olmstead Decision. Accessed at <https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688>.

³⁰ Medicaid and the Olmstead Decision. Accessed at <https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688>.

States must use to implement or supplement the implementation of one or more activities to enhance, expand, or strengthen HCBS under the Medicaid program.³¹

Medicaid coverage of HCBS varies by State and can include a combination of medical and non-medical services, such as case management, homemaker, personal care, adult day health, habilitation (both day and residential), and respite care services. HCBS programs serve a variety of targeted population groups, such as older adults, and children and adults with intellectual or developmental disabilities, physical disabilities, mental health/substance use disorders, and complex medical needs. HCBS programs provide opportunities for Medicaid beneficiaries to receive services in their own homes and communities rather than in institutions.

CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across and within services, but instead vary depending on the authorities under which States are delivering services.

Additionally, States have flexibility to determine the quality measures they use in their HCBS programs. While we support State flexibility, a lack of standardization has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different populations.

In addition, although there are differences in rates of disability among demographic groups, there are very limited data currently available to assess disparities in HCBS access,

³¹ Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on Medicaid.gov at <https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html>.

utilization, quality, and outcomes. Few States have the data infrastructure to systematically or routinely report data that can be used to assess whether disparities exist in HCBS programs. This lack of available data also prevents CMS and States from implementing interventions to make improvements in HCBS programs designed to consistently meet the needs of all beneficiaries. Compounding these concerns have been notable and high-profile instances of abuse and neglect in recent years, which have been shown to result from poor quality care and inadequate oversight of HCBS in Medicaid. For example, a 2018 report, “Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,”³² (“Joint Report”), which was jointly developed by the U.S. Department of Health Human Services’ Administration for Community Living (ACL), Office for Civil Rights (OCR), and the Office of Inspector General (OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm. In addition, while existing regulations provide safeguards for all Medicaid beneficiaries in the event of a denial of Medicaid eligibility or an adverse benefit determination by the State Medicaid agency and, where applicable, by the beneficiary’s managed care plan, there are no safeguards related to other issues that HCBS beneficiaries may experience, such as the failure of a provider to comply with the HCBS settings requirements or difficulty accessing the services in the person-centered service plan unless the individual is receiving those services through a Medicaid managed care arrangement.

Finally, through our regular interactions with State Medicaid agencies, provider groups, and beneficiary advocates, we observed that all these interested parties routinely cite a shortage of direct care workers and high rates of turnover in direct care workers among the greatest challenges in ensuring access to high-quality, cost-effective HCBS for people with disabilities

³² Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at <https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf>.

and older adults. Some States have also indicated that a lack of direct care workers is preventing them from transitioning individuals from institutions to home and community-based settings. While workforce shortages have existed for years, they have been exacerbated by the COVID-19 pandemic, which has resulted in higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID-19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in types of retail and other jobs that tend to draw from the same pool of workers.^{33,34,35}

To address the list of challenges outlined in this section, we proposed Federal requirements to improve access to care, quality of care, and health and quality of life outcomes; promote health equity for people receiving Medicaid-covered HCBS; and ensure that there are safeguards in place for beneficiaries who receive HCBS through FFS delivery systems. We solicited comment on other areas for rulemaking consideration. The requirements we are finalizing in this rule are intended, individually and as a whole, to promote public transparency related to the administration of Medicaid HCBS programs.

D. Fee-For-Service (FFS) Payment

Section 1902(a)(30)(A) of the Act requires States to “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” Regulations at § 447.203 require States to develop and submit to CMS an access monitoring review plan (AMRP) for a core set of

³³ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

³⁴ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America’s direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

³⁵ American Network of Community Options and Resources (ANCOR). 2021. The state of America’s direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

services. Currently, the regulations rely on available State data to support a determination that the State's payment rates are sufficient to ensure access to care in Medicaid FFS that is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required under section 1902(a)(30)(A) of the Act.

In the May 6, 2011, **Federal Register**, we published the Medicaid Program; Methods for Assuring Access to Covered Medicaid Services proposed rule (76 FR 26341; hereinafter "2011 proposed rule"), which outlined a data-driven process for States with Medicaid services paid through a State plan under FFS to follow in order to document their compliance with section 1902(a)(30)(A) of the Act. We finalized the 2011 proposed rule in the November 2, 2015, **Federal Register** when we published the "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services" final rule with comment period (80 FR 67576; hereinafter "2015 final rule with comment period"). Among other requirements, the 2015 final rule with comment period required States to develop and submit to CMS an AMRP for certain Medicaid services that is updated at least every 3 years. Additionally, the rule required that when States submit a SPA to reduce or restructure provider payment rates, they must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid FFS payment rates on beneficiary access to care. We published the "Medicaid Program; Deadline for Access Monitoring Review Plan Submissions" final rule in the April 12, 2016 **Federal Register** (81 FR 21479; hereinafter "2016 final rule") with a revised deadline for States' AMRPs to be submitted to us.

Following the implementation of the AMRP process, numerous States have expressed concern regarding the administrative burden associated with the 2015 final rule with comment period requirements, especially those States with high rates of beneficiary enrollment in managed care. In an attempt to address some of the States' concerns regarding unnecessary administrative burden, we issued a State Medicaid Director letter (SMDL) on

November 16, 2017 (SMDL #17-004), which clarified the circumstances in which provider payment reductions or restructurings would likely not result in diminished access to care, and therefore, would not require additional analysis and monitoring procedures described in the 2015 final rule with comment period.³⁶ Subsequently, in the March 23, 2018 **Federal Register**, we published the “Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold” proposed rule (83 FR 12696; hereinafter “2018 proposed rule”), which would have exempted States from requirements to analyze certain data or monitor access when the vast majority of their covered beneficiaries receive services through managed care plans. That proposed rule, if it had been finalized, would have provided similar flexibility to all States when they make nominal rate reductions or restructurings to FFS payment rates. Based on the responses received during the public comment period, we decided not to finalize the proposed exemptions.

In the July 15, 2019, **Federal Register**, we published the “Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission” proposed rule (84 FR 33722; hereinafter “2019 proposed rule”) to rescind the regulatory access requirements at §§ 447.203(b) and 447.204, and concurrently issued a CMCS Informational Bulletin (CIB)³⁷ stating the agency’s intention to establish a new access strategy. Based on the responses we received during the public comment period, we decided not to finalize the 2019 proposed rule, and instead continue our efforts and commitment to develop a data-driven strategy to understand access to care in the Medicaid program.

States have continued to question whether the AMRP process is the most effective or accurate reflection of access to care in a State’s Medicaid program, and requested we provide additional clarity on the data necessary to support compliance with section 1902(a)(30)(A) of the

³⁶ State Medicaid Director Letter #17-0004 Re: Medicaid Access to Care Implementation Guidance. Accessed at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf> (November 2017).

³⁷ CMCS Informational Bulletin: Comprehensive Strategy for Monitoring Access in Medicaid, Accessed at <https://www.medicaid.gov/federal-policy-guidance/downloads/CIB071119.pdf> (July 2019).

Act. In reviewing the information that States presented through the AMRPs, we also have questioned whether the data and analysis consistently address the primary access-related question posed by section 1902(a)(30)(A) of the Act -- namely, whether rates are sufficient to ensure access to care at least as great as that enjoyed by the general population in geographic areas. The unstandardized nature of the AMRPs, which largely defer to States to determine appropriate data measures to review and monitor when documenting access to care, have made it difficult to assess whether any single State's analysis demonstrates compliance with section 1902(a)(30)(A) of the Act.

While the AMRPs were intended to be a useful guide to States in the overall process to monitor beneficiary access, they are generally limited to access in FFS delivery systems and focus on targeted payment rate changes rather than the availability of care more generally or population health outcomes (which may be indicative of the population's ability to access care). Moreover, the AMRP processes are largely procedural in nature and not targeted to specific services for which access may be of particular concern, requiring States to engage in triennial reviews of access to care for certain broad categories of Medicaid services -- primary care services, physician specialist services, behavioral health services, pre- and post-natal obstetric services, and home health services. Although the 2016 final rule discussed that the selected service categories were intended to be indicators for available access in the overall Medicaid FFS system, these categories do not directly translate to the services authorized under section 1905(a) of the Act, granting States deference as to how broadly or narrowly to apply the AMRP analysis to services within their programs. For example, the category "primary care services" could encompass several of the Medicaid service categories described within section 1905(a) of the Act and, without clear guidance on which section 1905(a) services categories, qualified providers, or procedures we intended States to include within the AMRP analyses, States were left to make their own interpretations in analyzing access to care under the 2016 final rule.

Similarly, a number of the AMRP data elements, both required and suggested within the 2016 final rule, may be overly broad, subject to interpretation, or difficult to obtain. Specifically, under the 2016 final rule provisions, States are required to review: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Although service utilization and provider participation are relatively easy measures to source and track using existing Medicaid program data, an analysis of whether beneficiary needs are fully met is at least somewhat subjective and could require States to engage in a survey process to complete. Additionally, while most Medicaid services have some level of equivalent payment data that can be compared to other available public payer data, such as Medicare, private payer information may be proprietary and difficult to obtain. Therefore, many States struggled to meet the regulatory requirement to compare Medicaid program rates to private payer rates because of their inability to obtain private payer data.

Due to these issues, States produced varied AMRPs through the triennial process that were, as a whole, difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. In isolation, a State's specific AMRP most often presented data that could be meaningful as a benchmark against changes within a State's Medicaid program, but did not present a case for Medicaid access consistent with the general population in geographic areas. Frequently, the data and information within the AMRPs were presented without a formal determination or attestation from the State that the information presented established compliance with section 1902(a)(30)(A) of the Act. Because the States' AMRPs generally varied to such a great degree, there was also little to glean in making State-to-State

comparisons of performance on access measures, even for States with geographic and demographic similarities.

Based on results of the triennial AMRPs, we were uncertain of how to make use of the information presented within them other than to make them publicly available. We published the AMRPs on Medicaid.gov but had little engagement with States on the content or results of the AMRPs since much of the information within the plans could not meaningfully answer whether access in Medicaid programs satisfied the requirements of section 1902(a)(30)(A) of the Act. Additionally, we received little feedback from providers, beneficiaries, or advocates on whether or how interested parties made use of the triennial AMRPs. However, portions of the 2016 final rule related to public awareness and feedback on changes to Medicaid payment rates and the analysis that we received from individual States proposing to make rate changes was of great benefit in determining approvals of State payment change proposals. Specifically, the portion of the AMRP process where States update their plans to describe data and measures to serve as a baseline against which they monitor after reducing or restructuring Medicaid payments allows States to document consistency with section 1902(a)(30)(A) of the Act at the time of SPA submission, usually as an assessment of how closely rates align with Medicare rates, and to understand the impact of reductions through data monitoring after SPA approval.

Under this final rule, we balance elimination of unnecessary Federal and State administrative burden with robust implementation of the Federal and State shared obligation to ensure that Medicaid payment rates are set at levels sufficient to ensure access to care for beneficiaries consistent with section 1902(a)(30)(A) of the Act. The provisions of this final rule, as discussed in more detail later, will better achieve this balance through improved transparency of Medicaid FFS payment rates, through publication of a comparative payment rate analysis to Medicare and payment rate disclosures, and through a more targeted and defined approach to evaluating data and information when States propose to reduce or restructure their Medicaid payment rates. Payment rate transparency is a critical component of assessing compliance with

section 1902(a)(30)(A) of the Act. In addition, payment rate transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes discussed within this final rule. Along with improved payment rate transparency and disclosures as well as comparative payment rate analyses, we are finalizing a more efficient process for States to undertake when submitting rate reduction or restructuring SPAs to CMS for review. As we move toward aligning our Medicaid access to care strategy across FFS and managed care delivery systems, we will consider additional rulemaking to help ensure that Medicaid payment rate information is appropriately transparent and rates are fully consistent with broad access to care across delivery systems, so that interested parties have a more complete understanding of Medicaid payment rate levels and resulting access to care for beneficiaries.

II. Summary of the Proposed Provisions and Analysis of and Responses to the Public Comments

We received 2,123 public comments from individuals and organizations, including, but not limited to, individuals, State government agencies, non-profit health care organizations, advocacy groups, associations, law firms, managed care plans, academic groups, and tribal organizations. We thank and appreciate the commenters for their consideration of the proposed requirements for ensuring access to care, quality and health outcomes, and better addressing health equity issues in the Medicaid program across FFS and managed care delivery systems, and in HCBS programs. In general, commenters supported the proposed rule. In this section, arranged by subject area, we summarize the proposed provisions, the public comments received, and our responses. For a complete and full description of the proposed requirements, see the 2023 proposed rule, “Medicaid Program; Ensuring Access to Medicaid Services” (88 FR 27960, May 5, 2023) hereafter referred to as the “proposed rule.”

We also received a number of out-of-scope comments that are not addressed in this final rule. In addition, we received some comments which were solely applicable to the Managed Care proposed rule. Please see the Managed Care final rule for a summary of the comments CMS received pertaining to that proposed rule.

We are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. If any provision is held to be invalid or unenforceable, the remaining provisions which could function independently, should take effect and be given the maximum effect permitted by law. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear.

Finally, we note that we are finalizing with modification several of the dates for when we expect States to begin complying with the requirements being finalized in this rule, instead of what we proposed. Generally, we are finalizing that this rule, including the proposals being finalized herein, will be effective 60 days after publication of this final rule. However, we are finalizing that States are not required to begin compliance with most requirements being finalized in this rule until a specified applicability date, which we have specified for each such individual proposal being finalized. We discuss in detail the applicability date we are finalizing for each proposal being finalized in this rule in the respective section of this preamble. We encourage States, providers, and interested parties to confirm the applicability dates indicated in this final rule for any changes from the proposed. To assist, we are including Table 1 with the provisions and relevant timing information and dates.

TABLE 1: Provisions and Relevant Timing Information and Dates*

Regulation Section(s) in Title 42 of the CFR	Applicability Dates**
Medicaid Advisory Committee (MAC) & Beneficiary Advisory Council (BAC) § 431.12	<i>Establishment of MAC and BAC:</i> 1 year after the effective date of the final rule.
	<i>BAC crossover on MAC:</i> For the period from the effective date of the final rule through 1 year after the effective date, 10 percent; for the period from year 1 plus one day through year 2 after the effective date of the final rule, 20 percent; and thereafter, 25 percent of committee members must be from the BAC
	<i>Annual report:</i> States have 2 years from the effective date of the final rule to finalize the first annual report. After the report has been finalized, States will have 30 days to post the annual report.
Person-Centered Service Plans §§ 441.301(c)(1) and (3), 441.450(c), 441.540(c), and 441.725(c)	Beginning 3 years after the effective date of the final rule***
Grievance Systems §§ 441.301(c)(7), 441.464(d)(5), 441.555(e), and 441.745(a)(1)(iii)	Beginning 2 years after the effective date of the final rule
Incident Management System §§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v), and (b)(1)(i)	Beginning 3 years after the effective date of the final rule***; except for the requirement at § 441.302(a)(6)(i)(B) (electronic incident management system), which begins 5 years after the effective date of the final rule***
HCBS Payment Adequacy §§ 441.302(k), 441.464(f), 441.570(f), and 441.745(a)(1)(vi)	Beginning 6 years after the effective date of the final rule***
Reporting Requirements §§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii)	Beginning 3 years after the effective date of the final rule*** for § 441.311(b) (compliance reporting) and § 441.311(d) (access reporting)
	Beginning 4 years after the effective date of the final rule*** for § 441.311(c) (reporting on the HCBS Quality Measure Set) and (e) (HCBS payment adequacy reporting)
HCBS Quality Measure Set §§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)	HHS Secretary begins identifying quality measures no later than December 31, 2026, and no more frequently than every other year. HHS Secretary shall make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate.
Website Transparency §§ 441.313, 441.486, 441.595, and 441.750	Beginning 3 years after the effective date of the final rule***
Payment Rate Transparency Publication § 447.203(b)(1)	July 1, 2026, then updated within 30 days of a payment rate change.
Comparative Payment Rate Analysis Publication § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Payment Rate Disclosure § 447.203(b)(2) to (4)	July 1, 2026, then every 2 years
Interested Parties Advisory Group § 447.203(b)(6)	The first meeting must be held within 2 years after effective date of the final rule (then at least every 2 years).
Rate Reduction and Restructuring SPA procedures § 447.203(c)(1) and (2)	Effective date of the final rule

* Regulatory provisions in this table are applicable at the time this rule becomes effective.

** In this final rule, including the regulations being finalized herein, we use the term “applicability date” to indicate when a new regulatory requirement will be applicable and when States must begin compliance with the requirements as specified in that regulation.

*** In the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the managed care organization’s (MCO), prepaid inpatient health plan’s (PIHP), or prepaid ambulatory health plan’s (PAHP) contract, the applicability date is the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the applicability date specified in the chart.

A. Medicaid Advisory Committee and Beneficiary Advisory Council (§ 431.12)

The current regulations at § 431.12 require States to have a Medical Care Advisory Committee (MCAC) to advise the State Medicaid agency about health and medical care services. The regulations are intended to ensure that State Medicaid agencies had a way to receive feedback regarding health and medical care services from interested parties. However, these regulations lacked specificity related to how these committees can be used to ensure the proper and efficient administration of the Medicaid program more expressly by more fully promoting beneficiary perspectives.

Under the authority of section 1902(a)(4) of the Act, section 1902(a)(19) of the Act, and our general rulemaking authority in section 1102 of the Act, we are finalizing proposals to § 431.12 to replace the current MCAC requirements with a committee framework designed to ensure the proper and efficient administration of the Medicaid program and to better ensure that services under the Medicaid program will be provided in a manner consistent with the best interests of the beneficiaries. States will be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Council (BAC). Please note that in the proposed rule, the BAC was referred to as the Beneficiary Advisory Group, or BAG. The MAC and its corresponding BAC will serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program as determined by the State and MAC. With the changes in this final rule FFP, or Federal match, for Medicaid administrative activities will remain available to States for expenditures related to MAC and BAC activities in the same manner as the former MCAC.

The proposed and finalized requirements of the MAC amend previous and add new Federal requirements to: (1) expand the scope and use of States' MACs; (2) rename the Medicaid Advisory Committee, which will advise the State on a range of issues including medical and non-medical services; (3) require States to establish a BAC; (4) establish minimum requirements for Medicaid beneficiary representation on the MAC, membership, meetings materials, and

attendance; and (5) promote transparency and accountability between the State and interested parties by making information on the MAC and BAC activities publicly available. The finalized requirements aimed at promoting transparency and accountability also include a requirement for States to create and publicly post an annual report summarizing the MAC and BAC activities.

We note that some commenters expressed general support for all of the provisions in section II.A. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule, we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.A. of this final rule are intended to present a comprehensive approach to implementing Medicaid Advisory Committees and Beneficiary Advisory Councils, and these provisions complement the goals expressed and policies and regulations being finalized in sections II.B. (Home and Community-Based Services) and II.C.(Documentation of Access to Care and Service Payment Rates) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.A is distinct and severable from other final policies and regulations being finalized in this section or in sections II.B. or II.C of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further State action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to the State Plan requirement (section II.A.2 of this final rule) are distinct and severable from the policies and

regulations we are finalizing related to the MAC Membership and Composition requirement and the Annual Report requirement (sections II.A.4 and II.A.9 of this final rule, which we further intend are severable from each other).

1. Basis and Purpose (§ 431.12(a))

Under § 431.12 of the current regulation, paragraph (a) Basis and Purpose, sets forth a State plan requirement for the establishment of a committee (Medical Care Advisory Committee) to advise the Medicaid agency about health and medical care services. In the proposed rule, we proposed to amend the title of § 431.12 and paragraph (a) to update the name of the existing MCAC to the Medicaid Advisory Committee (MAC), and to add the requirement for States to establish and operate a dedicated advisory council comprised of Medicaid beneficiaries, the Beneficiary Advisory Group. In this final rule, we are changing the name from the Beneficiary Advisory Group to the Beneficiary Advisory Committee (BAC).

In the proposed rule, we stated that our goal was for the committee and its corresponding advisory council to serve in an advisory role to the State on issues related to health and medical services, as the MCAC did, as well as on other matters related to policy development and to the effective administration of the Medicaid program consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan.³⁸ The Medicaid program covers medical services and is increasingly also covering services designed to address beneficiaries' social determinants of health and their health-related social needs more generally. Therefore, we believe that the MAC should discuss topics directly related to covered services as well as the potential need for the coverage of additional services that may be necessary to ensure that beneficiaries are able to meaningfully access these services. Expanding the scope of the current committee is necessary in order to align with the expanding scope of the Medicaid program. These changes are consistent with section 1902(a)(4)(B) of the Act because the MAC

³⁸Medicaid Program; Ensuring Access to Medicaid Services,” (88 FR 27967).

creates a formalized way for interested parties and beneficiary representatives to provide feedback to the State about issues related to the Medicaid program and the services it covers. The feedback from the MAC and BAC will be used by the State to ensure that the program operates efficiently and as it was designed to operate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a large number of comments in support of the proposed changes to the MCAC regulation and structure as proposed in § 431.12(a). The commenters expressed broad support for creation of the dual structure of the MAC and BAC. They noted that the creation of the BAC was a positive and welcome step to better capturing the lived experiences of people enrolled in Medicaid. Commenters also noted that having the BAC advise the MAC on policy development was a way to prioritize beneficiaries' perspectives. Commenters noted that the improvements proposed to the existing MCAC structure had the potential to be transformative and make the State more attuned to the needs and priorities of Medicaid beneficiaries.

Response: We thank commenters for their support of our overhaul of the MCAC. We are finalizing as proposed, with minor technical changes, the creation of the MAC and BAC.

Comment: We also received comments in opposition to the creation of a BAC. Generally, opposing commenters wanted CMS to be less prescriptive and allow States to engage Medicaid beneficiaries in other ways (for example, using existing State committees to serve as the BAC, conducting focus groups, and fielding surveys). Other commenters noted that States would need resources to implement the BAC, citing the additional administrative burden and layering of meetings for certain members.

Response: We encourage States to engage with their Medicaid beneficiaries in a variety of ways, and we understand that many States may already operate groups or committees comprised of Medicaid beneficiaries. However, having a formalized structure to work directly

with Medicaid beneficiaries will help to ensure a level and manner of engagement across all State programs. For the commenters concerned with the BAC adding administrative burden, we acknowledge that implementing these changes will create administrative burden. We discuss administrative burden to States in the Regulatory Impact Analysis section of this rule. However, in an effort to minimize administrative burden for States, we note that existing committees can be used to fulfill the BAC requirement as long as the committees meet the membership requirements specified in § 431.12(e). Later in this section, we also note that States do not have to use the same BAC members to join all MAC meetings. While it may not be an ideal way to create long-term consistency of the MAC membership, States could, in an effort to lessen the time commitment of BAC members, choose to rotate which members attend the quarterly MAC meetings.

Comment: We received several comments asking for the BAG name to be changed. The commenters cited potentially negative connotations that could be associated with the acronym BAG. Additionally, a few commenters requested that States with existing beneficiary groups be able to maintain their names.

Response: We have changed the name of the BAG to the BAC, as noted earlier in this final rule. For commenters concerned with duplicative efforts, we noted in the proposed rule that States with existing BAC-like committees can use those committees to fulfill the BAC requirement as long as they meet the membership requirements specified § 431.12(e). States are not required to change their existing group names to match the BAC name as long as interested parties understand what existing group or committee is being used to fulfill regulatory requirement of the BAC. To clarify this for interested parties, States must note in their publicly posted by-laws (§ 431.12 (f)(1)) that the group is being used to fulfill the regulatory requirements of § 431.12.

Comment: Several commenters asked CMS to clarify the role of the MAC and BAC, citing that in the proposals, the language varies from “advisory” to “providing feedback.” Other

commenters expressed that they do not want the MAC and BACs to be approval bodies that lack the ability to make decisions.

Response: The primary role of the MAC and BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. It is our intention that the MAC and BAC serve in an advisory capacity to the State. However, serving in an advisory capacity does not preclude the MAC and BAC members from sharing experiential feedback. We did not propose to give the MAC or BAC a decision-making role because we want to allow States the freedom to administer their Medicaid programs in the manner they see fit, but be guided by these two entities' recommendations and experiences with the Medicaid program.

Comment: We received a comment asking CMS to require that the MAC and BAC not be used to take the place of a State's tribal consultation requirements.

Response: We do not anticipate that the MAC or BAC could be used to fulfill tribal consultation requirements under section 1902(a)(73) of the Act. For States with one or more Indian Health Programs or Urban Indian Organizations that furnish health care services, the State must consult with such Programs and Organizations on a regular, ongoing basis. While the statute specifically permits representatives of such Programs and Organizations to be included on the MCAC [now known as the MAC], this alone would not meet the requirement to consult on any State plan amendments (SPAs), waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations prior to submission.

Comment: We received a few comments requesting that CMS conduct a study to assess which States already have MCACs or BACs to ensure they are no duplicative efforts. Another commenter asked CMS to solicit feedback from existing MCAC members to see how it can be improved before making beneficiary groups a requirement.

Response: We clarify that MCACs are currently required of all States so conducting an assessment to see which States already have MCACs would not necessarily result in a lot of new information. However, we agree that understanding which States already have BAC-like committees in place would be helpful. In fact, when developing the proposed rule, we engaged with interested parties, both from State Medicaid agencies and the wider Medicaid community, to determine what improvements were needed to the MCACs to allow States and beneficiaries to obtain the most benefit from their work. For commenters concerned with duplicative BAC activities, we note again that States with an existing beneficiary group or beneficiary committee that meets the requirement of the BAC, as finalized in this rule at § 431.12(e), do not need to set up a second beneficiary committee.

Comment: We received a few comments asking CMS to require the MAC and BAC to coordinate with other State advisory committees.

Response: States will vary in how they run their advisory committees. Some States may choose to coordinate across their different advisory committees, while other States may have reasons for keeping their advisory committees and their processes separate. We do not want to add more administrative burden by adding a requirement to § 431.12 for States to coordinate across State advisory committees. However, if coordinating across these committees in some manner would be advantageous for the Medicaid program, then we encourage the State to do so.

After consideration of public comments, we are finalizing § 431.12(a) as proposed with the following change:

Language modifications to reflect the new name of the “Beneficiary Advisory Council (BAC).”

2. State Plan Requirement (§ 431.12(b))

Under § 431.12 of the current regulation, paragraph (b) State Plan Requirement, calls for a State plan to provide for a MCAC to advise the Medicaid agency director about health and medical care services.

We proposed conforming updates to paragraph (b) regarding the State plan requirements, to reflect the addition of the BAC and the expanded scope.

The Interested Parties Advisory Group, described in a later section of this final rule (Interested Parties Advisory Group § 447.203(b)(6)), is designed to advise States on rate setting and other matters for certain HCBS and is not related to the MAC or BAC specified here. In section II.C.2.c. of this final rule, under § 447.203(b)(6), we explain that States will have the option to use its MAC and BAC to provide recommendations for payment rates, thereby satisfying the requirements of § 447.203(b)(6). However, the MAC and BAC requirements finalized here are wholly separate from the Interested Parties Advisory Group.

We did not receive public comments on § 431.12(b). However, we are making one conforming edit to this paragraph based on a language change identified in § 431.12(c) to replace the term State Medicaid Director. We are finalizing as proposed with the following changes:

- Language modifications to reflect the new name of the “Beneficiary Advisory Council (BAC).”
- Replacing the term Medicaid Agency Director with the term, “director of the single State Agency for the Medicaid program.”

3. Selection of Members (§ 431.12(c))

Under § 431.12 of the current regulation, paragraph (c) Appointment of members, the agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

We proposed to revise paragraph (c) to specify that the members of the MAC and BAC must be appointed by the agency director or a higher State authority on a rotating and continuous basis. We also proposed to require the State to create a process for the recruitment and appointment of members of the MAC and BAC. Additionally, we proposed to require the State to post this information on the State’s website. As discussed in the proposed rule,³⁹ the website

³⁹ Medicaid Program; Ensuring Access to Medicaid Services,” (88 FR 27960, 27968).

page where this information is located would be required to be easily accessible by the public. These proposed updates align with how some States' existing MCACs are already run, which will facilitate the transition of these MCACs into MAC/BACs. Additionally, the proposed changes are designed to provide additional details to support States' operation of the MAC and BAC. Further, we believe these proposed updates will facilitate transparency, improving the current regulations, which did not mention nor promote transparency of information related to the MCAC with the public. We also believe that transparency of information can lead to enhanced accountability on the part of the State in making its MAC and BAC as effective as possible.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received several comments regarding the terms used to describe who should be given the authority to appoint members to the MAC and BAC. Many commenters supported the proposal of having the State Medicaid Director appoint the members. A few commenters suggested that we make clarifications to the proposed regulation language so that only the State Medicaid Director and not "a higher State authority" is referenced, since the work of the MAC and BAC is to advise the State Medicaid Director. Others noted that the correct term to use in the regulation when referring to the State Medicaid Director is the director of the single State agency for the Medicaid program. There was another category of commenters that did not believe the authority to select MAC and BAC members should sit with either the State Medicaid Director or a higher State Authority. These commenters instead stated it would be more equitable if prospective MAC and BAC members were selected by an outside company, a computer, at random, or by a lottery system. They noted that in their experiences sometimes parents or family members are excluded from selection processes. Finally, other commenters noted that the term "appointed" implied that the State did not use any kind of a "selection process" to choose its MAC and BAC members. These commenters may have felt that the term

“appoint” means that the State can simply pick whomever it wants to serve as a member rather than “selecting” members from a pool of people who submitted applications to serve as MAC or BAC members.

Response: We appreciate the comments provided on this section and acknowledge the complicated work that comes with selecting MAC and BAC members. Since the MAC and BAC serve in an advisory role to the Medicaid program, we believe strongly that the authority to select should lie with the director of the State Medicaid agency. We know that Medicaid agencies’ names may vary from State to State, and thus, agree that language in the regulation can be changed to more clearly reflect a more commonly used term for the Medicaid agency (that is, the single State Agency for the Medicaid Program). For commenters that expressed concern that parents or family members are excluded from the selection processes, we note that the BAC regulations require both Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries, such as family members to be selected. Finally, we agree that the word “appoint” in the proposed rule does not accurately reflect the intention of the regulation and could be misinterpreted to mean that the State did not use a selection process where interested parties submit an application and then the State reviews those applications before selecting its MAC and BAC members. Based on the comments we received, we now understand that the term “appoint” can be taken to mean that a selection process did not occur. We want to avoid any confusion that the requirements are asking the State to appoint members without using a selection process, which was not our intention. For clarity, we are also amending the regulatory language in § 431.12(c) to now state that the “director of the single State Agency for the Medicaid program,” must “select” members for the MAC and BAC.

Comment: We received comments on the proposed changes to § 431.12(c) related to term limits of the MAC and BAC members. The commenters were generally divided across wanting CMS to require States to have set term limits for members, not wanting any term limits, and not wanting short term limits. Commenters who expressed support for set term limits noted

that setting term limits ensured that new perspectives would be added on a regular basis while others noted that setting term limits allowed members to share recommendations or constructive criticism without fear of retaliation. The commenters who opposed term limits noted that finding people with Medicaid expertise may be difficult in some geographic areas and, as a result, the State would benefit from having the same members serve without term limits. Other commenters noted that it takes time for members to build their expertise and understanding of the Medicaid program and setting short term limits may not take into account the time needed to accumulate enough knowledge to contribute fully to the MAC and BAC. These commenters suggested term limits with lengths ranging from 2 to 6 years.

Response: States have the ability to determine the tenure of members, as States are best situated to assess their members' ability to participate in and meaningfully contribute to the MAC and BAC and for what length of time. In the proposed rule, we described the requirement for States to determine the length of terms for committee and council members. For clarity, we are amending the regulatory language in § 431.12(c) to reflect this information as well, to now state "...members to the MAC and BAC for a term of a length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis." We proposed this type of term because we believe there is value in ensuring new voices and perspectives are introduced to the committee and council. We further clarify that once a MAC or BAC member's term has been completed, the State will select a new member, thus ensuring that MAC and BAC memberships rotate continuously. Setting memberships as continuously rotating means that the State must seek to recruit members to fill open seats on the MAC and BAC on an ongoing basis. States can also select members to serve multiple non-consecutive terms.

After consideration of public comments, we are finalizing § 431.12(c) with the following changes:

- Language modifications to reflect the new name of the BAC.

- Replacing the term agency director or higher authority with the term, “director of the single State Agency for the Medicaid program.”

- Replacing the word “appoint” with “select” in various places.

- Adding language to the regulation to reflect that “the term of length for MAC and BAC members will be term of a length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis.”

4. MAC Membership and Composition (§ 431.12(d))

Under § 431.12 of the current regulation, paragraph (d), Committee Membership, States are required to select three types of committee members: (1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care; (2) Members of consumers' groups, including Medicaid beneficiaries, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and (3) the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

In the proposed rule, paragraph (d) of § 431.12, MAC membership and composition, we proposed in (d)(1) to require that a minimum of 25 percent of the MAC must be individuals with lived Medicaid beneficiary experience from the BAC. The BAC, which is defined later in § 431.12(e), is comprised of people who: (1) are currently or have been Medicaid beneficiaries, and (2) individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid).

We proposed 25 percent as the minimum threshold requirement for (d)(1) to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has meaningful representation in the feedback provided by the MAC. We did not propose a higher percentage because we acknowledge that States will benefit from a MAC that includes representation from a diverse set

of interested parties who work in areas related to Medicaid but are not beneficiaries, their family members, or their caregivers.

In terms of the required representation from the remaining MAC members, as specified in the proposed rule, paragraph (d)(2), we proposed that a State must include at least one from each category: (A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries; (B) clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care; (C) participating Medicaid managed care organizations or the State health plan association representing such organizations, as applicable; and (D) other State agencies serving Medicaid beneficiaries, as ex-officio members.

We believe that advisory committees and councils can be most effective when they represent a wide range of perspectives and experiences. Since we know that each State environment is different, we aimed to provide the State with discretion on how large the MAC and BAC should be. In the proposed changes we did, however, specify the types of categories of Committee members that can best reflect the needs of a Medicaid program. We believe that diversely populated MACs and BACs can provide States with access to a broad range of perspectives, and importantly, beneficiaries' perspective, which can positively impact the administration of the Medicaid program. This approach is consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. The changes in membership we proposed and are finalizing will support States to set up MACs that align with section 1902(a)(4)(B) since States will now have to select the membership composition to reflect the community members who represent the interests of Medicaid beneficiaries. The State also benefits from having a way to hear how the Medicaid program can be responsive to its beneficiaries' and the wider Medicaid community's needs.

We also noted in the proposed rule that we encourage States to take into consideration, as part of their member selection process, the demographics of the Medicaid population in their State. Keeping diverse representation in mind as a goal for the MAC membership can be a way for States to help ensure that specific populations and those receiving critically important services are appropriately represented on the MAC. For example, in making MAC membership selections, the State may want to balance the representation of the MAC according to geographic areas of the State with the demographics and health care needs of the Medicaid program of the State. The State will want to consider geographical diversity (for example, urban and rural areas) when making its membership selections. We noted in the proposed rule, that a State could also consider demographic representation of its membership by including members representing or serving Medicaid beneficiaries who receive services in the following categories: (1) pediatric health care; (2) behavioral health services; (3) preventive care and reproductive health services; (4) health or service issues pertaining specifically to people over age 65; and (5) health or service issues pertaining specifically to people with disabilities. By offering these considerations, we seek to support States in their efforts to eliminate differences in health care access and outcomes experienced by diverse populations enrolled in Medicaid. We intend that the MAC and the BAC can support several of the priorities for operationalizing health equity across CMS programs as outlined in the CMS Framework for Health Equity (2022-2032) and the HHS Equity Action Plan which is consistent with E.O. 13985, which calls for advancing equity for underserved communities.

Rather than prescribing specific percentages for the other (non-BAC) categories in the proposed rule, we only required representation from each category as part of the MAC. The specific percentage of each of category (other than the BAC members) relative to the whole committee can be determined by each State. This approach will provide States with the flexibility to determine how to best represent the unique landscape of each State's Medicaid program. We solicited comment on what should be the minimum percentage requirement that

MAC members be current/past Medicaid beneficiaries or individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers of those enrolled in Medicaid). In addition to hearing directly from beneficiaries, the State can gain insights into how to effectively administer its program from other members of the Medicaid community.

States will determine which types of providers to include under the clinical providers or administrators category, and we recommend they consider a wide range of providers or administrators that are experienced with the Medicaid program including, but not limited to: (1) primary care providers (internal or family medicine physicians or nurse practitioners or physician assistants that practice primary care); (2) behavioral health providers (that is, mental health and substance use disorder providers); (3) reproductive health service providers, including maternal health providers; (4) pediatric providers; (5) dental and oral health providers; (6) community health, rural health clinic or Federally Qualified Health Center (FQHC) administrators; (7) individuals providing long-term care services and supports; and (8) direct care workers⁴⁰ who can be individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers).

We have also identified managed care plans, including Primary Care Case Management (PCCM) entities and Primary Care Case Managers (PCCMs),⁴¹ as an important contributor to the MAC, but we acknowledge that not all States have managed care delivery systems. We know many Medicaid managed care plans administer similar committees and thus allow for States to tailor managed care plan representation based on its delivery system and the experience and

⁴⁰ As finalized in § 441.302(k) of this final rule, CMS defines as Direct care worker as any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model: (A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart; (B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; (C) A direct support professional; (D) A personal care attendant; (E) A home health aide; or (F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

⁴¹ Throughout this document, the use of the term “managed care plan” includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) [as defined in 42 CFR 438.2] and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or primary care case management entities (PCCM entities).

expertise of managed care plans in the State. For example, States, if applicable, can fulfill this category with only one or with multiple managed care plans operating in the State. In addition, we also give States the flexibility to meet the managed care plan representation requirements with either participating Medicaid managed care plans or a health plan association representing more than one such organization.

The language in paragraph (d)(2)(D) broadens the previous MCAC requirement to allow for additional types of representatives from other State agencies to be on the committee. Specifically, the previous MCAC regulation requires membership by “the director of the public welfare department or the public health department, whichever does not head the Medicaid agency.” In the proposed rule, we expanded the requirement for external agency representation to be broader than the welfare or public health department, which would give States more flexibility in representing the Medicaid program’s interests based on States’ unique circumstances and organizational structure. States can work with sister State agencies to determine who should participate in the MAC (for example, foster care agency, mental health agency, department of public health). We also proposed that these representatives be part of the committee as ex-officio members, meaning that they hold the position because they work for the relevant State agency. In finalizing the proposals, we reviewed this requirement closer. While we believe it will be essential to have these State-interested parties present for program coordination and information-sharing, we intended to reflect in the proposed rule that the formal representation of the MAC should be comprised of beneficiaries, advocates, community organizations, and providers that serve Medicaid beneficiaries. Therefore, we clarify in this final rule that while these ex-officio members will sit on the MAC, they will not be voting members of the MAC. Therefore, on matters that the MAC decides by vote, including but not necessarily limited to finalizing the MAC’s recommendations to the State, the ex-officio members will not participate in voting.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments about the proposed requirement of having some BAC members serving on the MAC. Commenters either agreed with the importance of having a subset of Medicaid beneficiaries serve on both the BAC and the MAC, or they noted that having a subset of BAC members on both committees could lead to undue burden for these members based on the number of meetings they would have to attend. One commenter suggested a phased-in approach where the BAC members meet only as the BAC for a time (for example, a year) and then transition to serving on the MAC only.

Response: We understand the concerns raised by the commenters about putting undue burden on a subset of BAC members. We believe it is vital for the success of both the BAC and MAC that there is a point of integration via the crossover membership requirement since this is the way to ensure that the Medicaid beneficiary perspective is included in both groups. We created this crossover requirement to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has meaningful representation in the feedback provided by the MAC. For commenters that are concerned with undue burden of having a subset of BAC members also attend MAC meetings, in § 431.12(f)(3), we note that MACs and BACs are only required to meet once per quarter. While the regulation does not state that the subset of BAC members that join each MAC meeting has to be the same, we recognize that it would be more effective to have consistency in the BAC members that attend the MAC meetings in many cases. However, if States or the BAC are concerned with overburdening its BAC members, a potentially less efficient but workable alternative could be to rotate which BAC members attend the MAC in an effort to further reduce the number of meetings attended for a given BAC member. Nevertheless, the suggestion of having a member transition from solely being on the BAC to solely being on the MAC might not always promote the crossover concept we are seeking with

the requirement that the MAC membership consist of 10 to 25 percent members from the BAC, since we are striving for inclusion of the Medicaid beneficiary perspective in both groups via the BAC members.

Comment: In response to our solicitation about having 25 percent as the minimum threshold of BAC membership crossover on the MAC, the majority of the commenters stated that a minimum 25 percent was the appropriate amount of crossover members. They noted that 25 percent crossover membership would help to center and amplify beneficiary voices on the MAC. A few commenters stated that the percentage should be lower (for example 10 or 15 percent). These commenters cited several reasons why having a lower threshold number would be better. Some commenters noted that having a smaller number of BAC members would allow States to better support or train their members so they could fully participate in the MAC. Other commenters stated that having a smaller number of BAC members could lessen the burden on States of finding and recruiting members to participate. Another group of commenters wanted the percentage of BAC crossover to be higher than 25 percent (for example 33, 50, 51, or 75 percent). These commenters sought a higher BAC crossover in order to: safeguard against marginalization of beneficiary members on the MAC; amplify diverse voices through a higher crossover number; and rectify any power imbalances that may exist. There were also a few commenters who noted that States should have the ability to determine their own percentages for the BAC crossover. Finally, we received comments asking CMS to consider allowing States to use a graduated approach to reach the 25 percent minimum requirement of BAC crossover on the MAC.

Response: We thank the commenters who agreed with our proposed threshold of the requirement for a minimum of 25 percent BAC crossover on the MAC. For commenters who thought the percentage should be lower, we understand States may face challenges with finding, recruiting, and training beneficiary members to serve on the BAC. To account for these challenges, we are extending the timeframe for implementation of this requirement in this final

rule so that States have 2 years to achieve the 25 percent minimum threshold requirement of MAC members that come from the BAC. Instead of the 25 percent minimum threshold coming into effect right away, we are revising this final rule to provide in § 431.12(d)(1) that, for the period from [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

For commenters who expressed the need for a percentage higher than 25 for the BAC member crossover, we note that the policy we proposed and are finalizing establishes a minimum percentage threshold for States to meet. If a State so chooses, it can select a percentage higher than the minimum of 25 percent, provided the MAC membership also satisfies the requirements of § 431.12(d)(2) of this final rule. For commenters who raised the issue of providing training for BAC members, we have a comment/response on this topic under § 431.12(h)(3).

Comment: The majority of comments received on § 431.12(d) were about § 431.12(d)(2), MAC composition categories. We received comments that fell into four groups. The first group of commenters shared their broad support for the MAC committee member categories that we proposed and also urged CMS to ensure that States select members that represented the Medicaid community and who were geographically as well as racially/ethnically diverse. The second group of commenters asked for the MAC to include representation from members who would qualify for the BAC (for example, Medicaid beneficiaries, their families, and caregivers). It is unclear from the comments if these commenters were asking for an additional group of Medicaid beneficiaries be added to the MAC (in addition to the 25 percent of MAC we proposed to require be from the BAC) or if they did not understand that the MAC composition already includes a category which accounts for this category of members. The third group of commenters asked that specific types of interested parties be required to be represented

on the MAC categories (for example, specific provider types, unions, HCBS provider agencies, hospitals, protection and advocacy programs, legal professionals, and medical billing professionals). The fourth group of commenters suggested ideas for types of MAC members that States could use to meet categories specified in the proposed rule (for example add a State Ombudsman to the ex-officio category). We also received a few suggestions to add specific member categories (for example, a member category for FFS members, a member category for people with behavioral health conditions, and a youth member category).

Response: We appreciate the wide range of comments that were submitted about the MAC membership composition. We developed the MAC composition framework in the proposed rule by creating broad membership categories that captured a range of interested parties who are members of the Medicaid community while giving States as much flexibility as possible to build their MACs in ways that account for the unique features of the State's environment. All of the membership categories, as currently written, are broad enough to accommodate the types of members described by the commenters. For example, a State Ombudsman can be used to fulfil the State agency category; a State with both managed care and FFS could chose to select two members (one for each type of delivery system) for the MAC; a person with behavioral health condition(s) could be suitable for multiple categories depending on whether they are a Medicaid beneficiary (current or former) or represent a consumer advocacy or community-based organization. Finally, for the commenter asking for a specific youth member category, we will note that there are no Federal requirements or limitations concerning youth participation on the MAC or BAC, and this is in the State's discretion. The State could select a youth member to fulfill a MAC or BAC member category as long as that person meets the requirements of that membership category.

We also want to clarify for commenters that Medicaid beneficiaries, their families, and caregivers have their own MAC category in the regulation, because the BAC is listed in the final regulation as one of the categories of MAC members at § 431.12(d)(1).

After consideration of public comments, for § 431.12(d), we are finalizing as proposed with:

- Language modifications to reflect the new name of the BAC;
- Replacing the language at § 431.12 (d)(1) to clarify the timeframe for States to reach 25 percent of MAC members coming from the BAC. The new sentence will now read, “For the period from [insert effective date of the final rule] through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 10, 2026 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.”
- Language modifications to § 431.12 (d)(2)(C) to replace “managed care plan” with “MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2”; and
- Adding the word “non-voting” to ex-officio members at the end of § 431.12 (d)(2)(D).

5. Beneficiary Advisory Council (§ 431.12(e))

The current requirements governing MCACs require the presence of beneficiaries in committee membership but do little else to ensure their contributions are considered or their voices heard. For example, in the current regulations of § 431.12, paragraph (e) Committee participation, only briefly mentions the participation of beneficiary members. The current requirement provides little guidance about how to approach the participation of beneficiary members on the committee.

We proposed to add new paragraph § 431.12(e). The proposed rule noted that in the new paragraph, (e) Beneficiary Advisory Council, States would be required to create a BAC, a dedicated Beneficiary Advisory Council, that will meet separately from the MAC on a regular basis and in advance of each MAC meeting.

Specifically, at new paragraph (e)(1), we proposed to require that the MAC members described in paragraph (d)(1) must also be members of the BAC. This requirement will facilitate the bi-directional communication essential to effective beneficiary engagement and allow for

meaningful representation of diverse voices across the MAC and BAC. In paragraph (e)(2), we proposed to require that the BAC meetings occur in advance of each MAC meeting to ensure BAC member preparation for each MAC discussion. BAC meetings will also be subject to requirements in paragraph (f)(5), described later in this section, that the BAC meetings must occur virtually, in-person, or through a hybrid option to maximize member attendance. We plan to expound on best practices for engaging beneficiary participation in committees like the MAC in a future toolkit.

We proposed the addition of the BAC because we believe that it will result in providing States with increased access to beneficiary perspectives. The creation of a separate beneficiary-only advisory council also aligns with what we have learned from multiple interviews with State Medicaid agencies and other Medicaid interested parties (for example, Medicaid researchers, former Medicaid officials) conducted over the course of 2022 on the operation of the existing MCACs. These interested parties described the importance of having a comfortable, supportive, and trusting environment that facilitates beneficiaries' ability to speak freely on matters most important to them. Further, we believe that the crossover structure for the MAC and BAC proposed in § 431.12(d) allows for the beneficiary-only group to meet separately while still having a formal connection to the broader, over-arching MAC. It is important the MAC members can directly engage with the beneficiaries and hear from their experience. We noted earlier that some States may already have highly effective BAC-type councils operating as part of their Medicaid program. These existing councils may represent specific constituencies such as children with complex medical needs or older adults or may be participants receiving services under a specific waiver. In these instances, States may use these councils to satisfy the requirements of this rule, as long as the pre-existing BAC-type council membership includes the type of members required in the proposed paragraph of § 431.12(e).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments in support of the BAC as specified in the newly proposed § 431.12(e). Commenters noted that the BAC would provide a necessary and less-intimidating venue where Medicaid beneficiaries along with their families and caregivers can share first-person experiences and feedback to the State. While many commenters stated the BAC was needed and a welcomed improvement, a few commenters cautioned that States would need more than just to set up a BAC; they will also need to invest in creating opportunities for meaningful engagement.

Response: We agree that the BAC must be supported and used by the State in ways that create opportunities for BAC members to be actively involved and have their contributions considered.

Comment: A few commenters asked CMS to clarify how existing community groups or advisory councils could be used to satisfy the requirements of the BAC. One commenter asked if the BAC would meet a State's inclusive Community First Choice (CFC) requirements.

Response: The proposed new paragraph (e) requires that States form a BAC, but notes that the State can use an existing beneficiary group. Prior to rulemaking, CMS spoke to several States and researchers to understand how States were implementing the MCAC requirements. From the information gathered, we know that many States already have active Medicaid beneficiary groups that could fill these requirements and can function as their BACs. In these instances, it is not our intention to ask a State to create a second Medicaid beneficiary group to meet the BAC requirements. If a State wants to use an existing group to satisfy the BAC requirements, they will need to ensure that the existing committee's membership meets the membership requirements of the BAC and that the existing committee's bylaws are developed or updated, and published, to explain that the committee functions to meet the BAC requirements.

Regarding the ability to use the BAC to meet CFC requirements of the State, CMS notes in the "Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting

Requirements for Community FirstChoice and Home and Community Based Services (HCBS) Waivers” final rule,⁴² that States may utilize existing advisory bodies in the implementation of CFC, as long as the statutory requirements as specified in § 441.715 for the Development and Implementation Council are met. We acknowledge the benefits of the Implementation Council coordinating with related interested parties councils and commissions and encourage States to do so. States may also choose to leverage these councils and/or include members from these councils to meet the requirements for CFC.

Comment: The majority of the comments received related to the newly proposed § 431.12(e) were commenters providing recommendations on which groups of people should also be required to be included as BAC members. We received a range of suggestions such as: HCBS beneficiaries, individuals with specific chronic diseases and disabilities, individuals using long term care services and supports (LTSS), individuals who are receiving perinatal health services, individuals who have lived experience with behavioral health conditions, and Medicaid beneficiaries who are deaf, hard of hearing, or deaf blind. Commenters also requested that the BAC members represent a cross-section of Medicaid beneficiaries that can also be regarded as demographically and geographically diverse.

Response: We agree with commenters that the States should select the types of BAC members that can provide them with representative views of the experience of Medicaid beneficiaries in their State. The regulatory language provides States with the flexibility to make those determinations based on the characteristics of their individual State Medicaid program. It can be challenging to find beneficiaries available to serve on a council, particularly if the requirements of membership are very specific. By keeping our regulations broad for what types of beneficiaries should be selected for the BAC, we seek to ensure States are able to recruit members with fewer challenges.

⁴² “Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community FirstChoice and Home and Community Based Services (HCBS) Waivers <https://www.medicaid.gov/sites/default/files/2019-12/cfc-final-settings.pdf>,” (79 FR 2948, 2982).

Comment: A few commenters asked for CMS to clarify or further define a few terms used in newly proposed § 431.12(e). Specifically, a couple of commenters asked CMS to clarify the phrase “individuals with direct care experience supporting Medicaid beneficiaries.” Another commenter asked if CMS could define whether the term “caregivers” included paid caregivers.

Response: In the proposed and in this final rule, we have described individuals with direct experience supporting Medicaid beneficiaries as “family members or caregivers of those enrolled in Medicaid.” In the proposed rule’s preamble,⁴³ we state that caregivers can be paid or unpaid caregivers. To better clarify these definitions, we are adding the words “paid or unpaid” before the word caregiver to the proposed regulatory language at new paragraph § 431.12(e) so that the phrase reads, “...individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State...”

Comment: As noted in an earlier section, several commenters asked CMS to clarify the role of the BAC, citing that in the proposals, the language varies from “advisory” to “providing feedback.”

Response: The primary role of the BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. To better clarify the BAC’s advisory role, we are removing from the proposed regulatory language at new paragraph § 431.12(e) the words and to “provide input to.” The phrase now reads “...to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.”

Comment: A few commenters shared suggestions related to the BAC meetings described in new paragraph § 431.12(e)(2). One commenter asked CMS to encourage States to hold BAC and MAC meetings on the same day, with the BAC meeting occurring first in an effort to

⁴³ “Medicaid Program; Ensuring Access to Medicaid Services,” (88 FR 27960, 27968).

minimize travel. Other commenters asked CMS for additional meetings for the BAC to be required to attend (for example, meetings with the State Medicaid Director and meetings with CMS regional administrators).

Response: The meeting structure specified in the BAC proposal is focused on the interplay between the BAC and MAC meetings. In new paragraph § 431.12(e)(2), we are requiring that the BAC meetings be held separate from the MAC and in advance of the MAC, so that the BAC members have the opportunity to prepare and hold an internal discussion among themselves. Holding MAC and BAC meetings in the same day could be in line with the meeting requirements. States may wish to hold additional BAC meetings with other parties, as needed.

Comment: Some commenters asked CMS to create a Federal-level BAC to ensure consistency across States.

Response: A Federal-level BAC would not further the goal of providing States with beneficiary input into their programs because it would not focus on the particular features of each individual State's Medicaid program or beneficiary and provider communities. Such a group is beyond the scope of this rulemaking.

After consideration of public comments, we are finalizing new § 431.12(e) as proposed, with changes to:

- Language modifications to reflect the new name of the BAC;
- Adding language that caregivers on the BAC can be “paid or unpaid.” Section 431.12(e) will now state, “...individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid)”
- Deleting the phrase “...and provide input to....” Section 431.12(e) will now state “...to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.”

6. MAC and BAC Administration (§ 431.12(f))

We proposed to add new paragraph § 431.12(f), MAC and BAC administration, to provide an administrative framework for the MAC and BAC that ensures transparency and a meaningful feedback loop to the public and among the members of the committee and council.⁴⁴

Specifically, in new paragraph (f)(1), we proposed that State agencies would be required to develop and post publicly on their website bylaws for governance of the MAC and BAC, current lists of MAC and BAC memberships, and past meeting minutes for both the committee and council. In paragraph (f)(2), we proposed that State agencies would be required to develop and post publicly a process for MAC and BAC member recruitment and selection along with a process for the selection of MAC and BAC leadership. In paragraph (f)(3), we proposed that State agencies would be required to develop, publicly post, and implement a regular meeting schedule for the MAC and BAC. The proposed requirement specified that the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. In paragraph (f)(4), we proposed requiring that at least two MAC meetings per year must be opened to the public. For the MAC meetings that are open to the public, the meeting agenda would be required to include a dedicated time for public comment to be heard by the MAC. None of the BAC meetings were required to be open to the public unless the State's BAC members decided otherwise. We also proposed that the State ensure that the public is provided adequate notice of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance. We solicited comment on this approach. In paragraph (f)(5), we proposed that States would be required to offer in-person, virtual, and hybrid attendance options including, at a minimum telephone dial-in options at the MAC and BAC meetings for its members to maximize member participation at MAC and BAC meetings. If the MAC or BAC meeting was deemed open to the public, then the State must offer at a minimum a telephone dial-in option for members of the public.

⁴⁴ "Medicaid Program; Ensuring Access to Medicaid Services," (88 FR 27960, 27920).

With respect to in-person meetings, we proposed in paragraph (f)(6) that States would be required to ensure that meeting times and locations for MAC and BAC meetings were selected to maximize participant attendance, which may vary by meeting. For example, States may determine, by consulting with their MAC and BAC members, that holding meetings in various locations throughout the State may result in better attendance. In addition, States may ask the committee and council members about which times and days may be more favorable than others and hold meetings at those times accordingly. We also proposed that States use the publicly posted meeting minutes, which lists attendance by members, as a way to gauge which meeting times and locations garner maximum participate attendance.

Finally, in paragraph (f)(7), we proposed that State agencies were required to facilitate participation of beneficiaries by ensuring that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, that communication with individuals with disabilities is as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

Interested parties' feedback and recent reports^{45,46} published on meaningful beneficiary engagement illuminate the need for more transparent and standardized processes across States to drive participation from key interested parties and to facilitate the opportunity for participation from a diverse set of members and the community. Further, we believe that in order for the State to comply with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to

⁴⁵ Resources for Integrated Care and Community Catalyst, "Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils", 2019. Retrieved from https://www.resourcesforintegratedcare.com/listening_to_voices_of_dually_eligible_beneficiaries/.

⁴⁶ Centers for Medicare & Medicaid Services, Person & Family Engagement Strategy: Sharing with Our Partners. Retrieved from: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategic-Plan-12-12-16.pdf#:~:text=person%E2%80%99s%20priorities%2C%20goals%2C%20needs%20and%20values.%E2%80%9D%20Using%20these,to%20guide%20all%20clinical%20decisions%20and%20drives%20genuine.>

meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan, it needs to be responsive to the needs of its beneficiaries. To be responsive to the needs of its beneficiaries, the State needs to be able to gather feedback from a variety of people that touch the Medicaid program, and the MAC and BAC will serve as a vehicle through which States can obtain this feedback.

We acknowledge that interested parties may face a range of technological and internet accessibility limitations, and proposed requiring that, at a minimum, States provide a telephone dial-in option for MAC and BAC meetings. While we understand that in-person interaction can sometimes assist in building trusted relationships, we also recognize that accommodations for members and the public to participate virtually is important, particularly since the beginning of the COVID-19 pandemic. We solicited comment on ways to best strike this balance.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing broad support of § 431.12(f)(1) proposals requiring States to post publicly information on the MAC and BAC (bylaws, meeting minutes). The commenters noted that transparency plays an important role in promoting multi-directional accountability and could also help ensure the success of the MAC and BAC. While commenters were supportive, they also recommended that States consider their Medicaid communities' communication access needs, including cultural competency and linguistic needs, when posting these materials to their websites.

Response: We agree with commenters that States should take steps to ensure that any publicly posted materials are accessible to the various interested parties that comprise their Medicaid community.

Comment: We received a few comments asking us to reconsider the requirement of having States to post their BAC membership list on their websites. Several commenters suggested that States should give BAC members the choice of being publicly identified.

Response: We thank commenters for raising this issue, as we want to avoid any situation where a Medicaid beneficiary, family member or caregiver, does not want to be publicly identified. In response to these comments, we are updating and finalizing the proposed regulations to permit BAC members to choose whether to be publicly identified in materials such as membership lists and meeting minutes. If BAC members choose not to be identified in public materials, they can be referred to as BAC member 1, BAC member 2 and so on. Specifically, we are updating and finalizing the proposed language under new paragraph § 431.12(f)(1) to state, “Develop and publish by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members...States will give BAC members the option to include their names on the membership list and meeting minutes that will be posted publicly.”

Comment: We received comments supporting the § 431.12(f)(2) requirement of having States publicly post their process for recruitment and selection. Commenters emphasized that these processes must be inclusive and reflect the diversity of their State’s Medicaid community and beneficiaries. Other commenters asked for CMS to provide guidance or best practices on how to recruit members, as well as marketing best practices and the preferred format for print and audio materials.

Response: We agree that States should develop recruitment strategies that will result in identifying members that are representative of a State’s Medicaid community and beneficiaries. However, we have kept the requirements flexible to be cognizant of the fact that States can experience challenges in recruiting Medicaid beneficiaries to serve on the BAC. We also encourage States to examine best practices from entities that specialize in marketing, recruitment, and the accessibility of published materials as outlined on *Digital.gov*.⁴⁷

Comment: We received some comments asking that States have a process for identifying conflicts of interest when making member selections.

⁴⁷ <https://digital.gov/resources/an-introduction-to-accessibility/?dg>.

Response: We agree that avoiding conflicts of interest is important, and we encourage States to establish conflict of interest policies, to be documented in the MAC/BAC bylaws or other organizing documents that govern the membership and operations of the MAC/BAC, and to ensure these policies are respected when selecting MAC/BAC members. Since MAC and BAC membership represent a variety of backgrounds and interest relevant to Medicaid, we also believe that building in a time for conflict-of-interest disclosure into each meeting's agenda is important. Specifically, under new § 431.12(f)(3) we are now adding that each MAC and BAC meeting agenda should have time set aside for members to disclose any matters that are not incompatible with their participation on the MAC and/or BAC under the State's conflict of interest policy, but which nevertheless could give rise to a perceived or actual conflict of interest and therefore should be disclosed. We also believe our requirements for MAC and BAC meetings, including the posting of meeting minutes and membership lists, will provide the public and States with the transparency needed to know if a conflict of interest (perceived, apparent, or actual) occurred during a meeting.

Comment: We received comments regarding the requirement in § 431.12(f)(3) for both the MAC and BAC to each meet at a minimum of once quarterly. Commenters noted the number of meetings could pose a burden to the States and members. Several commenters suggested that CMS allow Medicaid agencies to hold meetings in a way that matches their administrative resources and goals.

Response: We selected a quarterly meeting versus a monthly meeting schedule for the MAC and BAC because we believe it will provide States with more flexibility in determining when to meet. For example, rather than having the MAC and BAC members meeting every month (12 times annually), we reduce the time commitment for members by having the State select which month per quarter works best for the MAC and BAC members (4 times annually). Further, the goal of the MAC and BAC is to advise the State on matters related to policy development and to the effective administration of the Medicaid program. We believe that

holding a quarterly meeting, as a minimum, allows States to integrate their Medicaid community's voice into the effective administration of the Medicaid program in a way that is timely and meaningful. Further, we believe that holding quarterly meetings would result in the least amount of burden for States. Holding more meetings per year would likely result in additional strain of time and resources for the State and its members. Holding meetings less frequently than quarterly would not assist the timely integration of the community voice into the administration of the Medicaid program. We also strive to further reduce the burden to MAC and BAC members by structuring the meeting requirements in a way that allows States to select non-traditional meeting times and to use different telecommunications options (for example, online meetings) for its meetings which would eliminate members' commuting times to meetings.

Comment: We received several comments about new § 431.12(f)(4) in support of the requirement that each MAC meeting must have a public comment period, citing the importance of all interested parties to be able to share feedback. Additionally, a few commenters asked that States also have a process to accept input from interested parties while developing MAC agendas.

Response: States will have the flexibility to develop the MAC agendas in accordance with their own processes and procedures. We encourage commenters to work with their State regarding those processes.

Comment: A couple of commenters suggested that all MAC and BAC meetings be open to the public.

Response: We place great importance on meeting transparency, but we also believe that States may need the flexibility to keep closed some of their meetings each year. The proposed requirement in § 431.12(f)(4) related to BAC meetings notes that BAC meetings are not required to be open to the public unless the State and the BAC members decide otherwise. It is important for States to create a dedicated space for this group of Medicaid beneficiaries and people with

lived Medicaid experience to share their interactions with and perceptions of the Medicaid program. Having a comfortable, supportive, and trusting environment will encourage members to speak freely on matters most important to them. We note that in order to support overall transparency, we proposed that the meeting minutes of the BAC meetings be required to be posted online and MAC members who are also on the BAC will share input from the BAC with the broader MAC.

Comment: We received comments in response to our request for comments about in-person and virtual attendance options for the MAC and BAC meetings. The comments emphasized the need for States to offer both in-person and virtual attendance options. One commenter questioned if the proposed requirement meant that offering an in-person attendance option was a requirement for each meeting.

Response: We thank commenters for responding to our request for comments. In response to those comments, we are updating new § 431.12(f)(5) to list the different types of meeting options. Specifically, § 431.12(f)(5) states, “Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in-person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have, a minimum, telephone dial-in option at the MAC and BAC meetings for its members.” For the commenter who questioned if States had to always provide in-person attendance options, we are clarifying that if the meeting is designated as a virtual-only meeting, States do not need to have in-person attendance.

Comment: One commenter suggested we add a requirement for meetings to be held both during and after work hours.

Response: In new § 431.12(f)(6), we require that States ensure that the meeting times selected for MAC and BAC meetings maximize member attendance. We encourage States to consider working hours and the impact on their MAC and BAC membership, as appropriate.

Comment: Several commenters expressed broad support for the proposal to ensure that MAC and BAC meetings are accessible by people with disabilities and Limited English Proficiency (LEP). Commenters also provided suggestions to better ensure meaningful participation, such as making sure States have available: interpreter services, American Sign Language translation services, closed captioning for virtual meeting, and making materials available in plain language.

Response: As reflected in § 431.12(f)(7), we agree that MAC and BAC members with disabilities and LEP should have access to the types of supports needed to meaningfully engage in meetings. We have updated the relevant Federal requirements for States to meet in this final rule.

Comment: One commenter requested that CMS clarify what is meant by the phrase, “that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency....”

Response: Title VI of the Civil Rights Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide meaningful access to their programs or activities for individuals with Limited English Proficiency.⁴⁸ Section 1557 of the Affordable Care Act similarly requires recipients of Federal financial assistance to take reasonable steps to provide meaningful access to their health programs or activities for individuals with Limited English Proficiency, and the implementing regulation requires the provision of interpreting services and translations when it is a reasonable step to provide meaningful access.⁴⁹

After consideration of public comments, we are finalizing § 431.12(f) as proposed with:

- Language modifications to reflect the new name of the BAC.

⁴⁸ *Lau v. Nichols*, 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students of Chinese origin with limited English proficiency to take affirmative steps to provide the students with a meaningful opportunity to participate in federally funded educational programs).

⁴⁹ 45 CFR 92.101; see also <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html>.

- Updates to § 431.12(f)(1) to now state, “States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.”

- Updates to § 431.12(f)(3) to state, “Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.”

- Updates to § 431.12(f)(4) to move one sentence up to be the new second sentence and the deletion of a repetitive sentence so that third sentence now reads as, “The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.”

- Updates to § 431.12(f)(5) to state, “Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in-person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always have at a minimum, telephone dial-in option at the MAC and BAC meetings for its members.”

- Updates to paragraph (f)(7) to reflect additional Federal requirements (adding reference to the Title VI of the Civil Rights Act of 1964). The sentence will now state, “...that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.”

7. MAC and BAC Participation and Scope (§ 431.12(g))

We proposed to replace former paragraph (e) Committee participation, with new paragraph (g) MAC and BAC Participation and Scope. The original paragraph (e), Committee participation, required that the MCAC must have opportunity for participation in policy

development and program administration, including furthering the participation of beneficiary members in the agency program.

In new paragraph § 431.12(g), we proposed and are finalizing the expansion of the types of topics which provide the MAC and BAC should advise to the State. The list of topics we proposed included at a minimum topics related to: (1) addition and changes to services; (2) coordination of care; (3) quality of services; (4) eligibility, enrollment, and renewal processes; (5) beneficiary and provider communications by State Medicaid agency and Medicaid managed care plans; (6) cultural competency, language access, health equity and disparities and biases in the Medicaid program; or (7) other issues that impact the provision or outcomes of health and medical services in the Medicaid program as identified by the MAC, BAC or State.

In researching States' MCACs, we know that some already use the MCACs advice on a variety of topics relating to the effective and efficient administration of the Medicaid program. With these changes, we aim to strike a balance that reflects some States' current practices without putting strict limitations on specific topics for discussion in a manner that would constrict flexibility for all States. Broadening the scope of the topics that the MAC and BAC discuss will benefit the State by giving greater insight into how it is currently delivering coverage and care for its beneficiaries and thereby assist in identifying ways to improve the way the Medicaid program is administered.

The State will use this engagement with the MAC and BAC to ensure that beneficiaries' and other interested parties' voices are considered and to allow the opportunity to adjust course based on the advice provided by the committee and council members. The State will base topics of discussion on State need and will determine the topics in collaboration with the MAC and BAC to address matters related to policy development and matters related to the effective administration of the Medicaid program. In finalizing the proposals, we reviewed the wording for this requirement closer. When listing the types of topics on which the MAC and BAC should advise to the State, we used the term "or". However, using the term "or" does not represent the

intention behind the regulation. The MAC or BAC should not be limited to advising the State on one topic at a time. Our intent is that the MAC and BAC, in collaboration with the State, should be able to provide recommendations on all or any of the subset of the topics listed. We clarify this intention in this final rule by making a technical change to replace the word “and” with the word “or” in the list of the types of topics on which the MAC and BAC should advise the State.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: As noted in other sections, we received a few comments asking CMS to clarify the advisory authority of the MAC and BAC, noting that language fluctuated between advisory and experiential feedback.

Response: As discussed earlier with respect to § 431.12(a), the role of the MAC and BAC is to advise the State Medicaid agency. In reviewing the language proposed in § 431.12(g), we see similar opportunities where CMS can refine its wording to make clear the advisory roles that the MAC and BAC hold. The primary role of the MAC and BAC is to advise the State Medicaid agency on policy development and on matters related to the effective administration of the Medicaid program. By replacing the wording in § 431.12(g) from “provide recommendations” to “advise” we are being consistent with the wording used in similar updates made in this final rule and also making clear that our intention is for the MAC and BAC to serve in an advisory capacity to the State.

Comment: All commenters who addressed § 431.12(g) supported the change in the MAC and BAC scope. The majority of those commenters also suggested additional topics for which the MAC and BAC should advise the State. These topics include getting feedback on Secret Shopper studies, external quality organization reports, consumer facing materials, enrollment materials, implementation of integrated programs for dually eligible individuals, rate reviews, and annual medical loss ratio report. We also received a comment noting the importance of access to services with a request that it be added to the list of topics.

Response: We appreciate the support to the proposed changes. We clarify that the categories of topics we named in this section were selected as examples because they represented far-reaching parameters related to the effective administration of the Medicaid program. We believe that the proposal we are finalizing in this final rule allows for a broad interpretation of the topics that are within scope while leaving the ultimate decision on which topics the MAC and BAC will advise on to the MAC, BAC, and State. We encourage commenters to work with their States to define the topics that will be discussed at the MAC and BAC. Finally, we agree that specifically mentioning access to services is important, as it represents a key topic area of this regulation. Therefore, we are redesignating the proposed § 431.12(g)(7) as (g)(8) and adding a new § 431.12(g)(7), access to services.

After consideration of public comments, we are finalizing § 431.12(g) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Replacing the wording at § 431.12(g) “to participate in and provide recommendations” with “advise” so as to clarify the advisory role of the MAC and BAC.
- Conforming edits to replacing the term State Medicaid Director at § 431.12(g) with the term, “director of the single State Agency for the Medicaid program.”

Language modifications to § 431.12(g)(5) to replace “managed care plan” with “MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in §438.2.”

- Redesignating and finalizing proposed § 431.12(g)(7) as (g)(8) and adding a new § 431.12(g)(7), “access to services.”
- Replacing the word “or” with the word “and” after 431.12(g)(7), access to services.

8. State Agency Staff Assistance, Participation, and Financial Help (§ 431.12(h))

Under § 431.12 of the current regulation, paragraph (f) Committee staff assistance and financial help, the State was required to provide the committee with—(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective

recommendations; and (2) Financial arrangements, if necessary, to make possible the participation of beneficiary members.

In the proposed rule, we proposed to redesignate previous paragraph § 431.12(f) to new paragraph (h) and expand upon existing State responsibilities for managing the MAC and BAC regarding staff assistance, participation, and financial support. The changes we proposed and are finalizing to new paragraph (h) are for the State to provide staff to support planning and execution of the MAC and the BAC to include: (1) Recruitment of MAC and BAC members; (2) Planning and execution of all MAC and BAC meetings; and (3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include: (i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement; (ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and (iii) Attendance by at least one staff member from the State agency's executive staff at all MAC and BAC meetings.

The overlap of the current regulation with our proposed changes will mean much of the work to implement is already occurring. We are not changing the existing financial support requirements. We understand from States and other interested parties that many States already provide staffing and financial support to their MCACs in ways that meet or go beyond what we require through our updated requirements. We believe that expanding upon the current standards regarding State responsibility for planning and executing the functions of the MAC and BAC will ensure consistent and ongoing standards to further beneficiaries' and other interested parties' engagement. For example, we know that when any kind of interested parties council meets, all members of that council need to fully understand the topics being discussed in order to meaningfully engage in that discussion. This is particularly relevant when the topics of discussion are complex or based in specific terminology as Medicaid related issues often can be.

We believe that when States provide their MACs and BACs with additional staffing support that can explain, provide background materials, and meet with the members in preparation for the larger discussions, the members have a greater chance to provide more meaningful feedback and be adequately prepared to engage in these discussions. The proposed changes to the existing requirements seek to create environments that support meaningful engagement by the members of the MAC and the BAC, whose feedback can then be used by States to support the efficient administration of their Medicaid program. We anticipate providing additional guidance on model practices, recruitment strategies, and ways to facilitate beneficiary participation, and we solicited comments on effective strategies to ensure meaningful interested parties' engagement that in turn can facilitate full beneficiary participation.

Further, the proposed changes to the requirement for beneficiary support, including financial support, are similar to the original MCAC requirements. For example, using dedicated staff to support beneficiary attendance at both the MAC and BAC meetings and providing financial assistance to facilitate meeting attendance by beneficiary members are similar to the current regulations. Staff may support beneficiary attendance through outreach to the Medicaid beneficiary MAC and BAC members throughout the membership period to provide information and answer questions; identify barriers and supports needed to facilitate attendance at MAC and BAC meetings; and facilitate access to those supports.

In the proposed rule, we proposed to add a new requirement that at least one member of the State agency's executive staff attend all MAC and BAC meetings to provide an opportunity for beneficiaries and representatives of the State's leadership to interact directly.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the modifications proposed at § 431.12(h), but they emphasized the importance of requiring States to appropriately compensate members that are beneficiaries for their participation. The comments noted that there should be financial

compensation to beneficiary members for the time spent on BAC activities, as well as financial reimbursement for any travel, lodging, meals, and childcare associated with their participation in the BAC and/or MAC. Commenters also asked CMS to exclude the value of any financial compensation paid to members for their participation in the MAC and/or BAC from consideration in determining eligibility for Medicaid. A few commenters expressed that the term “if necessary” should be dropped from the regulatory language, noting that States should offer reimbursement to all participating Medicaid beneficiaries.

Response: Under the policies we are finalizing at § 431.12(h)(3)(ii), States will have the ability to reimburse all beneficiaries to facilitate Medicaid beneficiary engagement in the MAC and the BAC. This can include, at the State’s discretion, reimbursement for travel, lodging, meals, and childcare. We did not remove the words “if necessary” to account for Medicaid beneficiaries who may not need financial support to engage in the MAC and BAC activities.

We are also clarifying the circumstances in which compensation provided to beneficiary members would be considered income for Medicaid eligibility purposes. For both MAGI and non-MAGI methodologies, reimbursements (such as for meals eaten away from home, mileage, and lodging) do not count as income, but other compensation (such as a daily stipend) for participating in an advisory council is countable income under applicable financial methodologies. For non-MAGI methodologies, the State could submit a SPA to CMS to disregard such stipends or other countable income under section 1902(r)(2) of the Act. Other means tested programs may have other rules for counting income, and we encourage States to assess those rules and advise Medicaid beneficiary members of the MAC and BAC accordingly.

Comment: Many commenters in support of the proposed requirements in § 431.12(h)(3) noted how critical it will be for States to provide appropriate technical support and preparation to MAC and BAC members who are also Medicaid beneficiaries in order to ensure their full and active participation in discussions. Commenters shared a variety of suggestions for the type of support that can help prepare these members to feel comfortable fully and meaningfully

engaging in the process. The suggestions made by the commenters included specific areas to be addressed in the trainings and materials that the State agency staff provides, such as providing background materials in plain language, implementing techniques to empower members to participate successfully and equally in MAC and BAC discussions, supporting health literacy needs, and training members on digital access to meetings/technology. Additionally, some commenters suggested that States be required to provide MAC and BAC members with a mentor and training on the Medicaid program throughout the length of their membership term. Several commenters suggested that States be required to select an independent (outside of the Medicaid agency) policy advisor or technical expert to provide BAC members with support in understanding Medicaid topics and policy.

Response: We appreciate the support for our proposals and understand the interest in ensuring support for beneficiary members of the MAC and BAC. The underpinning of meaningful member engagement is that members have a substantial understanding of the topics to be discussed. We agree with commenters' suggestions in general, but given the differences in States' structures and resources, we believe there is a benefit in leaving the decision of how best to provide training and support to the MAC and BAC members to the States. As we noted earlier in the preamble, CMS will post publicly a MAC best practices toolkit.

Comment: We received a couple of comments asking CMS to clarify the role of the State Medicaid agency staff attending the MAC and BAC meetings.

Response: The purpose of requiring a member from the State Medicaid agency's executive staff to attend MAC and BAC meetings is to provide an opportunity for beneficiaries and representatives of the State's Medicaid agency leadership to interact directly. The role of the executive staff person is not to be a MAC/BAC co-chair, nor to facilitate these meetings. The executive staff person's role is to hear directly from and interact with Medicaid beneficiaries and with the wider Medicaid community in that State. The person attending generally will be expected to share take-aways from these meetings with State's Medicaid agency leadership.

After consideration of public comments, we are finalizing § 431.12(h) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Conforming edits to replace the word “State Agency” with the “single State agency

for the Medicaid program” in several places across § 431.12(h).

Language modifications to § 431.12(h)(3) to state, “...MAC and BAC members who are Medicaid beneficiaries...”

9. Annual Report (§ 431.12(i)).

In the spirit of transparency and to ensure compliance with the updated regulations, we added in the proposed rule⁵⁰ and are finalizing new paragraph § 431.12(i) to require that the MAC, with support from the State and in accordance with the requirements updated at this section, must submit an annual report to the State. The State must review the report and include responses to the recommended actions. The State must also: (1) provide MAC members with final review of the report; (2) ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State’s responses to the recommendations; and (3) post the report to the State’s website. In the proposed rule, we noted that States had one year to implement the annual report requirement and we sought comment on that timeline. In finalizing the proposals, we reviewed these requirements closer. It is our intention that the MAC is required to submit an annual report to the State. We clarify this intention in this final rule by making a technical change to add the word “must” which was unintentionally omitted in the proposed rule.

The proposed requirements of this paragraph seek to ensure transparency while also facilitating a feedback loop and view into the impact of the MAC and BAC’s recommendations. We solicited comment on additional ways to ensure that the State can create a feedback loop with the MAC and BAC.

⁵⁰ “Medicaid Program; Ensuring Access to Medicaid Services,” (88 FR 27960, 27971).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed requirements in new § 431.12(i), of having States submit an annual report that describes activities of the MAC and BAC, including the topics discussed and their recommendations. Commenters noted that requiring these reports is critical to building trust as well as ensuring transparency and accountability among the State, MAC, and BAC members. In addition, several commenters agreed with the annual report requirement, but they also wanted CMS to stipulate the contents of the annual report. One commenter suggested that States' annual reports include results from anonymous surveys of MAC and BAC members indicating whether these members felt they have been listened to and if they felt the State used members' feedback.

Response: We appreciate the support for the proposed regulations. We carefully considered the benefits of national uniformity of the contents of an annual report. However, due to the differences in how States may approach setting priorities, creating their MAC and BACs, and the varying level of resources, we believe that States should have the flexibility to adopt an approach to the content of the annual report that works best within their State.

Comment: A few commenters asked CMS to either further require that the BAC issue its own set of reports and recommendations independently or as part of the MAC report.

Response: While we fully understand and agree with the importance of the BAC and ensuring that their voices are heard, we believe that requiring States to create a second BAC-only annual report would add administrative burden. The proposed regulatory language requires that States create an annual report that reflects the activities of both the MAC and BAC. Since the annual report is required to contain the priorities and activities of both the MAC and BAC, there is no need for a separate BAC-only report.

Comment: There were a handful of commenters that wanted CMS to reconsider the report requirement because they thought the resource burden was too great to develop an annual

report, the reporting requirement lacked meaning, or they wanted CMS to allow Medicaid agencies to set their own cadence to the reports.

Response: We understand the concerns of the commenters, but we have written the annual report requirement broadly to ensure maximal flexibility for States to meet this requirement. It is critical that States document the work and key outcomes of the MAC and BAC. Further, we believe the annual report requirement supports the implementation of the principles of bi-directional feedback, transparency, and accountability on the part of the State, MAC, and BAC. In response to comments about burden to States, we have adjusted the proposed applicability date for this requirement of 1 year and are now finalizing it as, States have 2 years from [insert the effective date of the final rule] to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

Comment: A few commenters asked CMS to require States to conduct additional activities related to monitoring the MAC and BAC, in addition to the annual report. The commenters' suggestions included: implementing a corrective action plan for States that failed to meet the MAC requirements; requiring process evaluations on the experiences of the MAC and BAC members be conducted and the findings be made public; and requiring States to engage in program improvement activities in response to the recommendations made by the MAC that appear in the annual report.

Response: We carefully considered the benefits of requiring additional studies and activities to be captured by States and included in the annual report. However, we want to keep the parameters of our expectations on the content of a State's annual report to be as broad as possible to give each State the ability to create a report that will help them best document the interested parties' engagement with the MAC and the BAC and serve as a tool for helping advance programmatic goals over time.

Comment: A couple of commenters requested CMS publish the annual reports on its website.

Response: We thank the commenters for this suggestion. Currently, we believe each respective State Medicaid agency's website to be the most appropriate place for the annual reports to be published. However, we will consider whether the needs of interested parties would be better served with CMS collecting and publishing annual reports as well.

Comment: A few commenters inquired about how CMS would provide oversight on compliance with activities such as the annual report and number of meetings requirements.

Response: We thank commenters for these questions. We are currently assessing the most effective strategies with which to provide oversight. As these requirements implement State plan requirements in section 1902(a)(4) and (a)(19) of the Act, noncompliance with the provisions of this final rule could result in a State plan compliance action in accordance with § 430.35.

After consideration of public comments, we are finalizing § 431.12(i) as proposed with:

- Language modifications to reflect the new name of the BAC.
- Additional sentences at the end of § 431.12(i)(3), "States have 2 years from [insert the effective date of the final rule] to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report."

10. Federal Financial Participation (§ 431.12(j))

In the current regulation, paragraph (g) Federal financial participation, noted that FFP is available at 50 percent in expenditures for the committee's activities. As noted in the proposed rule, we are not making changes to, and thus are maintaining, the current regulatory language on FFP from previous paragraph (g) to support committee activities, to appear in new paragraph (j) with conforming edits for the new MAC and BAC names.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received a few comments about the newly proposed § 431.12(j), encouraging CMS to offer a higher FFP than 50 percent. One commenter suggested that 90 percent FFP would be ideal.

Response: For Medicaid, all States receive a statutory 50 percent Federal matching rate for general administrative activities. States may also receive higher Federal matching rates for certain administrative activities, such as design, development, installation, and operation of certain qualifying systems. Federal matching rates are established by Congress, and CMS does not have the authority to change or increase them.

After consideration of public comments, we are finalizing new paragraph § 431.12(j) as proposed with:

- Language modifications to reflect the new name of the BAC.

11. Applicability dates § 431.12(k)

For this final rule, we are adding new paragraph § 431.12 (k) *Applicability dates*. In the proposed rule, we noted that the requirements of § 431.12 would be effective 60 days after the publication date of the final rule, although we established different applicability dates by which States must implement certain provisions. We then solicited comment on whether 1 year was too much or not enough time for States to implement the updates in this regulation in an effective manner. We understand that States may need to modify their existing MCACs to reflect the finalized requirements for MACs and may also need to create the BAC and recruit members to participate if they do not already have a similar entity already in place.

We received public comments on proposed implementation timeline. The following is a summary of the comments we received and our responses.

Comment: We received several comments related to the implementation timeframes specified in the MAC and BAC provisions of the proposed rule. The majority of comments fell into two categories: commenters who noted that 1 year should be sufficient to implement the required changes; and commenters who suggested that CMS provide at least 2 years for

implementation. Other commenters suggested that CMS consider a graduated approach that would allow States to demonstrate compliance with the minimum 25 percent BAC crossover requirement over a period of time. The commenters who requested additional time shared concerns about States' many other ongoing priorities, workforce shortages, the amount of time and resources it would take to set up the MAC and BAC, and having enough time to submit budget requests to their legislature so they can get the resources to support the required activities.

Response: We have carefully considered the comments received and acknowledge that additional time for implementation of the requirements could be beneficial for States given competing priorities, budgeting and other challenges States may encounter. Additionally, we weighed the request for a graduated approach to demonstrate compliance with a 25 percent BAC crossover requirement, and we agree that a graduated approach will allow States a longer ramp-up time to modify their current MCACs, as well as to set up the BAC and recruit members to participate.

In the proposed rule, we proposed that States have 1 year from the effective date of the final rule to recruit members, set up their MAC and BAC, hold meetings, and submit their first annual report. Based on public comment, we understand that 1 year is not enough time to complete all of these activities. As a result, we are adding and finalizing in this final rule a second implementation year. Based on these changes, States would now recruit members and set up their MACs and BACs during the first year implementation year. In the second implementation year, States would hold the required MAC and BAC meetings. At the end of that second implementation year, States would summarize the information from the MAC and BAC activities and use that information to complete an annual report. States would then fulfill the annual report requirement by finalizing the report and posting the annual report to their websites. This annual report would need to be posted by States within 30 days of the report being completed.

Additionally, as noted in section II.A.4., and in response to public comment asking for States to have a more graduated approach to reach the requirement of having 25 percent of MAC members be from the BAC, we are finalizing in this rule an extended implementation timeline for this requirement. The finalized provision at § 431.12(d)(1) will require that, for the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC. We developed this approach based on the comments we received about competing State priorities and the time and resources that a State would need to meet the new requirements. Additionally, we understand States may face challenges with finding, recruiting, and training beneficiary members to serve on the BAC.

Based on the comments received, we are changing two applicability dates. We note in this new paragraph *Applicability dates* § 431.12(k), that except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) are applicable July 9, 2025.

B. Home and Community-Based Services (HCBS)

To address several challenges that we described in the proposed rule (88 FR 27964 and 27965), we proposed both to amend and add new Federal HCBS requirements to improve access to care, quality of care, and beneficiary health and quality of life outcomes, while consistently meeting the needs of all beneficiaries receiving Medicaid-covered HCBS. The preamble of the proposed rule (88 FR 27971 through 27996) outlined our proposed changes in the context of current law.

As we noted in the proposed rule (88 FR 27971), we have previously received questions from States about the applicability of HCBS regulatory requirements to demonstration projects approved under section 1115 of the Act that include HCBS. As a result, we proposed that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in the proposed rule would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project.

We proposed not to apply the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services that we proposed in the proposed rule to the Program of All-Inclusive Care of the Elderly (PACE) authorized under sections 1894 and 1934 of the Act, as the existing requirements for PACE either already address or exceed the requirements outlined in the proposed rule, or are substantially different from those for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services.

We received public comments on these proposals for HCBS under the Medicaid program. The following is a summary of the comments we received and our responses. We discuss the comments we received related to specific proposals, and our responses, in further detail throughout the sections in this portion of the final rule (section II.B.).

Comment: Many commenters expressed general support for our efforts to increase transparency and accountability in HCBS programs, and ultimately improve access to Medicaid services. Commenters in particular noted general support for our proposed provisions in this section that are designed to support HCBS delivery systems through improvements in data collection around waiting lists and service delivery, enhancements to person-centered planning, standardization of critical incident investigation and grievance process requirements, and establishment of defined quality measures. While overall reaction to the payment adequacy minimum performance level (discussed in section II.B.5. of the proposed rule and this final rule) was mixed, many commenters agreed that HCBS programs are facing shortages of direct care workers that pose obstacles to beneficiaries' access to high-quality HCBS.

Commenters also shared several ideas for ways we could improve beneficiaries' access to, or the overall quality of, HCBS beyond the provisions presented in the proposed rule.

Some commenters expressed concerns that the HCBS provisions we proposed, when taken together, could present significant administrative costs to States and, in some cases, to providers.

Response: We thank commenters for their support. Comments on specific provisions that we proposed are summarized below, along with our responses. We also appreciate the many thoughtful suggestions made by commenters for other ways they believe HCBS could be improved beyond what we proposed in the proposed rule. While comments that are outside the scope of what we proposed in the proposed rule and not relevant are not summarized in this final rule, we will take these recommendations under consideration for potential future rulemaking.

We recognize that we must balance our desire to stimulate ongoing improvements in HCBS programs with the need to give States, managed care plans, and providers sufficient time to make adjustments and allocate resources in support of these changes. After consideration of comments we received, we are finalizing many of our proposals, some with modifications. These modifications are discussed in this section (section II.B.) of the final rule.

We also note that some commenters expressed general support for all of the provisions in section II.B. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule (particularly in section II.B related to HCBS), we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.B. of this final rule are intended to present a comprehensive approach to improving HCBS and complement the goals expressed and policies and regulations being finalized in sections II.A. (Medicaid Advisory Committee and Beneficiary Advisory Group) and II.C. (Documentation of Access to Care and Service Payment Rates) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.B is distinct and severable from other final policies and regulations being finalized in this section or in sections II.A. or II.C of this final rule, as well as from rules and regulations currently in effect.

Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to person-centered planning and related reporting requirements (sections II.B.1 and II.B.7. of this final rule) are distinct and severable from the policies and regulations we are finalizing related to grievance system (section II.B.2. of this final rule), and incident management system and related reporting requirements (sections II.B.3 and II.B.7. of this final rule). The standalone nature of the finalized provisions is further discussed in their respective sections in this rule.

Comment: Several commenters addressed the relationship between the proposed HCBS requirements and HCBS authorized under a section 1115 demonstration project. A few commenters requested clarification about the application of the proposed HCBS requirements in this section to services delivered under section 1115 authority. A few commenters expressed concern about what they perceived was the exclusion of services provided through a managed care delivery system under section 1115 demonstration authority. One commenter recommended only applying the finalized rules to new section 1115 demonstration programs; in the alternative, if applying the finalized requirements to current section 1115 demonstration programs, the commenter recommended that States develop transition plans and be given a reasonable timeframe for bringing their programs into compliance. A few commenters recommended that we add a specific reference to section 1115 demonstration authority of the Act in our proposed HCBS requirements (if finalized), including at § 438.72(b) (applying various finalized requirements to managed care programs) and § 441.302(k) (applying new payment adequacy requirements to section 1915(c) waiver programs).

Response: We are confirming that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this final rule, apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project. Further, we have not identified a compelling reason to treat States operating section 1115 demonstration projects differently from States operating other HCBS programs in terms of implementation, such as by requiring States with section 1115 demonstration programs to develop transition plans (as was recommended by one commenter). We also believe that the timeframes that are finalized in this rule are reasonable and sufficient to allow all States operating programs under all relevant authorities to come into compliance. If States have specific

questions or concerns regarding compliance with the finalized requirements, we will provide assistance as needed.

We note that we have already included references to managed care delivery systems implemented under section 1115(a) of the Act in the implementation requirements at §§ 441.301(c)(3)(iii) (implementing the person-centered planning process minimum performance requirements), 441.302(a)(6)(iii) (implementing the critical incident management system minimum performance requirements), 441.302(k)(8) (implementing the payment adequacy minimum performance requirement), 441.311(f) (implementing reporting requirements), and 441.313(c) (implementing the website transparency provision). We decline commenters' recommendations that we include additional references to section 1115 of the Act, as we believe doing so would be duplicative. We will ensure that the approved standard terms and conditions of States' section 1115 demonstration projects are clear that the States must comply with all applicable HCBS requirements that we are finalizing in this rule.

We did not receive any comments on our proposal not to extend HCBS requirements that we are finalizing in this rule to PACE. We are finalizing our proposal to not apply the requirements we are finalizing in this rule for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services to PACE authorized under sections 1894 and 1934 of the Act.

1. Person-Centered Service Plans (§§ 441.301(c), 441.450(c), 441.540(c), and 441.725(c))

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as person-centered service plans or service plans). Existing Federal regulations at § 441.301(c) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised, upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs⁵¹ (hereinafter the 2014 guidance) that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in 42 CFR part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. We refer readers to section II.B.1. of the proposed rule (88 FR 27972) for a detailed discussion of the six assurances identified in the 2014 guidance.

In the proposed rule (88 FR 27972 through 27975), we proposed a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in 42 CFR part 441, subpart G, including the requirements regarding assurances around service plans. We proposed this approach based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through a request for information (RFI)⁵² we released in the spring of 2022. Through this feedback, many States and interested parties expressed, and we identified, that there is a need to standardize reporting and set minimum standards for HCBS. We proposed HCBS requirements to establish a new strategy for oversight, monitoring, quality assurance, and quality improvement for section 1915(c) waiver programs, including minimum performance requirements and reporting requirements for section 1915(c) waiver programs. Further, as is discussed later in this section (section II.B.1. of the rule), to ensure consistency and alignment across HCBS authorities, we proposed to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services, as appropriate.

⁵¹ Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.

⁵² CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

As support for our proposals, we noted that under section 1902(a)(19) of the Act, States must provide safeguards to assure that eligibility for Medicaid-covered care and services are determined and provided in a manner that is consistent with simplicity of administration and that is in the best interest of Medicaid beneficiaries. While the needs of some individuals who receive HCBS may be relatively stable over some time periods, individuals who receive HCBS experience changes in their functional needs and individual circumstances, such as the availability of natural supports or a desire to choose a different provider, that necessitate revisions to the person-centered service plan to remain as independent as possible or to prevent adverse outcomes. Thus, the requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly or at the request of the individual, are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services change to meet the beneficiary's needs most appropriately as those needs change.

We also noted that effective State implementation of the person-centered planning process is integral to ensuring compliance with section 2402 of the of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148, March 23, 2010). Section 2402 of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to facilitate the participant's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁵³

⁵³ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at <https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf>.

Finally, we noted that since the release of the 2014 guidance, we have received feedback from States, the HHS Office of Inspector General (OIG), Administration for Community Living (ACL), and Office for Civil Rights (OCR), and other interested parties on how crucial person-centered planning is in the delivery of care and the significance of the person-centered service plan for the assurance of health and welfare for section 1915(c) waiver program participants that underscored the need for the proposals.⁵⁴

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, we proposed several changes to our person-centered service plan requirements in section II.B.1 of the proposed rule (88 FR 27972 through 27975), as discussed in more detail in this section of the final rule. First, we proposed revisions to § 401.301(c)(3)(i) to clarify that: (1) States are required to ensure person-centered service plans are reviewed and revised in compliance with requirements set forth therein; and (2) changes to the person-centered service plans are not required if the reassessment does not indicate a need for changes. Second, we proposed to establish a minimum performance level for States to demonstrate they meet the requirements at § 441.301(c)(3). Specifically, at § 441.301(c)(3)(ii)(A), we proposed to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. At § 441.301(c)(3)(ii)(B) we proposed to require that States demonstrate that they reviewed the person-centered service plan, and revised the plan as appropriate, based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. Finally, we proposed to

⁵⁴ Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at <https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf>.

apply the requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan services at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter questioned whether States would continue to be required to demonstrate compliance with the six assurances and the related subassurances, including those related to person-centered service plans described in the 2014 guidance, or whether the minimum performance requirements and reporting requirements that we proposed in the proposed rule for the section 1915(c) waiver program, if finalized in the final rule, supersede these six assurances and related subassurances.

Response: We noted in the proposed rule (88 FR 27972), and reiterate here, that States must demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around person-centered service plans.

We proposed new minimum performance requirements and new reporting requirements for section 1915(c) waiver programs that are intended to supersede and fully replace the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance. Further, to ensure consistency and alignment across HCBS authorities, we proposed to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services as appropriate.

We confirm that the section 1915(c) six assurances and the related subassurances,⁵⁵ including those related to person-centered service plans, continue to apply. The requirements proposed at § 441.301(c)(3)(ii)(A) and (B) (discussed in the next section, II.B.1.b. of this rule) assess State performance with the requirements at § 441.301(c)(3) and we did not intend to

⁵⁵ Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.

suggest that they would fully supersede the section 1915(c) six assurances and the related subassurances in the 2014 guidance. Further, as finalized later in this rule, States will be required to report on the minimum performance levels at § 441.301(c)(3)(ii)(A) and (B). To reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements, we plan to work with States to phase-out the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance as they implement these requirements in the final rule.

Comment: A commenter requested we clarify what the impacts would be to the existing section 1915(c) waiver reporting tools as defined in the Version 3.6 HCBS Waiver Application if we finalize our proposals.

Response: We expect to implement new reporting forms for the new reporting requirements that we are finalizing in this final rule. However, some components of the existing reporting forms may remain in effect to the extent that they cover other requirements that remain unchanged by the requirements that we are finalizing in this final rule. States and interested parties will have an opportunity to comment on the new reporting forms and the revised forms through the Paperwork Reduction Act notice and comment process.

a. Finalization of Amended Requirement for Review of the Person-Centered Service Plan (§441.301(c)(3)(i))

At § 441.301(c)(3), we proposed to revise the regulatory text so that it is clearer that the State is the required actor under § 441.301(c)(3), and that changes to the person-centered service plan are not required if the reassessment does not indicate a need for changes. In the proposed rule (88 FR 27973), we noted that, with this revision to the regulatory text, the State could, for instance, meet the requirement that the person-centered service plan was reviewed, and revised as appropriate, based on the results of the required reassessment of functional need by documenting that there were no changes in functional needs or the individual's circumstances upon reassessment that necessitated changes to the service plan. However, the State would still

be expected to review the service plan to confirm that no revisions are needed, even if the reassessment identified no changes in functional needs or the individual's circumstances.

Specifically, we proposed to move the sentence at § 441.301(c)(3) beginning with "The person-centered service plan must be reviewed..." to a new paragraph at § 441.301(c)(3)(i) and reposition the regulatory text under the proposed title, *Requirement*. In addition, we proposed to revise the regulatory text at the renumbered paragraph to clarify that the person-centered service plan must be reviewed, and revised as appropriate, based on the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

We received public comment on this proposal. Below is the summary of the comment and our response.

Comment: Commenters did not raise specific concerns about the proposal at § 441.301(c)(3)(i). However, one commenter raised concerns about the impact the minimum performance requirement proposed at § 441.301(c)(3)(ii) (discussed in greater detail in the next section) would have on the requirement at § 441.301(c)(3)(i). The commenter expressed concern that States may interpret the 90 percent minimum performance levels proposed at § 441.301(c)(3)(ii)(A) and (B) as meaning they are only required to conduct the reassessments and updates to person-centered service plans as required by § 441.301(c)(3)(i) for 90 percent of beneficiaries, not for 100 percent of beneficiaries receiving HCBS. This commenter also suggested that CMS clarify that States should conduct functional assessments and person-centered plan updates for every individual to make sure that the requirement at § 441.301(c)(3)(i) is not open to interpretation.

Response: We intend that the 90 percent minimum performance requirements proposed at § 441.301(c)(3)(ii) would assess States' minimum performance of the requirements at § 441.301(c)(3)(i); we do not suggest that reassessments of functional need and reviews, and revisions as appropriate, of the person-centered service plan, based on the results of the required

reassessment of functional need, are required for only 90 percent of individuals enrolled in the waiver program. The minimum performance requirements at § 441.301(c)(3)(ii) (and the associated reporting requirements at § 441.311(b)(3), discussed in section II.B.7. of this final rule), while important for aiding in our oversight and States' accountability for complying with § 441.301(c)(3)(i), are distinct and severable requirements from § 441.301(c)(3)(i). In other words, States would be expected to comply fully with § 441.301(c)(3)(i) even had we not also proposed the specific minimum performance requirement at § 441.301(c)(3)(ii). Thus, the minimum performance of 90 percent proposed in § 441.301(c)(3)(ii) notwithstanding, it is our intent to require at § 441.301(c)(3)(i) that States ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual. To ensure that this expectation is clear in the requirement, we are finalizing § 441.301(c)(3)(i) with a modification to specify that the requirement at § 441.301(c)(3)(i) applies to every individual.

Upon further review, we also determined that retaining the reference to § 441.301(c)(3) in § 441.365(e), governing the frequency of functional assessments for section 1915(d) waiver programs, at the redesignated § 441.301(c)(3)(i), is both obsolete and unnecessary. Section 441.365(e) was a standard used by section 1915(d) waiver programs, which were time-limited programs that are no longer in effect, to establish the frequency of functional assessments. The requirements at § 441.301(c)(3) establish the frequency of functional assessments for section 1915(c) programs, thus referencing § 441.365(e), which is obsolete, is unnecessary.

Accordingly, we are finalizing § 441.301(c)(3)(i) with the previously noted modifications to specify that the requirement applies to every individual and removing reference to § 441.365(e), as well as a minor technical modification to remove an extraneous comma after the word "revised." As finalized, § 441.301(c)(3)(i) specifies that the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based

upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

b. Minimum Performance Level (§ 441.301(c)(3)(ii))

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, we proposed to codify a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3) (88 FR 27973).

Specifically, at new § 441.301(c)(3)(ii)(A), we proposed to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also proposed, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We intended that these proposed minimum performance levels would strengthen person-centered planning reporting requirements while taking into account that there may be legitimate reasons why assessment and care planning processes occasionally are not completed timely in all instances. We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we decided not to propose good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these minimum performance levels. Further, we noted that there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster (88 FR 27973).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposals to codify at § 441.301(c)(3)(ii)(A) and (B) minimum performance levels for States to demonstrate that they meet the requirements at § 441.301(c)(3)(i). These commenters noted that, by CMS establishing minimum performance levels for the person-centered planning requirements, beneficiaries who receive HCBS may be more empowered to actively participate in decision-making processes related to their care and services.

Response: We appreciate the support for our proposals.

Comment: One commenter suggested we specify that a beneficiary's services should not be reduced, suspended, or terminated because the reassessment of functional need or person-centered service plan update did not occur within the specified timeframe.

Response: The proposed requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly, or at the request of the individual, are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services are reassessed to ensure they continue meeting the beneficiary's needs most appropriately as those needs change. Any changes in the services and supports included in the person-centered service plan for beneficiaries should be based on changes in circumstances or needs or preferences of the individual; they should not result from a failure by the State or managed care plan to conduct required assessment and service planning processes timely. Further, States should not reduce, suspend, or terminate a beneficiary's services solely to reach the minimum performance level required at § 441.301(c)(3)(ii)(A) and (B).

Comment: A couple of commenters suggested we clarify whether States would be required to implement corrective action for noncompliance with the 90 percent performance level if the same beneficiaries do not receive timely reassessments or updated person-centered

plans repeatedly. One commenter questioned whether a 90 percent performance level provides an acceptable margin of error (10 percent) and requested clarification on whether States will be expected to remediate through corrective action if this threshold is not met.

Response: Corrective actions or other enforcement actions will be determined on a case-by-case basis, using our standard enforcement authority, for States that are determined to not be compliant with the requirements at § 441.301(c)(3)(ii)(A) and (B). We will take this feedback into account as we plan technical assistance and develop guidance for States.

Comment: One commenter stated that the person-centered planning requirements are essential to ensure choice and access to appropriate service and suggested that, although the proposed approach meets compliance oversight and monitoring objectives, a quality improvement strategy to address improving outcomes with the person-centered planning requirements is needed.

Response: We note that the proposed requirements at § 441.301(c)(3)(ii)(A) and (B) were intended to strengthen person-centered planning reporting requirements by codifying a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3). We encourage States to consider implementing quality improvement processes to strengthen and improve person-centered planning in their HCBS programs. Further, as discussed in section II.B.8. of this final rule, we are finalizing the HCBS Quality Measure Set reporting requirements to include requirements for States to implement quality improvement strategies in their HCBS programs; while the HCBS Quality Measure Set is distinct from the person-centered planning requirements being finalized at § 441.301(c)(3), we believe the HCBS Quality Measure Set requirements support the quality improvement objectives described by this commenter.

Comment: A few commenters suggested CMS include a good cause exception for States that do not meet the minimum performance level to take into account certain instances that fall outside of the specified performance standards for appropriate reasons, such as for resource challenges in rural areas, or for beneficiary-related events that could delay the ability to complete

the assessment, such as medical emergencies/hospitalizations. Alternatively, a few commenters supported our proposal to not allow good cause exceptions to the performance level, observing that the 90 percent minimum performance level already gives States leeway for unexpected occurrences.

Response: We believe that the 90 percent minimum performance level proposed at § 441.301(c)(3)(ii)(A) and (B) sets a realistic and achievable threshold.

As we noted in the proposed rule (88 FR 27973), we decided to not propose any good cause exceptions because the minimum 90 percent performance level accounts for various scenarios that might impact the State's ability to achieve these performance levels, and there are existing disaster authorities, such as the waiver authority under section 1135 of the Act, that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. We decline to include good cause exceptions in the minimum performance level in this final rule.

After consideration of public comments, we are finalizing our proposals at § 441.301(c)(3)(ii) with minor modifications to clarify that the State must ensure that the minimum performance levels specified at § 441.301(c)(3)(ii)(A) and (B) are met (since States typically have person-centered planning requirements carried out by entities such as case managers or providers, rather than directly by the State). We are also finalizing § 441.301(c)(3)(ii)(B) with minor technical modifications to make the same punctuation correction as the modification finalized in § 441.301(c)(3)(i).

c. Application to Managed Care and Fee-for-Service (§ 441.301(c)(3))

To ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we proposed to add the requirements for services delivered under FFS at § 441.301(c)(3) to services delivered under managed care delivery systems. Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to

achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care plan to its enrollees. Therefore, we proposed that a State must ensure compliance with the requirements in § 441.301(c)(3) with respect to HCBS delivered both under FFS and managed care delivery systems.

We note that in the proposed rule at 88 FR 27974, we made the statement that to ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we propose to add the requirements at § 441.301(c)(3) to 42 CFR 438.208(c). This statement was published in error, and we did not intend to propose this specific regulation text include reference to § 438.208(c). We note that § 438.208(c)(3)(v) already requires that managed care plans comply with § 441.301(c)(3), generally, so we believe that referencing § 438.208(c) is not necessary. We also note that § 438.208(c)(3)(ii) requires compliance with the other person-centered planning requirements at § 441.301(c)(1) and (2). Thus, also referring to § 438.208(c) would be unnecessary.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the proposed requirements at § 441.301(c)(3) to be applied to managed care delivery systems as well, noting that States must ensure compliance with respect to HCBS delivered both in FFS and managed care delivery systems. Commenters also noted that the process of conducting reassessments and making updates to a person-centered service plan is agnostic to whether a provider is paid by a managed care plan or through a FFS delivery system.

Response: We appreciate the support for our proposal.

After consideration of public comments received, we are finalizing our proposed policy to require that the person-centered planning requirements at § 441.301(c)(3) finalized in this section are applied to HCBS delivered under both managed care and FFS delivery systems. As

noted above, we are not finalizing a new reference to § 441.301(c)(3) at § 438.208(c), as § 438.208(c) already requires that managed care plans comply with § 441.301(c)(1) through (c)(3), which includes the requirements being finalized in this rule at § 441.301(c)(3)(i) and (ii).

Additionally, as is discussed in section II.B.11. of this rule, we are finalizing our proposal at § 438.72(b) to direct States to comply with the requirements finalized in this final rule, including the revised person-centered centered planning requirements at § 441.301(c)(1) through (c)(3), for services authorized under HCBS authorities and provided under managed care delivery systems.

d. Person-Centered Planning – Definition of Individual (§ 441.301(c)(1))

We also proposed updates to existing language describing the person-centered planning process specific to section 1915(c) waivers. Current language describes the role of an individual's authorized representative as if every waiver participant will require an authorized representative, which is not the case. This language has been a source of confusion for States and providers. We proposed to amend the regulation text at § 441.301(c)(1) to better reflect that the individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term individual is used throughout this section, it includes the individual's authorized representative will lead the person-centered planning process if applicable. We note that, in the proposed rule, we described our proposal as removing extraneous language and not as an amendment of § 441.301(c)(1) (88 FR 27974). Upon further consideration, we believe characterizing this proposal as an amendment is more accurate. We intend that this proposed language as finalized will bring the section 1915(c) waiver regulatory text in line with person-centered planning process language in both the section 1915(j) and (k) State plan options.

We did not receive public comments on this proposal. However, after further consideration of the proposed requirement, we are finalizing § 441.301(c)(1) with a technical modification to clarify that the language contained in § 441.301(c)(1), as finalized, applies to the person-centered planning requirements **throughout § 441.301(c)(1) through (3)**. (New language

identified in bold.) This modification expresses our intent that § 441.301(c)(1) applies to the person-centered planning requirements in § 441.301(c)(1) through (3), rather than § 441.301(c) in its entirety.

e. Applicability date (§ 441.301(c)(3)(iii))

We proposed at § 441.301(c)(3)(iii) to make the performance levels under § 441.301(c)(3)(ii) effective 3 years after the effective date of § 441.301(c)(3) (in other words, 3 years after the effective date of the final rule) in FFS delivery systems. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the managed care organization's (MCO's), prepaid inpatient health plan's (PIHP's), or prepaid ambulatory health plan's (PAHP's) contract, we proposed to provide States until the first rating period with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of the final rule to implement these requirements. We solicited comment on whether the timeframe to implement the proposed regulations is sufficient, whether we should require a shorter timeframe or longer timeframe to implement these provisions, and, if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported the 3-year timeframe for the effective date as defined at § 441.301(c)(3)(iii). A few commenters expressed concerns about the overall burden they believe will be associated with the final rule, due to competing priorities, and the effect it may have on States' ability to implement the proposed person-centered planning provisions at § 441.301(c)(3)(ii) within 3 years following the effective date of the final rule. A few commenters expressed that the performance levels under § 441.301(c)(3)(ii) may require States to have a longer runway to implement and operationalize State regulation changes and processes, revise policies, and hire critical staff. A few commenters also requested we consider alternative

effective dates for the person-centered planning minimum performance requirements, ranging from 18 months to 4 years.

Response: We noted, in the proposed rule (88 FR 27974), that we recognize many States may need time to implement the proposed HCBS requirements we are finalizing in the final rule. We acknowledge that States will have to expend resources in addressing the person-centered planning minimum performance requirements, including needing time to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these person-centered planning requirements.

We believe that 3 years for States to ensure compliance with the person-centered planning minimum performance requirements being finalized at § 441.301(c)(3)(ii) is realistic and achievable for States. We also note that the minimum performance requirements measure performance of the requirements at § 441.301(c)(3)(i), which substantively reflect activities States are currently expected to perform under existing § 441.301(c)(3). For States implementing a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the in the MCO's, PIHP's, or PAHP's contract, we similarly believe it is realistic and achievable to provide States with a date to comply that is until the first rating period with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of this final rule to implement these requirements. We will provide technical assistance to States as needed with meeting the timeframe for compliance.

After consideration of the comments received, we are finalizing the substance of § 441.301(c)(3)(iii) as proposed, but with minor modifications to correct erroneous uses of the word "effective" and to make technical modifications to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are retitling the requirement at § 441.301(c)(3)(iii) as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(3)(iii) to specify

that **States must comply with** the requirements at § 441.301(c)(3)(ii) **beginning** 3 years from the effective date of this final rule (rather than stating that the performance levels described in § 441.301(c)(3)(ii) are effective 3 years after the date of enactment of the final rule); and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first **rating period for contracts with the MCO, PIHP, or PAHP beginning** on or after **the date that is** 3 years after the effective date of this **final rule**. (New language identified in bold.).

f. Application to Other Authorities

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act and because HCBS State plan options have similar person-centered planning and service plan requirements, we proposed to include the proposed requirements at § 441.301(c)(3) in section 1915(j), (k), and (i) State plan services, at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements under section 1902(a)(19) of the Act, which authorizes safeguards necessary to assure that eligibility for care and services under the Medicaid program will be determined, and such care and services will be provided, in a manner consistent with the best interest of beneficiaries. We believe these same reasons for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We considered whether to apply the proposed person-centered plan requirements at § 441.301(c)(3) to section 1905(a) "medical assistance" State plan personal care services, home health services, and case management services. However, we did not propose that these requirements apply to any section 1905(a) State plan services at this time. First, States do not

have the same data collection and reporting capabilities for these services as they do for other HCBS at section 1915(c), (i), (j), and (k). Second, person-centered planning and service plan requirements are not required by Medicaid for section 1905(a) services, although we recommend that States implement person-centered planning processes for all HCBS. We note that the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. However, the small overall percentage includes large numbers of people with mental health needs who receive case management.

We solicited comment on whether we should establish similar person-centered planning and service plan requirements for section 1905(a) State plan personal care services, home health services and case management services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for applying the proposed person-centered planning and person-centered plan requirements at § 441.301(c)(3) to section 1915(j), (k), and (i) State plan services.

Response: We appreciate the support for our proposal. As noted earlier, we are finalizing modifications to § 441.301(c)(3)(i) to specify that the requirement applies to every individual and to make a technical correction to remove an extraneous comma. We are finalizing corresponding edits for section 1915(k) in § 441.540(c) and section 1915(i) in § 441.725(c). The revised language for both § 441.540(c) and § 441.725(c) will specify that the State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3).

Comment: A few commenters responded to our request for comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care services, home health services, and case management services. Several commenters supported that we decided not to propose to extend the person-centered plan requirements at § 441.301(c)(3) to section 1905(a) services. These commenters expressed concern that applying these requirements to these State plan benefits could pose critical challenges for State Medicaid and other operating agencies, due to varying levels of HCBS provided and different data reporting infrastructure States have for section 1905(a) services. A few commenters recommended that CMS apply the person-centered planning requirements to mental health rehabilitative services delivered under section 1905(a) State plan authority. A couple of other commenters suggested that mental health rehabilitative services are considered HCBS under the broader definition enacted by Congress in the American Rescue Plan Act of 2021 (Pub. L. 117-2, March 11, 2021), suggesting that CMS should consider including these services in the person-centered plan requirements at § 441.301(c)(3).

Response: At this time and as noted in the proposed rule (88 FR 27974 and 27975), we are not applying the person-centered service plan requirements at § 441.301(c)(3) to section 1905(a) services, due to the statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. For example, there are no statutory provisions in section 1905(a) of the Act that attach State-level reporting requirements to any section 1905(a) service. Relatedly, States do not have the same data collection and reporting capabilities for these services as they do for HCBS at section 1915(c), (i), (j), and (k).

Additionally, we note that section 1905(a) services do not have the same person-centered planning requirements at § 441.301(c)(1) through (6). Formal person-centered service planning requirements are established for section 1915(j) services in § 441.468, for section 1915(k) services in § 441.540, and for section 1915(i) services at § 441.725. While service planning

might be part of some specific 1905(a) services, it is not a required component of all section 1905(a) services.

We acknowledge that many beneficiaries, particularly those receiving mental health services, are served by section 1905(a) services, and encourage States to implement effective person-centered planning processes that are based on individual preferences and personal goals and support full engagement in community for Medicaid beneficiaries receiving section 1905(a) State plan personal care services, home health services, case management services, and rehabilitative services. We thank commenters for their feedback on this request for comment, which we may consider in future rulemaking.

After consideration of public comments, we are finalizing the application of § 441.301(c)(3), as finalized in this rule, to section 1915(j), (k), and (i) State plan services by finalizing relevant requirements at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. We are finalizing §§ 441.450(c), 441.540(c), and 441.725(c), with a technical modification to clarify that service plans must meet the requirements of § 441.301(c)(3), but that references therein to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively. We are finalizing the requirements at §§ 441.540(c) and 441.725(c) with minor modifications. To maintain consistency with modifications finalized in § 441.301(c)(3)(i), we are finalizing §§ 441.540(c) and 441.725(c) with modifications to specify that the requirements apply to every individual and to remove an extraneous comma.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the proposals at §§ 441.301(c)(1), 441.301(c)(3), 441.450(c), 441.540(c), and 441.725(c) as follows:

- We are finalizing the requirement at § 441.301(c)(1) with a technical modification to clarify that § 441.301(c)(1) applies to paragraphs (c)(1) through (3) of this section.

- We are finalizing § 441.301(c)(3)(i) with modifications to specify that the requirement applies to every individual and to remove the reference to § 441.365(e), as well as finalizing a minor technical change to remove an extraneous comma.

- We are finalizing our proposals at § 441.301(c)(3)(ii) with minor modifications to clarify that the State must ensure that the minimum performance levels specified at § 441.301(c)(3)(ii)(A) and (B) are met. We are also finalizing § 441.301(c)(3)(ii)(B) with minor technical modifications to correct the punctuation (consistent with the change finalized in § 441.301(c)(3)(i)).

- We are finalizing the applicability date requirement at § 441.301(c)(3)(iii), with a technical modification to the language to improve accuracy and alignment with common phrasing in managed care contracting policy. We also are finalizing § 441.301(c)(3)(iii) to specify that States must comply with the performance levels described in paragraph (c)(3)(ii) of this section beginning 3 years after [insert the effective date of this rule]; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after [insert effective date of this rule].

- We are finalizing §§ 441.450(c) , 441.540(c), and 441.725(c), with a technical modification to clarify that service plans must meet the requirements of § 441.301(c)(3), but that references therein to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

- We are finalizing §§ 441.540(c) and 441.725(c), consistent with modifications finalized in § 441.301(c)(3)(i), with a modification to specify that the requirements apply to every individual, and with technical modification to correct the punctuation.

2. Grievance System (§ 441.301(c)(7); Proposed at § 441.464(d)(2)(v), Being Finalized at § 441.464(d)(5); Proposed at § 441.555(b)(2)(iv), Being Finalized at § 441.555(e); and § 441.745(a)(1)(iii))

a. Scope of Grievance System and Definitions (§ 441.301(c)(7)(i) and § 441.301(c)(7)(ii))

Section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁵⁶ Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. Further, section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interest of Medicaid beneficiaries.

Federal regulations at 42 CFR part 431, subpart E, require States to provide Medicaid applicants and beneficiaries with an opportunity for a fair hearing before the State Medicaid agency in certain circumstances, including for a denial, termination, suspension, or reduction of Medicaid eligibility, or for a denial, termination, suspension, or reduction in benefits or services. These fair hearing rights apply to all Medicaid applicants and beneficiaries, including those receiving HCBS regardless of the delivery system. Under 42 CFR part 438, subpart F, Medicaid managed care plans must have in place an appeal system that allows a Medicaid managed care enrollee to request an appeal, which is a review by the Medicaid managed care plan of an adverse benefit determination issued by the plan; and a grievance system, which allows a

⁵⁶ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at <https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf>.

Medicaid managed care enrollee to file an expression of dissatisfaction with the plan about any matter other than an adverse benefit determination. Currently, our regulations do not provide for a venue to raise concerns about issues that HCBS beneficiaries in an FFS delivery system may experience which are not subject to the fair hearing process, such as the failure of a provider to comply with the HCBS settings requirements at § 441.301(c)(4) (which are issues that a managed care enrollee could file a grievance with their plan).

Under our authority at section 1902(a)(19) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we proposed to require that States establish grievance procedures for Medicaid beneficiaries receiving services under section 1915(c), (i), (j) and (k) authorities through a FFS delivery system. Specifically, for section 1915(c) HCBS waivers, we proposed at § 441.301(c)(7) that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). This proposal was based on feedback obtained during various public engagement activities conducted with interested parties over the past several years about the need for beneficiary grievance processes in section 1915(c) waiver programs related to these requirements. We also proposed to apply this requirement to section 1915(i), (j) and (k) authorities, which are discussed below in section II.B.2.h. of this final rule.

To avoid duplication with the grievance requirements at part 438, subpart F, we proposed not to apply this requirement to establish a grievance procedure to managed care delivery systems. We note, though, that the requirements in this section are similar to requirements for managed care grievance requirements found at part 438, subpart F, with any differences reflecting changes appropriate for FFS delivery systems. The proposed requirements included at § 441.301(c)(7) in the proposed rule (88 FR 27975) were focused specifically on grievance systems and did not establish new fair hearing system requirements, as appeals of adverse eligibility, benefit, or service determinations are addressed by existing fair hearing requirements

at 42 CFR part 431, subpart E. We solicited comments on any additional changes we should consider in this section with respect to a grievance system.

As discussed earlier in this section II.B.2. of this final rule, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. In addition, section 2402(a)(3)(A) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS. As such, we believe the proposed requirement for States to establish grievance procedures for Medicaid beneficiaries receiving HCBS through a FFS delivery system is necessary to comply with the HCBS complaint system requirements at section 2402(a)(3)(B)(ii) of the Affordable Care Act and to ensure consistency in the administration of HCBS between managed care and FFS delivery systems. Further, in the absence of a grievance system requirement for FFS HCBS programs, States may not have established processes and systems for people receiving HCBS through FFS delivery systems to express dissatisfaction with or voice concerns related to States' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), as such concerns are not subject to the existing fair hearing process at 42 CFR part 431 subpart E. As a result, we believe the proposal for a grievance system for FFS HCBS programs is necessary to assure that care and services will be provided in a manner that is in the best interests of the beneficiaries, as required by section 1902(a)(19) of the Act.

We specifically focused our proposed grievance system requirement on States' and providers' compliance with the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) because of the critical role that person-centered planning and service plans play in appropriate care delivery for people receiving HCBS. Additionally, we focused the grievance system requirements on the

HCBS settings requirements because of the importance of the HCBS settings requirements to ensuring that HCBS beneficiaries have full access to the benefits of community living and are able to receive services in the most integrated setting appropriate to their needs. Beneficiary advocates and other interested parties indicated to us that these are especially important areas for which to ensure that grievance processes are in place for all Medicaid beneficiaries receiving HCBS. Further, focusing the grievance systems requirements on the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) helps to ensure that the proposed grievance requirements do not duplicate or conflict with existing fair hearing requirements at part 431, subpart E, as HCBS settings requirements and person-centered planning requirements are outside the scope of the fair hearing requirements.

At § 441.301(c)(7)(ii), we proposed to define a grievance as an expression of dissatisfaction or complaint related to the State's or a provider's compliance with the person-centered service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), regardless of whether the beneficiary requests that remedial action be taken to address the area of dissatisfaction or complaint. Also, at § 441.301(a)(7)(ii), we proposed to define the grievance system as the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for our proposal to require that States establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). In general, commenters believed that clear, transparent, and accessible grievance processes are critical to

ensuring that beneficiaries can address violations of their rights, provide feedback on their experiences in HCBS, and more fully participate in HCBS programs. One commenter noted that a Federal requirement will help establish national best practices.

Some commenters connected a strong grievance process with improved safety and service quality in HCBS programs. For instance, one commenter noted that a grievance process can complement other quality mechanisms (such as performance measures) because a grievance system can address problems as they happen, thus preventing harm before it can occur. Another commenter suggested that preventing or remediating poor service delivery has the potential of improving the HCBS workforce by promoting professionalism and improving the public perception of HCBS providers, which could aid providers' worker recruitment and retention efforts; this commenter noted that a strong workforce would promote quality in HCBS.

Other commenters noted that a grievance system would allow beneficiaries to state their rights and provide a fair and unbiased review of beneficiaries' concerns. Several commenters were specifically supportive of the proposal's potential to collect and track standardized information about service system issues, including obstacles to informed choice and person-centered planning.

A few commenters also described frustrations with current State or provider grievance processes that they have found difficult to access, unresponsive, ineffective, or opaque. One commenter described our proposal as "overdue," but also expressed concerns about whether providers will comply with requirements moving forward. In this vein, a few commenters suggested that CMS involvement and oversight may be critical to ensuring that existing or newly created grievance processes are effective. One commenter expressed the hope that beneficiaries would be able to contact CMS if they believe the State is not complying with grievance process obligations.

Response: We thank commenters for their support. We believe the personal experiences with grievance systems that commenters shared underscore the need for national standards.

Additionally, while States will have a great deal of responsibility for developing and monitoring their own systems, having Federal requirements for grievance systems will facilitate our ability to engage in oversight. We note that members of the public are able to share concerns with us about their State's Medicaid activities, which would include the grievance system, once implemented.⁵⁷ We also note that in addition to the grievance process finalized under this rule, individuals who believe they have been discriminated against in HCBS programs, including the right to be served in the most integrated setting, may file a civil rights complaint with the HHS Office for Civil Rights at <https://www.hhs.gov/civil-rights/filing-a-complaint/index.html>.

Comment: Several commenters expressed opposition to the proposal, suggesting that it was too prescriptive and would result in unnecessary information technology (IT) systems changes in States that already have grievance systems in place. Several commenters also noted concerns that the proposal would place administrative burdens on providers. Additionally, several commenters noted that this requirement could be administratively burdensome for States with a small percentage of their population enrolled in FFS. One commenter suggested that we provide an exceptions process in these circumstances.

Response: We address specific concerns from commenters – including concerns about potential duplication, burden, and provider involvement – in more detail in subsequent responses. As described below, we are seeking to balance State flexibility with the need for accountability and consistency among State systems. We also do not believe that this proposal should place excessive burdens on providers, as we are requiring that States, and not providers, bear the primary responsibility of managing the grievance system. Finally, as part of our goal of establishing national standards, we do not intend to exempt States from these requirements based on the size of their FFS populations.

⁵⁷ Specific questions or concerns regarding the application or implementation of the regulations finalized in section II.B. of this rule may be directed to HCBS_Access_Rule@cms.hhs.gov.

Comment: One commenter requested clarification on whether the State or CMS is “in charge” of the grievance process.

Response: We have proposed and, as discussed further below, we are finalizing Federal requirements that States operate and maintain a grievance system. The State is responsible for this system. However, we will monitor the States’ compliance with these requirements.

Comment: A few commenters raised concerns or expressed confusion about how the proposed grievance system requirement will affect dually eligible beneficiaries who are enrolled in managed care plans that already have grievance processes. One commenter raised concerns about the possibility of multiple investigations being conducted parallel to one another. Other commenters inquired if Medicare Advantage care navigators could be required to help beneficiaries file grievances, or if the proposed grievance system requirements can be made part of dual eligible special needs plan (D-SNP) contracts. One commenter noted that it is critical for dually eligible beneficiaries to have one place to file grievances about both Medicare and Medicaid services. Another commenter requested clarification on how the grievance systems should work for dually eligible beneficiaries who have, as described by the commenter, “multiple, perhaps conflicting plans of care.”

Response: We plan to provide States with technical assistance to help address issues specific to dually eligible beneficiaries. We note that we proposed that the grievance system requirements at § 441.301(c)(7), and as finalized in this rule, apply only to beneficiaries receiving services under section 1915(c), (i), (j), and (k) authorities through FFS delivery systems, and to issues arising with these services. The new grievance system requirement would not affect, for instance, dually eligible beneficiaries who receive services under section 1915(c), (i), (j), or (k) authorities through fully integrated dual eligible special needs plans (FIDE SNP), highly integrated dual eligible special needs plans (HIDE SNP), or D-SNPs otherwise affiliated with MLTSS plans, as those beneficiaries receive their HCBS through managed care and not through FFS. We also note that some dually eligible beneficiaries may be enrolled in managed

care plans known as applicable integrated plans (AIP), which are subject to the integrated grievance requirements at § 422.630. AIPs must resolve and notify enrollees within required timeframes for integrated grievances filed for Medicare and Medicaid services. We will provide technical assistance as needed regarding the application of the requirements finalized at §441.301(c)(7) to beneficiaries in different categories of dual eligibility.

Comment: One commenter recommended continuity across grievance systems in FFS and managed care delivery systems to ensure consistent and equitable processes for addressing enrollee concerns.

Response: We agree that such continuity is important. In drafting the proposed requirements at § 441.301(c)(7) for FFS grievance systems, which we are finalizing as described in this section II.B.2 of the final rule, we attempted to mirror the requirements for managed care grievance processes in part 438, subpart F, as much as possible in order to promote consistency between the two systems.

Comment: A few commenters requested that we allow States to arrange for the operations of the grievance procedures to be performed by a vendor, local agencies, or other contracted entity. Conversely, a few other commenters raised concerns about the possibility of the grievance process being administered by providers. Some of these commenters expressed concerns that the requirement might be burdensome for local and regional entities to administer, and one commenter raised concerns that administration of the grievance process by local agencies might cause problems in terms of oversight and conflict of interest.

A few commenters also noted that, unlike in managed care where care is managed under one plan, some FFS delivery systems involve multiple State agencies or agency divisions operating different programs. The commenters requested more clarification about which agency or department is responsible for oversight of the system and coordination in these circumstances.

Response: The requirements proposed, and being finalized, in § 441.301(c)(7) are applied to the State, by which we refer (as we do in many of our regulations) to the single State

agency as described in § 431.10(b). However, we believe that some States may find it more efficient or effective to have the operations of the grievance system performed by other government agencies or contractors, depending on how a State's systems are organized. Allowing such contracting may also help preserve existing State grievance processes; we address additional comments about preservation of existing grievance systems later in this section II.B.2. of the final rule. However, the single State agency must retain ultimate responsibility for ensuring compliance with the requirements set forth in § 441.301(c)(7). We expect that States are familiar with their local resources (including the capacity of local agencies) and would only have the operations of the grievance system performed by an entity that had the necessary infrastructure and resources to operate a system that would comply with the requirements in § 441.301(c)(7). To ensure that the responsibility of the single State agency is clear, we are finalizing § 441.301(c)(7)(i) with a modification to specify that the State may contract with contractors or other government entities to perform activities described in § 441.301(c)(7) provided however that the State retains responsibility for ensuring performance of and compliance with these provisions.

We also note that we intend that the proposed requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as discussed in detail later in this section II.B.2. of the final rule, promote an unbiased review of grievances because they prohibit someone who has previously made decisions related to the grievance from reviewing the grievance. While we do not intend to specify any additional restrictions on the entities operating the grievance system in this final rule, we believe that it would be difficult to envision scenarios in which it would be appropriate for the State to contract with a provider (or local agencies that act as providers) to operate the grievance system. For example, an employee of a provider who signed off on the provider's actions that gave rise to the grievance would be someone who was involved with making a decision about the grievance and thus neither that employee (nor their subordinates) would be appropriate decisionmakers in the grievance process. If a State believed it necessary to arrange

for the operations of the grievance system to be performed by a local agency that also provided services, firewalls would have to be put in place to ensure that grievances were reviewed by a neutral decisionmaker within that agency.

Comment: Several commenters supported the definition of grievance we proposed at § 441.301(c)(7)(ii). Overall, these commenters supported the focus on compliance with the person-centered planning process and the HCBS settings rule. One of these commenters observed that issues with these requirements are often at the core of challenges experienced by beneficiaries. One commenter, however, questioned the inclusion of concerns about the HCBS settings requirements, noting that if a setting violates the HCBS settings requirements, the individual has the choice of moving to a different setting.

Response: We appreciate commenters' support for the definition of grievances. We specifically included noncompliance with the HCBS settings requirements as one of the bases for grievances so that beneficiaries do not have the burden of addressing violations of their rights by having to change providers, which could result in some circumstances in having to move out of their home. We do not believe that beneficiaries should have to choose between their rights or their homes. As a practical matter, switching residences can be disruptive, emotionally and physically demanding, costly, and time-intensive, not to mention particularly difficult in areas that lack plentiful affordable and accessible housing options. We also believe that requiring States to address these issues related to compliance with HCBS settings requirements in the context of a grievance system may encourage States and providers to prevent similar issues from occurring with other beneficiaries.

Comment: One commenter stated that the definition of grievance was too broad and requested that CMS narrow the scope of allowable grievances. The commenter stated that although the proposed requirements limit the grievance system to person-centered planning, service plan requirements, and HCBS settings requirements, they would still allow a beneficiary to file a grievance on nearly every aspect of their HCBS experience, which would in turn create

the potential for an unreasonably high volume of grievances to which States would be required to respond.

A few commenters stated that the definition of grievance was subjective, and asked for general clarification on what is meant by an “expression of dissatisfaction.” Conversely, a few commenters stated the definition of grievance was not broad enough. One commenter stated that the reference to §§ 441.301(c)(1) through (3) would only allow for the filing of grievances in relation to the person-centered planning process but would not allow for grievances in relation to beneficiaries’ dissatisfaction with the delivery of the services in the plan. The commenter provided examples, such as a care provider handling an HCBS beneficiary roughly, failing to assist the beneficiary with certain activities of daily living or perform other services in the care plan, being slow to respond to the beneficiary’s requests for assistance in residential settings, improper administration of chemical restraints, or general poor care that leads to injuries such as bed sores. The commenter recommended that the regulatory language be revised to include the right to file a grievance to protect beneficiary health and welfare.

One commenter suggested that we specify that grievances may include issues regarding timeliness, quality, and effectiveness of services, in addition to the HCBS setting, person-centered planning, and service plan requirements. The commenter noted that, in the commenter’s State, beneficiaries have had to wait for long periods of time for the initiation of services after being approved for the services.

Finally, another commenter noted that they believed that the managed care regulations’ grievance definition includes an expression of dissatisfaction about any matter other than an adverse benefit determination and recommended adding clarifying language to the definition of a grievance to ensure that beneficiaries do not mistakenly file grievances about issues that are adverse benefit decisions and that entitle them to a fair hearing.

Response: We disagree with commenters that the proposed definition is overly broad. The definition of grievance proposed at § 441.301(c)(7)(ii) was crafted to strike a balance

between providing beneficiaries with broad, but not unlimited, bases for filing a grievance. We believe that the requirements in §§ 441.301(c)(1) through (6) provide a clear list of activities that the States and providers must perform to ensure that HCBS beneficiaries receive appropriate person-centered planning, receive the services described in the person-centered service plan to support the individual in the community, and have full access to the benefits of community living and are able to receive services in the most integrated setting appropriate to their needs.⁵⁸ We note that some specific examples of when a beneficiary may express dissatisfaction by filing a grievance are discussed further in this section.

We also disagree that the scope of the definition is too narrow. We proposed that the definition of grievance include an expression of dissatisfaction or complaint related to the State's or provider's compliance with the person-centered service planning process, required in §§ 441.301(c)(1) through (3). We note that some issues regarding the timeliness, quality, or effectiveness of services may need to be addressed as part of the person-centered service planning process itself. For instance, if a beneficiary believes the service is not effective, the beneficiary may request revision to the person-centered service plan, as required at § 441.301(c)(3), to identify either a more effective service or a more effective provider; non-responsiveness on the part of the entity responsible for updating the service plan could be a reason to file a grievance.

Additionally, § 441.301(c)(4) requires that home and community-based settings must meet certain requirements enumerated therein, including (but not limited to): being integrated in and supporting full access of individuals to community life; ensuring that an individual has rights to privacy, dignity and respect, and freedom from coercion and restraint; optimizing an individual's initiative, autonomy, and independence in daily activities and the physical

⁵⁸ We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

environment; and facilitating an individual's choice in services and supports, as well as who provides them. If, for instance, a beneficiary believes that a worker has not treated the beneficiary with respect, or the worker is chronically late, and the provider has failed to address the worker's behavior or provide a different worker at the beneficiary's request, it would be reasonable for a beneficiary to file a grievance, as the provider is not ensuring that all of the qualities of a home and community-based setting (as described by § 441.301(c)(4)) are being met. Accordingly, we believe that the activities set forth in §§ 441.301(c)(1) through (6) (both currently and as are being amended in this final rule) generally describe the actions of both providers and States that are necessary to uphold and promote high-quality service delivery that promotes respect for beneficiaries' rights.

While we believe the scope of grievances that may be considered under the grievance system that we proposed, and are finalizing, appropriately captures activities that promote delivery of quality HCBS and respect for beneficiaries' rights, we do believe further clarity is warranted. We believe it is more appropriate and precise to say grievances may be filed regarding the State's or a provider's performance of (rather than compliance with) the requirements described in §§ 441.301(c)(1) through (6). We note that the activities described in §441.301(c)(1) through (6) must, as required at § 441.301(c), be included in a State's waiver application; we want to make it clear that grievances may be filed when a State or provider fails to perform these activities (not solely if the State fails to include these items in a waiver application). To clarify this point, we are finalizing the scope of grievances that may be filed under the grievance system we proposed to set forth at § 441.301(c)(7) with modification, by revising the language in § 441.301(c)(7)(i) to specify that beneficiaries may file grievances regarding a State's or provider's performance of (rather than compliance with) the activities described in §§ 441.301(c)(1) through (6). We are finalizing a conforming modification to the definition of grievance at § 441.301(c)(7)(ii).

We observe that most of the examples provided by commenters, as described above, included instances in which a beneficiary experienced abuse or harm during the performance (or lack thereof) of services in the person-centered service plan. These types of complaints may be more appropriately addressed under the critical incident system being finalized at § 441.302(a)(6). As discussed in II.B.3. of this rule, we believe the critical incident system proposed at § 441.302(a)(6) is the appropriate mechanism for investigating harms to beneficiaries' health and safety. As we discuss in II.B.3 of this rule, we proposed additional performance measures and reporting requirements for the critical incident system (beyond what is proposed for the grievance system) to ensure more formal oversight of the investigations and resolutions of threats to beneficiary health and safety. We do not believe a grievance system is an appropriate mechanism for investigating threats to the beneficiary's health and welfare. Therefore, we decline to broaden the definition of grievances that may be addressed under the grievance system we are finalizing at § 441.301(c)(7) in such a way that would suggest that the grievance system is intended for complaints regarding health and safety. We believe doing so would create duplicative system requirements for the grievance process and critical incident system and potentially cause States to resolve threats to health and safety in the grievance system that should have been investigated and addressed within the critical incident system.

We also disagree with the commenter that suggested we align the definition of grievance we proposed at § 441.301(c)(7)(ii) with the definition of grievance for managed care grievance processes at § 438.400(b). We believe that, for the purposes of a FFS grievance system intended to address specific concerns with HCBS, using the same or similar definition of grievance for managed care grievance processes would be overly broad and will not diminish confusion about whether an issue is appropriate to be filed as a grievance, a critical incident, or a fair hearing. We plan to provide technical assistance to States as needed on this topic.

We refer readers to section II.B.2.b. of this final rule where we also address more specific concerns related to ensuring matters are filed with the correct system in our discussion of § 441.301(c)(7)(iii).

Comment: One commenter suggested that we broaden the definition of grievance to specify that beneficiaries can file grievances when their rights are violated, and suggested that the following be included in the definition of rights:

- Right to work and fair pay;
- Right to control one's own money;
- Right of possessions and ownership;
- Right to privacy, dignity, and respect;
- Freedom of choice and decision-making;
- Right to leisure activities;
- Freedom to marry and have children;
- Right to food, shelter, and clothing;
- Freedom of movement;
- Freedom of religion;
- Freedom of speech and expression;
- Free association and assembly;
- Freedom from harm;
- Access to health care;
- Right to citizenship and right to vote;
- Right to equal education;
- Right to equal access; and
- Due process.

Response: We believe that some of the consumer rights listed by the commenter are addressed in or mirrored by components of the existing HCBS settings rule requirements at §

441.301(c)(4), such as: ensuring that the individuals have access to the greater community, including engagement in community life, opportunities for employment in competitive integrated settings, and control over personal resources (§ 441.301(c)(4)(i)); the right to privacy, dignity and respect, and freedom from coercion and restraint (§ 441.301(c)(4)(ii)); allowing for individuals to choose their activities and set their own schedules (§ 441.301(c)(4)(iv) and (vi)(C)); the ability to determine with whom the individual will interact, as well as to have visitors of the individual's choosing at any time (§ 441.301(c)(4)(iv) and (vi)(D)); and control over the individual's own physical environment, living and sleeping space, and access to food (§ 441.301(c)(4)(iv), (v)(B), and (vi)(C)).

We note that many of the other rights suggested by the commenter are either addressed by other systems (such as access to health care which, if related to an adverse benefit determination made by the State Medicaid agency, may be subject to the fair hearings process or are out of scope of the State Medicaid agency's authority) or by other authorities (such as fair wages, equal access to education, or violations of constitutional rights).

Comment: Several commenters requested that the grievance process include issues such as authorization disputes and the provision of services.

Response: We are not certain if the commenters are referring to using the grievance system to allow beneficiaries or providers to challenge denials of services. We are also uncertain if disputes over "provision of services" refers to the quantity or quality of services. We note that the fair hearings process at 42 CFR part 431, subpart E, sets out the parameters that allow beneficiaries to challenge an adverse action by the State Medicaid agency. For the purposes of a fair hearing, an "action" is defined at § 431.201 in part, as the termination, suspension of, or reduction in covered benefits or services, or a termination, suspension of, or reduction in Medicaid eligibility. A State must provide an individual the opportunity for a fair hearing in the circumstances described in § 431.220(a), which include when the Medicaid agency has denied eligibility, services, or benefits, and when the claim for medical assistance has not been

acted on with reasonable promptness. In most circumstances, a refusal of a State Medicaid agency to authorize a particular service for a beneficiary, or to authorize the quantity of services the beneficiary believes is necessary, would be addressed in the fair hearings process. In contrast, the grievance process we have proposed is intended to allow beneficiaries to raise concerns about specific aspects of their services that have been authorized.

Comment: Several commenters who supported this proposal did so because they agreed that, currently, concerns regarding person-centered planning and HCBS settings requirements are not subject to the existing fair hearings process at 42 CFR part 431 subpart E. One commenter, however, suggested that, rather than create a grievance process to hear complaints about person-centered service plans and the HCBS settings requirements, we should require that concerns about person-centered service plans or the HCBS settings requirements be added to fair hearings processes. The commenter stated the belief that fair hearings permit an unbiased third-party Administrative Law Judge (ALJ) to consider the facts and render an objective decision. By contrast, the commenter believed that, in their State, the current State grievance process did not permit unbiased or effective review.

Response: We agree that it is important to provide beneficiaries with the opportunity to raise concerns about the person-centered service plans and planning process and the HCBS settings requirements. We do not, however, believe that these are necessarily appropriate matters for the fair hearings process. The authority for the fair hearings process comes from section 1902(a)(3) of the Act, which requires that States provide beneficiaries and applicants an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance is denied or is not acted upon with reasonable promptness.

While beneficiaries can request a fair hearing to address concerns about service denials (including partial denials) and other concerns described under § 431.220(a), we believe that an individual's concerns about person-centered service plans, the planning process, and HCBS settings are outside the scope of issues for which the statute requires that a fair hearing be

provided, and therefore we cannot require States to provide an opportunity for a fair hearing to address such issues. We note, however, that States have discretion to decide whether integrating their grievance processes with other State systems, including their fair hearings systems, is feasible and appropriate, and that the requirements for both systems may still be met.

Separate from the fair hearing requirement at section 1902(a)(3) of the Act, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires the development and monitoring of an HCBS complaint system. To address this statutory requirement, we proposed that the grievance system address matters that do not arise from a denial of Medicaid eligibility or denial of services, or failure to act upon the individual's claim for medical assistance with reasonable promptness, which are addressed separately under the required fair hearing process. We expect the grievance system will help beneficiaries resolve concerns about the quality of the services they are receiving. We also note that the purpose of our proposals in this section II.B.2. is to require that States create, implement, and maintain grievance systems that, while not necessarily as formal as a fair hearings process in all cases, will nevertheless result in unbiased and effective reviews of grievances.

We note that, while States may choose to use ALJs as hearing officers to conduct a Medicaid fair hearing, hearing officers are not required to be ALJs. Medicaid regulations at § 431.240(a)(3) require that all fair hearings be conducted by one or more impartial officials or other individuals who were not directly involved in the initial determination in question. We also note that the proposed requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as discussed in detail later in this section II.B.2. of the final rule, are intended to promote an unbiased review of grievances because they prohibit someone who has previously made decisions related to the grievance from reviewing the grievance.

Comment: A few commenters expressed concerns that, in States that already have grievance systems, the proposed requirements could result in duplication of processes and confusion for beneficiaries about where and how to report grievances. Several of these

commenters requested we allow States to use existing grievance systems to meet the Federal requirement. One commenter also suggested that if the State's existing system meets our proposed criteria, the State should be considered in compliance with the requirements. Another commenter suggested that providers or States with existing grievance systems should not have to modify their systems.

Commenters were especially concerned about the impact on States that already had multiple grievance systems for different programs, administered by different operating agencies. These commenters requested that we allow States flexibility to design grievance systems and processes to fit their unique program and systems structures and implement multiple grievance systems or processes tailored to their programs. One commenter raised specific concerns about having to consolidate current grievance systems into a single electronic system.

One commenter, however, requested that we require States to have a single grievance system; the commenter stated that having multiple grievance processes can be confusing and burdensome for beneficiaries.

Response: We acknowledge that many States already have grievance processes in place for HCBS, and it is not our intent for States to abandon these systems or create additional systems. We agree with the suggestion that, if a State already has a grievance process in place that meets the requirements that we are finalizing in this rule, that State will be considered in compliance with these requirements. However, we disagree that States with existing grievance systems should be allowed to maintain the system without modification where their systems do not meet Federal requirements. While we encourage States to economize by maintaining current systems as much as possible, we do expect that States will make any needed adjustments to bring their systems into compliance with the requirements we are finalizing in this rule. We believe that having Federal requirements for grievance systems will promote consistency and accountability across the country.

Additionally, we note that the definition of grievance system that we proposed referred to “processes,” suggesting that a grievance system may be made up of one or more processes (88 FR 28080). If a State wishes to maintain multiple grievance processes, and each of these processes comply with the Federal requirements we are finalizing in this rule, the State will be considered in compliance.

We did not propose a requirement for a State to maintain a single electronic system for their grievance system and, as discussed above, believe it would be acceptable to maintain multiple grievance processes. However, we also emphasize that part of the definition of grievance system we proposed, and are finalizing, in § 441.307(c)(7)(ii) is that the system allows States to collect and track information about grievances. If States choose to maintain separate systems, including separate electronic systems, they must develop ways to ensure that they are able to track trends across systems in meaningful ways. We refer readers to section II.B.2.f of this final rule, where we discuss our proposals related to recordkeeping requirements for the required grievance system.

Although not required, we encourage States to implement a single integrated system across their HCBS programs, as we echo one commenter’s concerns that a single integrated system would likely reduce confusion for beneficiaries and facilitate their ability to access the system. We also believe that a single system would best permit States to track trends across their HCBS programs and use the data and information generated by the grievance system to address systemic issues in their HCBS programs. Additionally, a single integrated system may be more cost-effective for States to operate once implemented.

Comment: One commenter requested clarification on whether there is a difference between a complaint and a grievance, as well as what would elevate a complaint to the level of a grievance.

One commenter asked for clarification on the role of conflict-free case managers in the grievance system.

Response: While section 2402(a)(3)(B)(ii) requires that we promulgate regulations to ensure that all States develop service systems that include development and monitoring of a complaint system, the Affordable Care Act does not define the terms complaint or complaint system. In developing our proposal to implement this requirement from the Affordable Care Act, we have chosen to use the term grievance, instead of complaint, and proposed to define grievance and grievance system at § 441.301(c)(7)(ii). If a State has implemented a system it calls a complaint system that meets the requirements we proposed, and are finalizing, at § 441.301(c)(7), it is possible that this system could satisfy the requirement for a State to have a grievance system.

We do not understand the specific nature of the comment regarding conflict-free case managers. We note, in general, that we will provide technical assistance to States to assist in adapting their HCBS programs and any associated existing grievance processes to comply with the requirements finalized at § 441.301(c)(7).

Comment: Several commenters observed that some States currently require providers to have policies and procedures in place related to service-delivery complaints. One commenter requested that we provide clarification, either in the final rule or subregulatory guidance, regarding the inclusion of the proposed grievance system requirements in existing provider-level complaint and grievance processes. Commenters stated that additional guidance is needed to help all interested parties understand when beneficiaries should file a grievance with their provider and when they should file with the State. One commenter recommended that beneficiaries be required to exhaust these processes at the provider level before a complaint is submitted to the State agency for investigation or intervention.

Response: Our goal for proposing uniform requirements for grievance systems applicable to all States providing HCBS under section 1915(c) waiver program authority, and other HCBS authorities as discussed in section II.B.2.h of this final rule, is to ensure consistent processes are available for Medicaid beneficiaries receiving such services. We decline to require

in this final rule that beneficiaries exhaust their provider-level complaint process prior to accessing the State grievance system. We believe that such a Federal requirement would be inapplicable or confusing in States that do not have provider-level complaint process requirements, do not require all providers to have them, or do not require that providers have uniform complaint processes. We have attempted to provide States with as much flexibility as possible in the design of their grievance system. Additionally, we have concerns that such an exhaustion requirement would be a barrier, or would cause unnecessary delay, for beneficiaries where the relationship between the beneficiary and the provider is contentious, or where the provider does not have an effective or efficient complaint process.

Comment: Commenters requested that grievance processes be developed with input from providers, beneficiaries, families, and advocacy groups to create a grievance system that is accessible, practical, and sets realistic expectations for its users.

Response: We have attempted to provide States with as much flexibility as possible in the design of their grievance system and decline to add a specific requirement on this point in this final rule. We encourage States to include input from interested parties when developing their grievance system policies and procedures to comply with the requirements we are finalizing in this rule.

Comment: Several commenters suggested that the grievance system be integrated with the critical incident system. One commenter stated that States should be required to enter the grievance information and data into a State database with standardized fields that is either part of, or integrated with an incident management system, so that grievance data can be compared to data on relevant individuals, providers, and incidents (both reported and unreported). Similarly, a few commenters suggested that the grievance system should be integrated with the fair hearings system in States.

Response: While we agree that States may find it useful to have a single, integrated system for grievances, critical incidents, and fair hearings, we are not requiring in this final rule

that States do so. We believe it is important for States to have flexibility in how they design their grievance systems so that they may expand on infrastructures and processes they already have in place and tailor the grievance systems to meet their programmatic and operational needs, even as they are held to standardized Federal grievance system requirements.

After consideration of the comments received, we are finalizing the language at § 441.301(c)(7)(i) and (ii) with modifications. For the reasons discussed above, we are modifying § 441.301(c)(7)(i) to include language specifying the State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions. Additionally, we are finalizing § 441.301(c)(7)(i) and the definition of grievance in § 441.301(c)(7)(ii) with the modification that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's *performance of* (rather than compliance with) the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). We are otherwise finalizing the definition of grievance system at § 441.301(c)(7)(ii) as proposed.

b. Grievance Process Requirements (§ 441.301(c)(7)(iii))

At § 441.301(c)(7)(iii)(A) through (C), we proposed new general requirements for States' grievance procedures for section 1915(c) HCBS waiver programs and other HCBS authorities as discussed in section II.B.2.h of this final rule. Specifically, at § 441.301(c)(7)(iii)(A), we proposed to require that a beneficiary or authorized representative be permitted to file a grievance under the section 1915(c) HCBS waiver program. As discussed below in section II.B.2.h. of this final rule, we also proposed to apply these same requirements to section 1915(i), (j) and (k) HCBS programs. Under the proposal, another individual or entity may file a grievance on a beneficiary's behalf, so long as the beneficiary or authorized representative provides written consent. We noted that our proposal would not permit a provider to file a grievance that would

violate conflict of interest guidelines, which States are required to have in place under § 441.540(a)(5). At § 441.301(c)(7)(iii)(A), we also proposed to specify that all references to beneficiary in the regulatory text of this section includes the beneficiary's representative, if applicable.

At § 441.301(c)(7)(iii)(B)(1) through (7), we proposed to require States to:

- Have written policies and procedures for their grievance processes that at a minimum meet the requirements of this proposed section and serve as the basis for the State's grievance process;
- Provide beneficiaries with reasonable assistance in completing the forms and procedural steps related to grievances and to ensure that the grievance system is consistent with the availability and accessibility requirements at § 435.905(b);
- Ensure that punitive action is not threatened or taken against an individual filing a grievance;
- Accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries;
- Provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);
- Review grievance resolutions with which beneficiaries are dissatisfied; and
- Provide information on the grievance system to providers and subcontractors approved to deliver services under section 1915(c) of the Act.

At § 441.301(c)(7)(iii)(C)(1) through (6)⁵⁹, we proposed to require that the processes for handling grievances must:

⁵⁹ At 88 FR 27976, we incorrectly stated that we were proposing these requirements at § 441.301(c)(7)(iii)(C)(1) through (5), rather than (1) through (6). This typo has been corrected.

- Allow beneficiaries to file a grievance either orally or in writing;
- Acknowledge receipt of each grievance;
- Ensure that decisions on grievances are not made by anyone previously involved in review or decision-making related to the problem or issue for which the beneficiary has filed a grievance or a subordinate of such an individual, are made by individuals with appropriate expertise, and are made by individuals who consider all of the information submitted by the beneficiary related to the grievance;
- Provide beneficiaries with a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance;
- Provide beneficiaries, free of charge and in advance of resolution timeframes, with their own case files and any new or additional evidence used or generated by the State related to the grievance; and
- Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal at § 441.301(c)(7)(iii)(A) to require that a beneficiary or the beneficiary's authorized representative be permitted to file a grievance, including allowing another individual or entity to file a grievance on a beneficiary's behalf, with written consent from the beneficiary or the beneficiary's authorized representative.

However, several commenters raised concerns about the proposed requirement that beneficiaries or their authorized representatives must provide written consent to another individual or entity to file a grievance on the beneficiary's behalf. A few commenters noted that some beneficiaries may not be able to give written consent, or that waiting for written consent to

be obtained could create unnecessary delays in grievance filings and investigations. One commenter suggested that we either remove the word “written” or specify that consent may be verbal or written. Another commenter, using their State as an example, suggested that a grievance could be filed with verbal consent from the beneficiary or authorized representative, with written consent obtained later. One commenter suggested an agency could obtain a beneficiary or authorized representative’s consent over the phone to allow another individual or entity to file a grievance on the beneficiary’s behalf.

Response: As discussed further herein, we are finalizing the requirement that consent must be written as proposed. We modelled the proposed requirement and language at § 441.301(c)(7)(iii)(A) on requirements for the managed care grievance process at § 438.402(c)(1)(ii), which provides that, if State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of a managed care enrollee. Our general intent is to align the FFS grievance system and managed care grievance process to the greatest extent possible. We also believe it is important to ensure that there is some documentation demonstrating that beneficiaries or their authorized representatives have provided consent for a grievance to be filed on the beneficiary’s behalf, especially as the investigation of a grievance may involve reviewing records pertaining to the beneficiary’s care.

We note that written consent may be broadly interpreted to include electronic signatures, voice signatures, or other methods that provide reasonable accommodations to individuals who might face challenges providing traditional written signatures. States will have flexibility in determining how written consent is obtained and verified, so long as the system States develop ensures that the process presents as few administrative barriers as possible for a beneficiary or authorized representative to provide the necessary consent.

Comment: Several commenters recommended that we clarify that beneficiaries be able to choose who represents them throughout the grievance process. One commenter recommended

that the grievance process should provide the beneficiary with the opportunity to indicate who they want to assist them in the process, and this should serve as a type of release.

Response: It was our intent that beneficiaries and their authorized representatives be able to involve other individuals or entities of their choosing to assist them throughout the grievance process, in addition to filing a grievance. We believe that it is logical to assume that if a beneficiary or their authorized representative needs assistance filing a grievance, they may also need assistance with other parts of the process (such as requesting and reviewing their case file, or presenting information to support their concerns at a hearing). We also note that while States are required at § 441.301(c)(7)(iii)(B)(2) to provide beneficiaries with reasonable assistance in completing forms and taking other procedural steps related to a grievance, beneficiaries may prefer to get this assistance from an individual or entity of their own choosing, particularly in situations where the beneficiary has filed a grievance against the State. To clarify this intent, we are finalizing § 441.301(c)(7)(iii)(A)(1) with a modification to specify that another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. We note that we expect that, as part of ensuring the process is person-centered, beneficiaries or their authorized representatives will be able to withdraw consent for this third-party representation at any time, and that beneficiaries can generally terminate the grievance process at any time.

We are finalizing § 441.301(c)(7)(iii)(B)(1) with a modification to correct an erroneous reference to subchapter in the regulatory language and replace subchapter with paragraph (c)(7).

Comment: Several commenters requested clarifications or made suggestions regarding our proposal at § 441.301(c)(7)(iii)(B)(2) to require that States provide beneficiaries reasonable assistance in completing forms and taking other procedural steps related to a grievance. One commenter recommended that we set minimum criteria for reasonable assistance in filing a grievance, including but not limited to the State making someone available to meet with the

beneficiary in person. Another commenter observed that many individuals who receive section 1915(c) waiver services, for example, have significant intellectual and developmental disabilities and as a result may need substantially more assistance than other beneficiaries to complete forms and procedural steps. The commenter requested clarification as to whether, in these circumstances, the reasonable threshold is determined by the needs of the beneficiary or the burden is on the State to determine how to provide reasonable assistance.

Response: We disagree that the term reasonable assistance that we proposed at § 441.301(c)(7)(iii)(B)(2) is unclear. We intentionally proposed language that would require States to determine, on a case-by-case basis, what constitutes reasonable assistance for beneficiaries utilizing the grievance system. Reasonable assistance may vary among beneficiaries and thus we intended to provide States with flexibility in determining what assistance is reasonable to provide. We decline to include additional formal definitions or criteria for the term reasonable assistance in this final rule lest we inadvertently set rigid standards that would, counterproductively, inhibit States from modifying processes for beneficiaries. For instance, if we were to require that States make someone available to meet with the beneficiary in person, we would not want this misinterpreted as a requirement that grievances may only be filed in person, which could pose significant barriers to individuals who lack transportation or live far from the physical locations in which grievances could be filed, even though we recognize that some beneficiaries may prefer to file a grievance in person.

We agree with the commenter that some beneficiaries may need more assistance, or different types of assistance, than other beneficiaries. We decline, however, to weigh in on what would be the threshold for determining reasonableness, as this appears to be a request for an opinion on hypothetical situations. We note that the concept of reasonableness is central to many areas of law and bodies of guidance regarding reasonableness are well-developed. We also note that the grievance system in general, by virtue of being administered by State Medicaid programs, will be subject to Title II of the Americans with Disabilities Act (ADA) of 1990, and

section 504 of the Rehabilitation Act of 1973 (section 504), which may provide some specific guidance for what may be considered a reasonable modification in a government service.

Comment: A number of commenters advocated for the creation of a requirement for an HCBS Ombudsman program, similar to those required by the Older Americans Act. Many commenters noted an independent ombuds program could provide more effective assistance to individuals in filing grievances, helping them navigate the process, and representing them during the proceedings, rather than relying on assistance provided by the State.

Response: We thank commenters for their interest in this issue. As commenters noted, Title VII of the Older American Act authorizes and provides Federal funding for the national Long-Term Care Ombudsman Program, which is administered at the State level. These programs provide advocacy on behalf of residents of long-term care facilities. While there is no similar Federal statutory requirement for States to create an HCBS ombuds program, States may create such a program or similar programs at their own discretion to assist during grievance processes or to provide other advocacy supports.

Comment: Several commenters expressed concerns that it will be challenging for beneficiaries to understand when and how to file grievances. Several commenters noted the possibility that beneficiaries will be confused by the grievance and fair hearings processes and will file grievances or appeals with the wrong entities. One commenter suggested that beneficiaries enrolled in managed care for some medical services but receive FFS HCBS may be confused when presented with multiple grievance processes.

A number of commenters recommended that the grievance system should be set up with a “no wrong door” process so that, for example, a managed care plan receiving a grievance related to a FFS service would be responsible for forwarding the grievance to the appropriate entity. Similarly, another commenter suggested that if an enrollee mistakenly files a grievance about an adverse benefit determination, we require that this submission be treated as a fair hearing request unless the beneficiary objects. One commenter cautioned that, based on the commenter’s

experience, creating a “no wrong door” approach to grievances can be complicated and resource intensive. Another commenter requested that, if setting up a “no wrong door” approach, we ensure that the burden does not fall entirely on local entities, such as local Area Agencies on Aging.

One commenter requested clarification on whether appropriate referral of a grievance to the critical incident management process will count as a successful resolution of the grievance.

Response: We take very seriously the concerns raised by commenters regarding potential confusion among beneficiaries about which matters should be filed with which system. Our understanding of the commenters’ suggestions is that such system should be coordinated for accepting grievances, fair hearing requests, and reports of critical incidents, among other engagements with beneficiaries, and ensure that each grievance, fair hearing request, or report of a critical incident is appropriately and seamlessly processed once it has been received by that system. However, we are not adding a formal “no wrong door” requirement in this final rule. Rather, we are finalizing the grievance system requirements we proposed with modifications as described below. We understand that, despite efforts to provide beneficiaries and interested parties with information and to make systems as user-friendly as possible, there will be instances in which beneficiaries attempt to access the “wrong” system. Additionally, there may be some matters where it is not immediately clear to the beneficiary if the problem, for instance, is a matter for the grievance system, critical incident investigation, or the fair hearings process. We also note that the beneficiary (or someone on their behalf) may report a critical incident (as defined at § 441.302(a)(6) of this final rule), or file an appeal under the fair hearings process that may not, as a whole, meet the definition of a grievance, but may contain elements that are more appropriate for consideration under the grievance system, while the remaining elements should still proceed as a critical incident investigation or in the fair hearing process. (We note that additional concerns about perceived overlap between grievances and critical incidents are addressed more fully later in this section.) Further, we agree that something akin to a “no wrong

door” approach may be a good solution, to ensure that matters that are brought to the grievance system are not rejected because they are really a matter for a fair hearing or critical incident investigation. We encourage States to create a “no wrong door” policy and system or integrate grievance filings with existing “no wrong door” systems, if feasible. We believe that such a system would help ensure that matters are filed correctly, which could reduce administrative burden on the grievance system.

However, we did not propose, nor are we requiring, that States create a “no wrong door” system. We note that some States may already have “no wrong door” systems that could be used to support beneficiary filings in the grievance system. While we encourage States that do not have such “no wrong door” systems to consider developing them, we recognize that there is variety among State systems and we do not wish to create a potentially rigid requirement that misaligns with States’ existing infrastructures. We also want to ensure that the grievance process requirements finalized in this section focus on standardizing the grievance process itself, and are concerned that an attempt to further standardize ancillary processes would distract from this intention. We will take commenters’ suggestions regarding “no wrong door” systems under consideration for potential future policy development or rulemaking.

While we are not requiring States develop a “no wrong door” system, we do take seriously commenters’ concerns that beneficiaries may attempt to file grievances with other systems operated by the State. We proposed a requirement at § 441.301(c)(7)(iii)(B)(2) that States must provide reasonable assistance to beneficiaries both with filing grievances and completing other procedural steps; we believe it is logical to expect that if a beneficiary needs reasonable assistance from the State for the procedural steps, then they may need assistance with determining where to file their grievance in the first place. To better address the concern about potential beneficiary confusion about the grievance, incident management, fair hearings, and managed care grievance and appeal systems, we are modifying the language in § 441.301(c)(7)(iii)(B)(2) to indicate more clearly that States must provide reasonable assistance to

ensure that grievances are appropriately filed with the grievance system (in other words, that States help beneficiaries identify whether their concern should be filed in the grievance system and, to the greatest extent possible, redirect grievances filed with other State systems to the grievance system).

Additionally, we note that the disposition of matters that are not grievances is outside the scope of the grievance process requirements at § 441.301(c)(7) finalized in this section regarding the grievance system; however, we strongly encourage States to ensure that grievances filed with the grievance system that contain matters that are appropriate for other systems, including the critical incident system (as finalized in section II.B.3. of this rule), the fair hearings system (as described in part 431, subpart E), or the managed care grievance or appeal system (as described in part 438, subpart F) are also considered filings with the appropriate system or systems in accordance with the requirements and timeframes for those systems.

We also remind States that States have the option under current regulations to assist beneficiaries with filing fair hearing requests (as described in part 431, subpart E). Section 431.221(c) provides that State Medicaid agencies may assist applicants or beneficiaries in submitting fair hearings requests and section 2901.3 of the State Medicaid Manual instructs States to make every effort to assist applicants and beneficiaries to exercise their appeal rights. Additionally, section 2902.1 of the State Medicaid Manual states that oral inquiries about the opportunity to appeal should be treated as an appeal for purposes of establishing the earliest possible date for an appeal. Thus, if a beneficiary submits a matter to the grievance system which the State recognizes as a matter more appropriate for a fair hearing, the State should treat this matter in accordance with the requirements of § 431.221(c) and the State Medicaid Manual by assisting the beneficiary with filing a fair hearing request and using the grievance submission date to establish the earliest possible submission date for the fair hearing requests. States also have the option to establish procedures that treat the request made to the grievance system as a

submission of a fair hearing request described at § 431.221(a) when the matter raised in the grievance filing is more appropriate for a fair hearing.

Finally, we clarify that matters that are mistakenly filed with the grievance system but are appropriately referred to another system may be considered “resolved grievances” unless the State determines that the matter also contains separate grounds for a grievance review. We note that should a matter be resolved through referral to another system, this matter would still be subject to the requirements at § 441.301(c)(7)(v) and (vi) (notifying the beneficiary of the resolution of a grievance) and § 441.301(c)(7)(iii)(B)(6) (review of grievance resolutions with which the beneficiary is dissatisfied), which are being finalized in this section II.B.2. of the final rule.

Comment: A few commenters provided support for our proposal at § 441.301(c)(7)(iii)(B)(2) that the reasonable assistance provided by the State includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and individuals with Limited English Proficiency. These commenters noted the importance of providing accessible information to beneficiaries, to ensure beneficiaries have full participation in the process.

Some commenters suggested modifications or additions to the accessibility requirements, including:

- Replacing the term, interpreter services, with the term, linguistic accommodations, noting this would better capture the need for trans creative supports that addresses differences in cultural norms and understandings;
- Requiring plain language explanations of the grievance procedures; and
- Adding mention of the regulations implementing section 1557 of the Affordable Care Act, particularly to reflect §§ 92.201 - 92.205 of the 2022 Nondiscrimination in Health Programs and Activities proposed rule (87 FR 47824).

Response: As discussed further herein, we are not making modifications to § 441.301(c)(7)(iii)(B)(2) in response to these comments. While it may be a term of art used in some fields, there is no Federal guidance or definition of the term, linguistic accommodations. We retain the term, interpreter services, as defined at § 441.301(c)(7)(iii)(B)(2), in this final rule to remain consistent with other Federal requirements. We thank the commenter for bringing the term linguistic accommodations to our attention, and we will take it into consideration for future technical assistance related to this provision.

We note that the proposed requirement at § 441.301(c)(7)(iii)(B)(2) already included a mention of existing accessibility requirements at § 435.905(b). Section 435.905(b) includes a requirement that communications be provided in plain language. We believe it would be duplicative to add a specific requirement that information be provided in plain language.

We also decline to add specific reference to section 1557 of the Affordable Care Act or its implementing regulations, as we find such an addition to be unnecessary. State Medicaid agencies must comply with all relevant requirements in section 1557 in all aspects of their programs, including the grievance process.

Upon review, we are finalizing § 441.307(c)(7)(iii)(B)(2) with some modifications to better align the provision with other regulations. We are finalizing a modification to revise the term “individuals who are limited English proficient” to “individuals with Limited English Proficiency.” This modification conforms with the language being finalized in § 431.12(f)(7) (discussed in section II.A. of this final rule). We are finalizing a modification to clarify that auxiliary aids and services are to be available where necessary to ensure effective communication (instead of upon request as originally proposed), which we believe better conforms to access standards such as those set forth in the ADA and section 504.

Comment: One commenter noted that the repeated references to the regulation at § 435.905(b) (in the proposed requirements at § 441.301(c)(7)(iii)(B)(2), (c)(7)(iii)(C)(6), and (c)(7)(vi)(A)) may suggest that these accessibility services are not necessary outside of the

specific provisions for which they are listed. The commenter suggested we create a separate provision related to language and disability access under the general requirements for the grievance system and specify that it applies to all components of the grievance system.

Response: We disagree that a separate, standalone accessibility requirement would add clarity to States' accessibility requirements. We also do not believe that we have overlooked a part of the process that must be accessible and note that the entire grievance system is subject to other accessibility requirements, including the ADA and section 504, by virtue of being administered by government agencies. As discussed further herein, we are finalizing the references to § 435.905(b) included in the provisions in § 441.301(c)(7) as proposed, as we believe that it is helpful to reiterate the importance of compliance with § 435.905(b) in the various steps of the grievance process.

Comment: One commenter recommended that we mandate that States accept electronic grievances with fill-in forms that could be completed by someone using a smart phone. Another commenter also requested that we require that the grievance system be web-based. One commenter, however, expressed concerns about a grievance system that is only accessible electronically, noting that some people may not have access to or be able to use computers.

Another commenter suggested that we specify that States must maintain a toll-free number, a regularly monitored e-mail address for receiving grievances from Medicaid HCBS beneficiaries, and multiple modes of submitting a grievance, including a request for assistance with articulating and submitting a grievance as a reasonable accommodation.

Response: We appreciate commenters' many thoughtful suggestions on how to ensure that the grievance process system is accessible and user-friendly. At this time, we are not making changes in this final rule at § 441.301(c)(7) to include specific regulatory requirements for exactly how States should implement an electronic system for filing grievances. We believe that the diversity of comments on this issue demonstrates that beneficiaries will likely need the ability to access the grievance filing process through multiple modalities. We encourage States to

consider user access (in addition to legally required accessibility considerations) and engage the interested parties within the HCBS community regarding the construction of a user-friendly grievance filing process that accommodates beneficiaries' different communication and technology needs.

Comment: A few commenters expressed support for our proposal to prohibit punitive actions against individuals who file grievances. One commenter noted that, in their State, beneficiaries are reluctant to complain about care due to fear of retaliation. Another commenter requested that CMS clarify that the requirement applies to punitive actions taken by either the State or a provider. The commenter also requested that CMS clarify that States must investigate punitive actions from providers. One commenter requested that CMS clarify that punitive action includes implying that an individual or family might lose services if they access the grievance process. Another commenter stated that the State should provide operational definitions of punitive actions and provide easily understood guidance to providers and State entities as to what types of actions would be considered punitive.

Several commenters offered specific suggestions for revising the proposed requirement at § 441.301(c)(7)(iii)(B)(3). One commenter suggested we revise the language to read “retaliatory action” or “retaliatory or punitive action.” Another commenter suggested that we amend the proposed regulatory text to define such action as “any negative action following a grievance, complaint, and appeal or reporting of any issue to any regulatory body.”

Response: We clarify that this requirement is intended to prohibit punitive actions from either the State or providers. We do expect that, as part of ensuring that beneficiaries (as well as authorized representatives or other individuals who have filed a grievance on the beneficiary's behalf) are protected from punitive action, States will have a system for both identifying and investigating allegations of punitive action. We agree with the commenter that verbal threats from a provider directed at the beneficiary, or the beneficiary's family, would be the type of punitive action contemplated by this provision that would merit investigation. We also agree

that providing additional definitions and examples of punitive actions will be an important part of States' grievance system policies.

To better clarify who is protected from punitive actions (both beneficiaries and those filing grievances on their behalf), we are finalizing a modification to § 441.301(c)(7)(iii)(B)(3) to clarify that prohibited actions are neither threatened nor taken against an individual filing a grievance *or who has had a grievance filed on their behalf*. As discussed in this section (section II.B.2.b.), we are finalizing our proposal at § 441.301(c)(7)(iii)(A)(I) to allow beneficiaries to have another individual or entity file a grievance on their behalf with written consent. We intend to make it clear that punitive action may not be taken against a beneficiary, whether the beneficiary personally filed the grievance or received assistance filing the grievance. We also want to ensure that authorized representatives or other individuals (including family members or other beneficiaries) are protected from punitive action when helping beneficiaries file grievances.

We agree that amending the regulatory language to “punitive or retaliatory actions” would further clarify the intent of the requirement, as “retaliation” is a common term associated with prohibited behavior in other types of complaints systems. While there is overlap in the connotations of “punitive” and “retaliatory” actions, we also believe that some actions that could be taken against individuals in response to the filing of a grievance could be perceived as “retaliatory” rather than “punitive.” We believe that the word “retaliatory” may particularly capture threats or actions that could negatively affect a beneficiary’s access to services, whether or not the threat or negative outcome actually materializes. For instance, if a provider noted negative things to other providers about a beneficiary or the beneficiary’s authorized representative and discouraged other providers from accepting that beneficiary as client after a grievance was filed against the provider, this action could be perceived as “retaliatory” rather than “punitive,” particularly if this did not ultimately result in a reduction or alteration of the beneficiary’s services. Therefore, we are finalizing § 441.301(c)(7)(iii)(B)(3) with modification in this final rule to specify that States must ensure that punitive or retaliatory action is neither

threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf.

We decline to make the other modifications that commenters suggested. We believe the requirement we proposed at § 441.301(c)(7)(iii)(B)(3), as modified herein, is sufficiently broad and clear to address the essential concerns raised by commenters. We believe including language prohibiting “any negative action” may be ambiguous and overly broad. Additionally, we do not believe the grievance system regulations should be used to prohibit punitive or retaliatory actions in response to actions performed outside of the grievance process. However, we note that, if a beneficiary believes they are experiencing poor treatment from a provider because the beneficiary has filed a complaint about the provider in a system other than the grievance system, the beneficiary may have grounds to file a grievance on the basis of the poor treatment.

Comment: Several commenters recommended the addition of more specific provisions to protect against punitive or retaliatory action, including a post-grievance follow-up with the beneficiary and assessing fines or other penalties against a provider who has taken retaliatory action. One commenter also requested that CMS require States to make the results of investigations into allegations of punitive behavior available to the public.

Response: We decline to make modifications to § 441.301(c)(7)(iii)(B)(3) based on these commenters’ suggestions because we believe that the proposed regulation text at § 441.301(c)(7)(iii)(B)(3), which we are finalizing with modification as discussed herein, is sufficient. To comply with the requirement that States ensure that punitive or retaliatory actions are neither threatened nor taken against individuals who have filed a grievance or have had a grievance filed on their behalf, we expect that States will develop a system for identifying, investigating, and deterring punitive or retaliatory actions. We believe creating more regulatory requirements as commenters suggested would not provide States with flexibility in how they comply with this requirement. Instead, States may develop processes in accordance with their

grievance system's structure and other relevant considerations, such as provider agreements and State laws.

Comment: We received a few comments on the requirement we proposed at § 441.301(c)(7)(iii)(B)(4) that States must accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries. One commenter recommended that § 441.301(c)(7)(iii)(B)(4) be revised to specify that no “magic language” is needed to initiate the grievance process. The commenter noted that a “demonstrated intent” to obtain assistance with an HCBS-related problem should be accepted as a grievance.

Response: We are concerned that the language proposed by the commenter is overly broad. We agree that States should make filing a grievance as simple and accessible as possible for beneficiaries, their authorized representatives, and other individuals or entities filing on a beneficiary's behalf. For example, we believe that it would be inappropriate for a State to create a complex grievance filing form and then refuse to review a grievance because the form was not filled out completely or properly. We note that this scenario would also be a plausible illustration of a State's failure to provide reasonable assistance and accessibility as required at § 441.301(c)(7)(iii)(B)(2). We also believe it is critical that States make every effort to ensure that beneficiaries and their advocates know that a grievance system exists and how to access it. We do not, however, expect that every expression of dissatisfaction, in any context, must be treated as a presumptive grievance filing. We believe it is acceptable for States to develop a grievance filing process that requires a clear intent to file a grievance. Further, we do not want to encourage situations in which grievances are pursued on the beneficiary's behalf without the beneficiaries' knowledge or consent.

Comment: We received a number of comments regarding the requirement we proposed at § 441.301(c)(7)(iii)(B)(5) that States provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance system and on how to file grievances. One commenter expressed particular support for this requirement.

Other commenters provided several suggestions for additional requirements to ensure that beneficiaries receive information regarding the grievance process, including:

- Requiring that States add an explanation of grievance rights in any HCBS-related communication from the State to the beneficiary;
- Requiring that providers include an explanation of grievance rights in the person-centered service planning process;
- Requiring that information on grievance procedures be posted in each group home or other provider owned or controlled residential setting, along with a toll-free number and e-mail address for filing grievances; and
- Including common examples of grievances in the information given to beneficiaries, so that beneficiaries are better able to understand the potential utility of the process.

A few commenters noted that, regardless of where or how the information was shared, the information should be in accessible plain language and large print formats.

Response: We do not intend to add additional requirements in this final rule regarding how States must inform beneficiaries about the grievance system, as we believe it is important for States to retain flexibility in how they communicate with beneficiaries. We believe the ideas shared by commenters are great examples of what could be done. We note that there is a lot of diversity among beneficiaries receiving HCBS, States' existing communication pathways, and HCBS program design – all factors that will affect the methods of informing beneficiaries about the grievance process. Therefore, we believe it may be necessary for the information about the grievance system to be presented in multiple ways and through multiple modalities. We encourage States to engage with interested parties to determine the most effective ways to inform beneficiaries. We will also work with States to identify effective ways to inform beneficiaries about the State's grievance system.

We also highlight that our proposed text at § 441.301(c)(7)(iii)(B)(5) requires that information provided to beneficiaries must comply with § 435.905(b), which does require that

materials use plain language. In addition, States generally must comply with the ADA and section 504, and their implementing regulations. We are finalizing § 441.301(c)(7)(iii)(B)(5) largely as proposed, although with a modification to change mention of individuals who are limited English proficient to individuals with Limited English Proficiency, consistent with the change to § 441.301(c)(7)(iii)(B)(2) discussed previously in this section.

Comment: One commenter requested clarification whether States have an ongoing obligation to provide this notice and information to beneficiaries, including to people who begin HCBS after the effective date of the grievance system requirements that we proposed at § 441.301(c)(7).

Response: We agree and clarify that States will have an ongoing responsibility to ensure that both new and current beneficiaries receive information about the grievance system to comply with § 441.301(c)(7)(iii)(B)(5), which we are finalizing as described in this section (section II.B.2. of the final rule.)

Comment: One commenter noted that our proposal at § 441.301(c)(7)(iii)(B)(6), requiring the State to review any grievance resolution with which the beneficiary is dissatisfied, is too vague. This commenter suggested that the regulations should specify that the reviewer be someone not involved in the original determination, and the beneficiary should have a process to submit information as to why the original resolution was insufficient. The commenter also suggested that we specify that the beneficiary must request review, believing that otherwise the expectation appears to be that the State must decide whether the beneficiary is dissatisfied. Finally, the commenter suggested that the notice of the original resolution should inform the beneficiary of this review process and how to initiate it.

One commenter also requested clarification on how beneficiaries should express dissatisfaction with a resolution for the purpose of seeking review of a resolution under § 441.301(c)(7)(iii)(B)(6).

Response: We believe that the requirements at § 441.301(c)(7)(iii)(C)(3), which we are finalizing as described in this section II.B.2, address several of the commenter's concerns. We clarify that the requirements at § 441.301(c)(7)(ii)(C)(3) apply to initially filed grievances and review of grievances under § 441.301(c)(7)(iii)(B)(6). We note that § 441.301(c)(7)(iii)(C)(3)(i) requires that the individual making a decision on a grievance is an individual who was neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual. Section 441.301(c)(7)(iii)(C)(3)(iii) specifies that the individual must consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State.

We expect that beneficiaries would express dissatisfaction by affirmatively requesting review of a grievance resolution. We agree that beneficiaries have the responsibility of requesting the review, and expect that States will include, as part of their written policies, the method for how beneficiaries may request review and how beneficiaries will be notified of this right.

Comment: We did not receive comments on the requirement we proposed at § 441.301(c)(7)(iii)(B)(7) that States must provide information on the grievance system to providers and subcontractors. However, one commenter requested that we require States to give providers 14 days' notice if the provider is a party to the grievance.

Response: We believe that whether, and how, a State chooses to involve providers in individual grievances filed pursuant to § 441.301(c)(7) will vary on a case-by-case basis and, thus, a standardized notification requirement may not be appropriate. For instance, some grievances may be resolvable without the provider's involvement, and in some cases, the beneficiary may not want the provider to know the beneficiary's identity. If the beneficiary and the State believe it is necessary to have the provider involved in the investigation, including appearing at the resolution meeting, we expect that States will give the provider reasonable

notice and ensure that the provider is able to participate in the process. Therefore, we intend to provide States with flexibility in determining their grievance system policies in this respect.

Comment: One commenter supported the requirement we proposed at § 441.301(c)(7)(iii)(C)(1) to allow beneficiaries to file grievances orally but recommended that we revise the requirement to specify that States must follow up with a written summary of the oral grievance so the beneficiary can ensure accuracy. Another commenter suggested that we revise the requirement at § 441.301(c)(7)(iii)(C)(2) to specify that acknowledgement of the receipt of a grievance must be in writing.

Response: We appreciate the comments and believe it is a best practice for States to provide a summary of the grievance to the beneficiary for accuracy. However, we decline to mandate that States provide a written summary, as we intend to allow flexibility for States to decide their own policies to operationalize this requirement. We believe that part of acknowledging the grievance, as required at § 441.301(c)(7)(iii)(C)(2), involves developing an appropriate system for providing beneficiaries with confirmation of their grievance.

Comment: One commenter requested that we specify whether all grievances filed must receive a full resolution or whether there are instances in which the acknowledgement of the grievance is sufficient. The commenter anticipated that because of the current direct care workforce crisis, many grievances may be filed related to provider shortages. While acknowledging that understaffing is a serious problem, the commenter believed that the grievance process is unlikely to be able to address the problem to the beneficiary's satisfaction.

Response: We note that the definition of grievance that we are finalizing at § 441.301(c)(7)(ii) indicates that a beneficiary may file a grievance regardless of whether remedial action is requested. We agree that, in instances in which the beneficiary does not wish to pursue remedial action and indicates they are not interested in presenting and debating their grievance as we proposed at § 441.301(c)(7)(iii)(C)(4), acknowledging the grievance may be considered resolving the complaint (rather than conducting additional inquiry). We note that should a matter

be resolved with an acknowledgment, this matter would still be subject to the requirements at § 441.301(c)(7)(v) and (vi) (notifying the beneficiary of the resolution of a grievance) and § 441.301(c)(7)(iii)(B)(6) (review of grievance resolutions with which the beneficiary is dissatisfied).

Comment: A few commenters commented on our proposal at § 441.301(c)(7)(iii)(C)(3), establishing requirements for decisionmakers reviewing grievances considered under the grievance system. Several of these commenters supported our efforts to require a system that would provide a fair and unbiased review of beneficiaries' concerns. However, one commenter noted that the requirement at § 441.301(c)(7)(iii)(C)(3) would require a separate set of personnel to respond to and investigate grievances than the staff that is currently allocated for program management, administration, and support, and expressed concern that this would require additional resources.

Response: We note that the requirement we proposed at § 441.301(c)(7)(iii)(C)(3) requires that individuals reviewing and making decisions about grievances are not the same individuals, nor subordinates of individuals, who made the original decision or action that has given rise to the grievance. This would require that the provider that made the decision or performed the action giving rise to the grievance would not be able to be the decisionmaker for the grievance. However, this would not preclude State Medicaid agency personnel from reviewing a grievance filed against a provider. Additionally, even for grievances filed about the State's performance, the requirement does not necessarily require review from separate departments or entities. With firewalls as needed, reviewers may be from the same department (or a different department) so long as the necessary expertise and independence standards are met, and the reviewer takes into account the information described in § 441.301(c)(7)(iii)(C)(3)(ii). We are not making modifications to § 441.301(c)(7)(iii)(C)(3) based on these comments.

Comment: One commenter questioned if the intent of the requirement we proposed at § 441.301(c)(7)(iii)(C)(3)(iii) is to require a “de novo” review of the grievances.

Response: *De novo* review typically refers to a standard of review of a matter on appeal after a trial court or administrative body has reached a determination. If a matter is being reviewed *de novo*, the reviewer is reviewing the whole matter as if it is freshly presented to them, without regard for what the prior decisionmaker determined, or their rationale supporting that determination. We did not specify in the regulation text (either proposed or finalized) whether this process is intended as a *de novo* review of grievances, as reference to *de novo* review would have been inapplicable. The general intent of the grievance system we proposed at § 441.301(c)(7) is not to address specific determinations that are being appealed, as would be the case in the fair hearing process. The grievance system is intended to address a beneficiary’s dissatisfaction or complaint related to the State’s or provider’s performance of person-centered planning or HCBS settings requirements. We expect that the grievance system will typically represent the first opportunity a beneficiary has had to present their concerns directly to the State. Because there likely has not been an initial determination to consider and possibly affirm or reverse, we do not believe *de novo* review is applicable.

For example, consider two scenarios in which a provider fails to send a personal care assistant to two beneficiary’s homes. For Beneficiary A, the failure was because the provider forgot to ensure a worker was scheduled to deliver the services. For Beneficiary B, the provider decided, unilaterally, that Beneficiary B had been authorized more personal care services than the provider believed was necessary and thus refused to send a personal care assistant to Beneficiary B’s home. In both scenarios, Beneficiary A and Beneficiary B could file grievances about the provider’s failure to provide services as outlined in the person-centered care plan or attempt to change the service plan without going through the process required in § 441.301(c)(1) through (3). The proper focus in both cases would be on whether the provider provided services in accordance with the current person-centered care plan. We would not expect in Beneficiary

B's situation that the State would treat the provider's actions as a formal determination requiring *de novo* review (such as reviewing whether the provider's objections to the number of service hours in the service plan were valid, or making the beneficiary prove that the service hours were needed). Further, even if there has been an initial decision by a provider or State that the beneficiary disputes, we did not intend the grievance system to operate like a formal legal proceeding (that is, an administrative hearing or trial) and, again therefore, we do not believe the concept of *de novo* review is applicable.

Comment: One commenter suggested that we amend the definition of "skilled professional medical personnel" to allow the designation to apply to staff administering the grievance process, which would make the activity eligible for a 75 percent Federal matching rate.

Response: We are not amending the definition of skilled professional medical personnel in this final rule. The term "skilled professional medical personnel" is defined at § 432.2 as physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. The term explicitly does not include other, nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers, or administrators of public assistance programs of the Medicaid program. Per § 432.50, the FFP rate for skilled professional medical personnel and directly supporting staff of the Medicaid agency is 75 percent. We do not intend to require that the administrative activities required for grievance process must be administered by personnel with specialized medical education and training. Even for those who meet the criteria to be considered skilled professional medical personnel, only the portion of their activities that require their advanced skills and expertise would be eligible for the enhanced matching rate. If similar functions are performed by non-skilled professional medical personnel, then the activities themselves would not qualify for the higher matching rate.

Comment: One commenter requested clarification as to whether a telephonic communication would satisfy the proposed requirement at §441.301(c)(7)(iii)(C)(4) that the State provide a beneficiary with a reasonable opportunity face-to-face, including through the use of audio or video technology.

Response: We believe that audio-only telephone calls, when requested by the beneficiary and with the inclusion of any necessary accommodations, satisfy this requirement.

Comment: One commenter recommended that we revise proposed § 441.301(c)(7)(iii)(C)(4) by removing the word “limited” from before “time available,” as the commenter believed the inclusion of the word “limited” was unnecessary.

Response: We disagree with the commenter’s statement that the word “limited” is unnecessary. The language in this requirement was intended to mirror similar language in the managed care grievance process requirements at § 438.406(b)(4). Further, we believe it is important that beneficiaries understand the timeframes associated with the grievance resolutions and understand that it is intended, for their benefit, to be a time-limited process.

Comment: One commenter recommended that we mandate a minimum number of days afforded to a beneficiary to review their record and submit additional germane evidence and testimony to the State agency before resolution. The commenter noted that the proposed regulation merely requires that the State agency provide the beneficiary with “a reasonable opportunity.” The commenter regarded this as a vague standard and was concerned that States would not grant beneficiaries sufficient time. The commenter noted that beneficiaries with disabilities or complex medical issues may need additional time and supports to prepare evidence and testimony. The commenter suggested that granting beneficiaries a minimum of 21 days to prepare their evidence and testimony after receipt of the agency record would ensure that the State provided the record well in advance of the resolution deadline and would protect beneficiaries from the imposition of unreasonable timeframes to prepare.

Response: We note that § 441.301(c)(7)(iii)(C)(4) requires that the State provide the beneficiary a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance, while § 441.301(c)(7)(iii)(C)(5) requires the State to provide the beneficiary with their case file and other records sufficiently in advance of the resolution timeframe for grievances. We are unclear on which provision the commenter is recommending we modify. We decline to modify either provision by prescribing specific deadlines within the overall resolution timeframe, to allow States to develop flexible processes to accommodate beneficiaries. We expect that States will develop appropriate processes to allow beneficiaries to request postponements or rescheduling of any face-to-face hearings that they have requested if they find they need more time to prepare, or other situations arise that would prevent a beneficiary from being able to participate in the hearing.

We also note that we are finalizing a requirement at § 441.301(c)(7)(v)(C) to allow beneficiaries to have the option of requesting 14-day extensions if (for any reason) a beneficiary requires additional time beyond the 90-day resolution timeframe we are finalizing at § 441.301(c)(7)(v)(B).

Comment: Several commenters expressed concern about legal representation during the process. One commenter stated that beneficiaries should get access to State-provided legal assistance. Another commenter requested that, if a beneficiary is unable to afford an attorney, the opposing party not be allowed an attorney.

Response: As discussed in a prior response, beneficiaries have flexibility in determining who will assist them throughout the grievance process – which could, if the beneficiary chose, include assistance from a legal professional. We believe that the grievance system should be easy to navigate and largely non-adversarial, such that beneficiaries would not be required, nor feel pressured, to have legal representation. We also believe that at least some portion of grievances filed will be for minor issues that do not require a formal inquiry. We agree with commenters that it is preferable that hearings neither be, nor have the appearance of being, imbalanced in

terms of support for the beneficiary. We encourage States, as they develop their policies, to consider what level of assistance beneficiaries will need during face-to-face meetings and ensure that reasonable assistance is provided.

Comment: One commenter stated that § 441.301(c)(7)(iii)(C)(5) should be revised to expand the documents beyond the beneficiary's "case file." The commenter recommended that the regulations require that the State obtain relevant files and other information held by the provider and then provide that information to the beneficiary. The commenter stated that, particularly in cases involving residential providers, provider-maintained information will be relevant and often pivotal.

Response: We disagree and believe adding this language is unnecessary. We believe that the term, case file, could have several meanings, depending on the circumstances, and could include the records related to the beneficiary's services maintained by the provider that would be obtained by the State as part of review of the grievance. We also note that proposed § 441.301(c)(7)(iii)(C)(5) already requires beneficiaries to receive other documents and records, as well as new and current evidence considered or relied upon by the State related to the grievance. We believe relevant records from providers could fall into these categories, depending on the record and the circumstances by which the State obtained it. We do not intend our requirement at § 441.301(c)(7)(iii)(C)(5), as proposed and being finalized in this rule, to amend any existing obligations for confidentiality of certain records and we expect States to comply with applicable Federal and State laws and regulations governing confidentiality of those records in determining what records to provide to the beneficiary related to their grievance in compliance with § 441.301(c)(7)(iii)(C)(5). We decline to make modifications to § 441.301(c)(7)(iii)(C)(5) as requested by the commenter.

Comment: One commenter suggested that we require that the grievance system be compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Response: We had proposed at § 441.301(c)(7)(iii)(C)(5) that medical records being used as part of a grievance be handled in compliance with 45 CFR 164.510(b) (a provision of the HIPAA Privacy Rule), to ensure that protected health information (PHI) used during the grievance review are obtained and used with beneficiaries' authorization. In general, whenever a beneficiary's PHI may be obtained, maintained, or disclosed by a State agency that is a covered entity as defined in 45 CFR 160.103 (such as a State Medicaid agency), States are responsible for ensuring compliance with the requirements of HIPAA and its implementing regulations, as well as any other applicable Federal or State privacy laws governing confidentiality of a beneficiary's records. We also note that 45 CFR 164.510(b) is just one provision of the HIPAA Privacy Rule that permits the disclosure of PHI, and other provisions may also permit the disclosure of PHI (such as disclosure of PHI to personal representatives under 45 CFR 164.502(g)); other permissions may also apply in addition to what is cited here and included in the regulatory text of this final rule. Upon further review, we have determined that, given that a number of requirements of the HIPAA Privacy Rule may apply to the obtaining and sharing of beneficiaries' information, we are finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the citation of 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

Finally, we also note that individuals who believe their health information privacy has been violated may file a complaint with the HHS Office for Civil Rights at <https://www.hhs.gov/hipaa/filing-a-complaint/index.html>.

After consideration of public comments, we are finalizing § 441.301(c)(7)(iii)(A) as proposed, with the following modification. We are finalizing § 441.301(c)(7)(iii)(A)(1) with modification to specify that another individual or entity may file a grievance on behalf of the beneficiary or provide the beneficiary with assistance or representation throughout the grievance process with the written consent of the beneficiary or authorized representative. We are finalizing § 441.301(c)(7)(iii)(A)(2) as proposed.

We are finalizing requirements at § 441.301(c)(7)(iii)(B) as proposed, with the following modifications. We are finalizing § 441.301(c)(7)(iii)(B)(1) with a modification to correct an erroneous reference to subchapter by replacing subchapter with paragraph (c)(7). We are finalizing § 441.301(c)(7)(iii)(B)(2) with modifications by: (1) adding to States' obligation the requirement that States must provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system; (2) modifying language to refer to individuals with Limited English Proficiency; and (3) clarifying that auxiliary aids and services must be made available where necessary to ensure effective communication. We are finalizing § 441.301(c)(7)(iii)(B)(3) with modifications to require that States ensure that punitive or retaliatory actions (rather than just punitive actions) are neither threatened nor taken. We are also adding language to specify that the punitive or retaliatory actions cannot be threatened or taken against an individual filing a grievance **or who has had a grievance filed on their behalf**. (New language identified in bold.)

For reasons we discuss in greater detail in the next section (section II.B.2.c. of this rule) we are finalizing § 441.301(c)(7)(iii)(B)(4) with a modification to remove the reference to expedited grievances. We are finalizing § 441.301(c)(7)(iii)(B)(5) with a modification to change the language to refer to individuals with Limited English Proficiency. We are finalizing § 441.301(c)(7)(iii)(B)(6) and (7) as proposed.

We are finalizing § 441.301(c)(7)(iii)(C)(1) through (5) with minor technical modifications. We are replacing the periods at the end of each paragraph with semi-colons and adding the word and at the end of § 441.301(c)(7)(iii)(C)(5) to accurately reflect that § 441.301(c)(7)(iii)(C)(1) through (6) are elements of a list, not separate declarative statements. Additionally, for reasons we discuss in greater detail in a later section (section II.B.2.d.) because we are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2), we are finalizing § 441.301(c)(7)(iii)(C)(5) with modifications to remove references to § 441.301(c)(7)(v)(B)(1) and (2) and add a reference to § 441.301(c)(7)(v). We are also

finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the citation of 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

c. Filing Timeframe (§ 441.301(c)(7)(iv))

At § 441.301(c)(7)(iv)(A), we proposed to require that the beneficiary be able to file a grievance at any time. At § 441.301(c)(7)(iv)(B), we proposed to require that beneficiaries be permitted to request expedited resolution of a grievance, whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, such as if, for example, a beneficiary cannot access personal care services authorized in the person-centered service plan.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters made suggestions or submitted clarifying questions about our proposal at § 441.301(c)(7)(iv)(A) that beneficiaries be able to file a grievance at any time. One commenter requested clarification on whether our intent was to prohibit limits on the timeframe between the occurrence of the subject of the grievance and the date when the individual files a grievance. Another commenter noted that there should be a 90-day time limit on when beneficiaries can file grievances.

Response: We do not intend for beneficiaries' ability to file grievances to be time-limited. We appreciate commenters' concerns regarding this issue; however, we defer to the rationale we used when declining to add a timeframe cap in the managed care grievance filing process (81 FR 27511). In the managed care grievance process, § 438.402(c)(2)(i) specifies that enrollees may file a grievance with their managed care plan at any time. As we previously noted, grievances do not progress to the level of a State fair hearing, which is a time-sensitive process; therefore, we found it unnecessary to include filing limits because grievances are resolved without having to consider the time limits of other processes (81 FR 27511).

We understand that States may be concerned about revisiting grievance issues that occurred in the past, but we believe this is a normal part of providing services and that beneficiaries should be permitted to file a grievance at any time. We also note, that, as discussed in more detail below, States believe that educating beneficiaries about the grievance process will take time; therefore, we do not want to prevent beneficiaries from filing grievances in cases where the delay in filing was because the beneficiary was not initially aware of their ability to file a grievance.

Comment: A few commenters supported the proposal at § 441.301(c)(7)(iv)(B) to create a pathway for expedited resolutions when there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare.

Several commenters, however, believed that the proposal at § 441.301(c)(7)(iv)(B) to create a pathway for an expedited resolution was unclear or overly broad and requested additional clarification as to what would constitute a grievance warranting expedited resolution. Some of these commenters stated that technical assistance would be needed to help States identify the criteria for determining whether a resolution should be expedited, and how to proceed if a beneficiary disagrees with the State's determination that a grievance request should be expedited or resolved in the standard timeframe. One commenter raised the concern that if a beneficiary's request for an expedited resolution was denied, they may follow up with submitting another grievance or file a fair hearing request. Another commenter suggested that expedited resolutions should be defined as being contingent on the timely receipt of information from the beneficiary.

Some commenters noted that the expedited resolution process's focus on health, safety, and welfare could lead to duplication with other systems, including the critical incident system. They expressed the belief that there are separate channels to address health and safety concerns. For this reason, a few commenters suggested that there should only be one standard grievance resolution and notice timeline of 90 calendar days. A few commenters also suggested that we

should not have an expedited resolution process in the FFS grievance system because there is not such a process in the managed care grievance system (as described in 42 CFR part 438, subpart F).

One commenter stated that, in their experience, few grievances were about issues affecting beneficiaries' health and safety, and thus it would not be appropriate to create a requirement for an expedited process as it was defined in proposed § 441.301(c)(7)(iv)(B). The commenter offered examples of typical grievances, based on the commenter's experience with operating a State grievance system. The commenter noted that many grievances involve education about the HCBS program (for example, additional services and limitations), information about available providers in their area as an alternative to their current provider, dissatisfaction with their paid caregiver, and frustrations with provider workforce shortages.

Response: We are persuaded by commenters' feedback summarized here, as well as comments summarized later in this section regarding the expedited resolution timeframe. After consideration of public comments, as discussed here in section II.B.2, we are not finalizing § 441.301(c)(7)(iv)(B) and are removing other references to the expedited resolution process where it appears in § 441.301(c)(7) in this final rule.

In particular, we are persuaded by the concern that the expedited resolution process as proposed could create overlap with the critical incident system, which is described in section II.B.3 of this final rule. We believe that the critical incident system is the most appropriate mechanism for investigating situations when a beneficiary has experienced actual harm or substantial risks to their health and safety. We do not want there to be a delay in the investigation of a critical incident because it was incorrectly filed as a grievance, nor do we want matters that should be investigated as critical incidents resolved only in the grievance process.

In addition, as some commenters correctly noted, the managed care requirements at 42 CFR part 438, subpart F, do not include an expedited grievance resolution process. We have not identified a compelling reason why beneficiaries receiving HCBS through FFS systems should

need an expedited resolution process for grievances when no similar process has, as yet, been deemed necessary in the managed care system. After reexamining these requirements in light of comments received, we do not wish to create misalignment between managed care and FFS systems' grievance resolution processes.

In general, we agree with the commenter that it is likely that many grievances filed would not meet the standard we proposed for expedited resolution (and, as noted above, if they did meet the standard, they are likely candidates for the critical incident or fair hearings systems).

However, we envision that there remains the potential for some grievances to require immediate attention and intervention, even if they do not rise to the level of a critical incident (as defined in § 441.302(a)(6)(i)(A)) or do not qualify for a fair hearing (as set out in part 431, subpart E).

Therefore, we encourage States to include in their grievance system a system for identifying, triaging, and expediting resolution of grievances that require, according to the State's criteria, prioritization and prompt resolution.

After consideration of the comments received about § 441.301(c)(7)(iv), we are finalizing our proposal at § 441.301(c)(7)(iv) with modification by removing the expedited resolution requirement at § 441.301(c)(7)(iv)(B) and redesignating § 441.301(c)(7)(iv)(A) as § 441.301(c)(7)(iv). Additionally, we are removing references to the expedited resolution process in § 441.301(c)(7)(iii)(B)(4). We are also removing requirements related to the expedited resolution process in § 441.301(c)(7)(v). These changes are discussed in their respective sections below.

d. Resolution and Notification (§ 441.301(c)(7)(v))

At § 441.301(c)(7)(v), we proposed resolution and notification requirements for grievances. Specifically, at § 441.301(c)(7)(v)(A), we proposed to require that States resolve and provide notice of resolution related to each grievance as quickly as the beneficiary's health, safety, and welfare requires and within State-established timeframes that do not exceed the standard and expedited timeframes proposed in § 441.301(c)(7)(v)(B). At

§ 441.301(c)(7)(v)(B)(1), we proposed to require that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. At § 441.301(c)(7)(v)(B)(2), we proposed to require that expedited resolution of a grievance and notice must occur within 14 calendar days of receipt of the grievance.

At § 441.301(c)(7)(v)(C), we proposed that States be permitted to extend the timeframes for the standard resolution and expedited resolution of grievances by up to 14 calendar days if the beneficiary requests the extension, or the State documents that there is need for additional information and how the delay is in the beneficiary's interest. At § 441.301(c)(7)(v)(D), we proposed to require that States make reasonable efforts to give the beneficiary prompt oral notice of the delay, give the beneficiary written notice, within 2 calendar days of determining a need for a delay but no later than the timeframes in paragraph (c)(7)(v)(B), of the reason for the decision to extend the timeframe, and resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires, if the State extends the timeframe for a standard resolution or an expedited resolution.

We also proposed at § 441.301(c)(7)(iv)(B) and (c)(7)(v)(B)(2) that beneficiaries be permitted to request, and the State provide for, expedited resolution of a grievance. However, we noted that these proposed requirements differ from the current grievance system requirements for Medicaid managed care plans at part 438, subpart F, which do not include specific requirements for an expedited resolution of a grievance. We solicited comment on whether part 438, subpart F should be amended to include the proposed requirements for expedited resolution of a grievance at § 441.301(c)(7)(iv)(B) and (v)(B)(2).

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We note that, as discussed in the previous section, we are not finalizing the expedited resolution process at § 441.301(c)(7)(iv)(B). We will discuss the impact of this change to the requirements in § 441.301(c)(7)(v) in our response to the comments below.

Comment: A few commenters requested that we provide additional information to clarify what is expected for a grievance to be considered resolved.

Response: We believe that the resolutions of grievances can take many forms and may vary on a case-by-case basis, and thus we decline to revise the requirements at § 441.301(c)(7)(v) to provide a more specific definition. We proposed and are finalizing as discussed in this section II.B.2 that a beneficiary may file a grievance even if the beneficiary does not request remedial action. We expect that grievances will vary not only in severity and urgency but will also vary according to the formality of the response. Some grievances, as noted in a response above, may require only a simple acknowledgment of the concern. Others may require immediate action(s), including intervention(s) with or action(s) taken against the provider. Still others may involve the State setting up a long-term corrective action plan or monitoring, consistent with applicable State laws governing such. We believe that a critical part of the grievance process involves collecting input from the beneficiary filing the grievance on the resolution or outcome they hope to achieve through the grievance process. This may include instances in which the beneficiary wishes to bring a concern to the State's attention but is not necessarily pursuing a specific resolution.

Comment: A few commenters raised concerns or questions about how States should ensure compliance with resolutions. One commenter noted the importance of ensuring corrective actions are taken in response to grievances so that policy and systems transformation can take place in a timely manner. One commenter requested that we provide States with more tools to ensure provider compliance, including appropriate monetary and nonmonetary penalties. Another commenter stated that the grievance resolution process should include an order for the creation of a corrective action plan and subsequent monitoring.

Response: We appreciate the commenters' suggestions, but we decline to add specific actions to the requirements at § 441.301(c)(7)(v). As noted above, we believe that there will be variety in both grievances and resolutions. It would be difficult, and perhaps detrimental, to

establish a set of Federal penalties that may be over- or under-responsive to the range of matters heard in the grievance process. Thus, we want to retain flexibility in the regulatory requirements to allow State grievance systems to respond appropriately to each situation. We expect that States will apply a reasonable interpretation to the requirement that the States “resolve” the grievance. For instance, if resolution reasonably requires a corrective action plan for a provider (for grievances resolved against providers) or a corrective action plan for the State (for grievances resolved against the State), we expect that a corrective action plan would be executed and monitored as part of the resolution in accordance with applicable State laws. Through State law and regulations, States can create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program.

Comment: Several commenters suggested that the grievance resolution process should include formal follow-up requirements. To ensure proper follow-up, one commenter recommended that the regulations specify that grievances and their resolutions be reviewed at the subsequent person-centered planning process. One commenter recommended that the State should perform a follow up at 30 and 90 days after the resolution.

Response: We decline to add specific follow-up requirements to § 441.301(c)(7)(v). As discussed in prior responses, we believe that grievances are likely to take many forms. We agree that, in some instances, follow-up or ongoing monitoring may be a critical element of a particular resolution and, thus, should be included. In other cases, the grievance may not require follow-up and, thus, a formal follow-up requirement would impose an unnecessary administrative burden. There may also be instances in which a beneficiary may not wish to be repeatedly contacted after they believe the matter has been resolved. We believe that determining the appropriateness of when, and how, to monitor outcomes of grievances should be part of policies States develop for their grievance system.

Comment: One commenter recommended that we revise the requirement at § 441.301(c)(7)(v)(A) to require that the State solicit more information from beneficiaries on how

a delayed resolution could hurt the beneficiary. One commenter suggested that we include the language from this provision in the timeframe requirement for expedited grievances at § 441.301(c)(7)(v)(B)(2) so that the requirement reads, “as expeditiously as the beneficiary’s health condition requires and no longer than 14 calendar days after the State receives the grievance.”

Response: We decline to make the suggested modifications to the requirement at § 441.301(c)(7)(v)(A). We clarify that this requirement at § 441.301(c)(7)(v)(A) sets a general expectation for expeditious resolutions for all grievances. We encourage States to ensure that beneficiaries provide, in their grievances, detailed information about their concerns (including negative impacts they are experiencing or believe they will experience). However, we have specifically not set requirements for the amount or type of information beneficiaries must submit when filing a grievance, as we do not wish to inadvertently mandate a process that is administratively burdensome for beneficiaries. We believe that commenters may have interpreted this requirement as a means of identifying grievances being filed for expedited resolution, which was not the intent. Additionally, as discussed above, we are not finalizing the requirement for an expedited resolution at § 441.301(c)(iv)(B)(2).

We also note that, consistent with our discussion above related to concerns about confusion between the purpose of the grievance system and the critical incident system described in § 441.302(a)(6), we are revising the language in this provision. Specifically, we are finalizing our proposal at § 441.301(c)(7)(v)(A) with modification to require that the State resolve each grievance and provide notice as expeditiously as the beneficiary’s health condition requires, instead of our proposal, which would have required that such notice be provided as expeditiously as the beneficiary’s health, safety, and welfare requires. We believe this avoids confusion with the critical incident system and aligns the language with a parallel requirement in the managed care grievance requirements at § 438.408(a), as well as our language in §§ 441.301(c)(7)(v)(D)(3) (pertaining to expeditious resolution during extensions). We believe that

“health condition” may be broadly interpreted to refer both to physical and mental health and well-being of the beneficiary.

Comment: A few commenters supported our proposal at § 441.301(c)(7)(v)(B)(I) that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. However, some commenters, while not specifically opposing the 90-day timeframe, expressed concerns that the timeframe proposed for resolving grievances may not always allow for a thorough investigation. One commenter noted that, while this timeframe might allow for investigation and resolution of some grievances, other grievances might require more extensive investigation (such as interviews, on-site visits, legal review and consultation, and request for additional documentation) and could take longer. The commenter also worried about the time involved in allowing the beneficiary a reasonable opportunity to present evidence face-to-face and in writing, as well as access to their case file to review in advance.

Conversely, a number of commenters recommended that the standard resolution timeframe be shortened to 45 days. Many of these commenters stated that 90 days is too long for an individual to wait for resolution if they are experiencing a serious violation of their rights or access to services.

Response: We agree with commenters that some grievances may take longer than 90 days to resolve properly and note that these extenuating circumstances can be addressed through the use of the 14-day extension we are finalizing at § 441.301(c)(7)(v)(C) if the conditions set forth in that requirement are met. We also agree with commenters that grievances should be resolved as expeditiously as possible, but we do not agree that cutting the proposed timeframe in half (to 45 days) would be a sufficient timeframe. We based our proposal of 90 calendar days on the current timeframe for resolution in the managed care grievance system at § 438.408(b), and we do not find reason to believe that FFS grievances would require less time to resolve than grievances in the managed care system. We do not wish to set a timeframe that encourages hasty investigations, nor the overuse of the 14-day extensions. We also note that 90 calendar days is

the maximum allowed timeframe and that States may choose to set a shorter timeframe, or several timeframes for different types of grievances, so long as none of the timeframes exceed 90 calendar days. We are finalizing the 90-calendar day timeframe for resolutions as proposed.

Comment: One commenter noted that the proposed timeframe of 14 days for expedited resolution was too long and suggested that it be reduced to 7 days. On the other hand, many commenters expressed concerns about staff capacity necessary to respond to expedited grievances within 14 calendar days, as well as the feasibility of completing investigations within the proposed 14-day timeframe. Commenters believed that, given the potential seriousness of grievance inquiries, it may be difficult for all necessary information to be gathered in 14 days and to grant the beneficiary a reasonable opportunity to present evidence in a face-to-face meeting. Several commenters recommended that, if finalizing an expedited resolution timeframe, we extend the timeframe to 30 calendar days, and one commenter recommended 30 business days.

Response: As discussed above, we are not finalizing the requirement for an expedited resolution process. In addition to the comments summarized above about the process itself, we agree with commenters that if a beneficiary has filed a grievance and wishes to present evidence and participate in a face-to-face meeting with the decisionmaker, 7 calendar days, or even 14 calendar days, may not be sufficient time for all relevant materials to be gathered and reviewed by the beneficiary and decisionmaker, nor to arrange for a resolution meeting. As discussed above, we are encouraging States to create their own processes for expediting resolution of certain grievances. We believe that there will be some grievances filed that may (and should) be resolved almost immediately, including by a referral to the critical incident system or fair hearings process. We note that several commenters suggested that 30 days is a reasonable timeframe for expediting resolutions, and States may want to take that recommendation under consideration when developing their own processes.

Consistent with our decision not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing § 441.301(c)(7)(v)(B)(2).

Comment: One commenter noted that imposing any timelines for resolving grievances could detract from staff resources needed to investigate critical incidents, particularly if the grievance and critical incident systems use the same staff.

Response: We recognize that States will have to supply staff and resources for both the grievance and critical incident systems that we are finalizing in this rule. We will provide technical assistance to States as needed to help identify ways to manage both systems, including setting priorities and managing the critical incident investigation and grievance resolution timeframes.

Comment: A number of commenters responded to our invitation to comment on whether part 438, subpart F should be amended to include the proposed expedited resolution requirements at § 441.301(c)(7)(iv)(B) and (v)(B)(2). Several commenters recommended that expedited procedures be extended to the managed care grievance procedures at part 438 subpart F. However, several commenters opposed adding expedited resolution timeframes to part 438 subpart F. Similar to the opposition presented to including expedited resolutions in the FFS grievance system, these commenters believed that very few expressions of dissatisfaction require expedited resolution and that other mechanisms exist to address health and safety concerns in a timely manner. A few commenters also provided suggestions on possible changes to the managed care grievance requirements, such as adding a prohibition of punitive action against beneficiaries who file grievances.

Response: We will take these comments under consideration. We note that we are not, at this time, finalizing an expedited resolution process in the FFS grievance system and are not finalizing the requirements we proposed at § 441.301(c)(7)(iv)(B) and at § 441.301(c)(7)(v)(B)(2) for such a process. We also note that, while outside the scope of this

proposal, we will take other recommendations regarding potential changes to the managed care grievance process under consideration as well.

Comment: A few commenters noted support for the proposal at § 441.301(c)(7)(v)(C) that States be permitted to extend the timeframes for the resolution of grievances by up to 14 calendar days.

Response: We thank the commenters for their support.

We did not receive comments on the requirements we proposed at § 441.301(c)(7)(v)(D).

After consideration of public comments, we are finalizing our proposal at § 441.301(c)(7)(v)(A) with modification to require that the State resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition (instead of health, safety, and welfare) requires. Additionally, consistent with our decision not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2), redesignating § 441.301(c)(7)(v)(B)(1) as § 441.301(c)(7)(v)(B), and retitling § 441.301(c)(7)(v)(B) as "Resolution timeframes." We are also removing the word "standard" in § 441.301(c)(7)(v)(B)(1) (which we are finalizing at § 441.301(c)(7)(v)(B)) since the finalized requirements do not distinguish between "standard resolution" and other types of resolutions.

We are finalizing § 441.301(c)(7)(v)(C), with a technical correction to redesignate paragraphs (C)(1)(i) and (C)(1)(ii) as (C)(1) and (C)(2), respectively. We are finalizing § 441.301(c)(7)(v)(D) as proposed, with minor technical corrections. Specifically, we are changing the periods at the end of § 441.301(c)(7)(v)(D)(1) and (2) to semi-colons and adding "and" at the end of § 441.301(c)(7)(v)(D)(2).

e. Notice of Resolution (§ 441.301(c)(7)(vi))

We proposed at § 441.301(c)(7)(vi) requirements related to the notice of resolution for beneficiaries. Specifically, at § 441.301(c)(7)(vi)(A), we proposed to require that States establish a method for written notice to beneficiaries and that the method meet the availability

and accessibility requirements at § 435.905(b). At § 441.301(c)(7)(vi)(B), we proposed to require that States make reasonable efforts to provide oral notice of resolution for expedited resolutions.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that we expand the requirements proposed at § 441.301(c)(7)(vi) pertaining to the information beneficiaries receive at the resolution of their grievance. The commenters requested we include a requirement that the notice explain what the grievance is, the information considered, the necessary remedial actions (if any) for resolution, and the ability to request further review.

Response: We encourage States to include this information in resolution notices as appropriate, but we decline to make changes to this requirement in our final rule. We note that this requirement, as written, is consistent with the parallel requirement in § 438.408(d), which provides States with flexibility in developing a method by which managed care plans will notify enrollees of resolutions. We intend to provide States with this same flexibility in the FFS system, as we see no compelling reason to impose more rigid requirements on one system than the other.

We also note that, consistent with the discussion above not to finalize the expedited resolution process, we are not finalizing § 441.301(c)(7)(vi)(B), which requires oral notice for expedited resolutions. We expect that States, should they decide to include an expedited resolution process in their grievance system, would develop an appropriate system for notifying beneficiaries of these resolutions.

After consideration of the comments received, we are finalizing § 441.301(c)(7)(vi)(A) without substantive changes. However, consistent with our decision (discussed above) not to finalize the expedited resolution process at § 441.301(c)(7)(iv)(B), we are not finalizing the requirement we proposed relating to the expedited resolution process at § 441.301(c)(7)(vi)(B) and redesignating § 441.301(c)(7)(vi)(A) as § 441.301(c)(7)(vi).

f. Recordkeeping (§ 441.301(c)(7)(vii))

We proposed at § 441.301(c)(7)(vii) recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we proposed to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B), we proposed to require that the record of each grievance must contain at a minimum the following information: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we proposed to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal at § 441.301(c)(7)(vii)(A) to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures, and for the proposal at § 441.301(c)(7)(vii)(C) that grievance records would be available upon CMS's request. A few commenters were also specifically supportive of what they regarded as the proposal's potential to collect and track standardized information about service system issues, including obstacles to informed choice and person-centered planning.

One commenter observed that there will be important lessons and conclusions that may be drawn from the data that should help the State to take steps to deter future service provider actions that lead to grievances. The commenter also hoped that such data could lead to educational opportunities to refine State and service provider knowledge of HCBS settings and person-centered service plan rules, and data should be collected on the efficacy of such educational interventions. One commenter suggested that we require qualitative, as well as quantitative, reporting.

Response: We decline to make any additional changes to our proposal at § 441.301(c)(7)(vii) in this final rule, but we agree with the commenters that the data and records that States collect as part of the grievance process may be critical in helping States improve their HCBS programs. While we are not finalizing specific requirements for how States must use this data, promising practices related to data collection and analysis, including methods of capturing qualitative data from the records, will likely be included in the technical assistance that will be available to States during the implementation period.

Comment: A few commenters recommended requiring States to make information on grievances publicly available, such as by releasing an annual report on the anonymized grievances received in the previous 12 months, categorized by issue, severity, and resolution or lack of resolution. One commenter suggested that such a report would enhance transparency and could assist with quality improvement by providing States, providers, and consumer advocates with insight into grievance patterns and trends. Another commenter recommended that we require public online disclosure of grievance details and resolutions. The commenter noted this would help individuals make informed choices about providers and would encourage compliance with person-centered planning and settings requirements. One commenter, presuming that the State's recordkeeping system would be made publicly available, suggested that we include the name of the decision maker in the records so that CMS, researchers, and advocacy groups can ensure that decision makers are making unbiased decisions.

Response: We did not propose that States publicly report information about grievance resolutions in this final rule; we note, for instance, that we did not include reporting on the grievance system as part of the reporting requirement being finalized at § 441.311, nor are we requiring that States report information about grievances as part of the website posting requirement being finalized at § 441.313. We decline to make any changes in this final rule to require such public reporting.

We believe that some public disclosures may not be suitable or appropriate in every instance, and it would be difficult to tailor a meaningful requirement to anticipate all of these circumstances. We are concerned that, for example, in States with smaller HCBS populations, it may be difficult to truly anonymize information about grievances. Relatedly, some beneficiaries may not want grievances published about specific providers, as some commenters suggest, as this would further complicate anonymity when some providers only serve a few clients. We are concerned also that public disclosure could have a chilling effect if beneficiaries believed their grievance could be made part of a public report. While we agree that, over time, data about trends in grievances could be useful to both the States and external interested parties in promoting systemic improvements of HCBS, we defer to States to determine when and how to make this information public and for what purpose. We also note that the specific recommendation to add the name of the decision maker to the record is addressed in another response later in this section.

Comment: One commenter recommended that we establish a process for an annual or regular review of the States' summary of issues and the States' resolution of the issues. Another commenter recommended requiring an independent evaluator periodically review States' grievance processes to identify common barriers, trends, participation rates, and effectiveness of resolutions.

Response: When developing the proposed requirements at § 441.301(c)(7), we did not intend to create a formal system in which we would routinely review individual resolutions made by States' grievance systems and are not persuaded otherwise after review of public comments received. As discussed further in this section II.B., we proposed, and are finalizing, the requirement at § 441.301(c)(7)(vii)(C) that States must make records available to us upon request. This provides CMS with authority to review records should we need to review the functioning of a State's grievance system on a case-by-case basis.

We believe that the grievance system's designated decision makers are generally in the best position to determine appropriate resolutions to beneficiaries' concerns and that the need to review individual records should be decided on a case-by-case basis. We do agree regular review of the States' grievance systems is a good suggestion, and we will take it under consideration for future guidance and rulemaking. Similarly, we are not requiring that States have their grievance system reviewed by an independent evaluator in this final rule – in part because we believe many States will likely do this anyway, as part of their standard audit processes. However, we agree that having the system regularly reviewed by an independent entity is a good practice that States may consider.

Comment: A few commenters suggested specific categories of information to be added to the record of each grievance proposed at § 441.301(c)(7)(vii)(B). One commenter suggested that all information considered should be included as a category in the record of each grievance. A few commenters recommended we add that the name of the decisionmaker be included in the record to ensure that conflict of interest requirements at § 441.301(c)(7)(iii)(C)(3) are preserved.

Response: We thank commenters for their suggestions, but we decline to add new record requirements for States at § 441.301(c)(7)(vii)(B). We believe capturing the names of staff and individuals who decided the outcome of each grievance is an operational and internal matter for States. States can record whatever information about a grievance resolution that they deem appropriate in addition to what is required. We believe § 441.301(c)(7)(vii)(B) as finalized reflects an appropriate minimum level of detail. We note that § 441.301(c)(7)(vii)(B) aligns with the managed care grievance system recordkeeping requirement at § 438.416.

After consideration of public comments received, we are finalizing § 441.301(c)(7)(vii) without substantive modifications. However, we are finalizing § 441.301(c)(7)(viii)(B)(1) through (5) with minor technical modifications. We are replacing the periods at the end of each paragraph with semi-colons, to accurately reflect that § 441.301(c)(7)(vii)(B)(1) through (6) are

elements of a nonexhaustive list, not separate declarative statements. We are also adding the word “and” to the end of § 441.301(c)(7)(vii)(B)(5).

g. Applicability date (§ 441.301(c)(7)(viii))

In the proposed rule (88 FR 27977), we recognized that many States may need time to implement the proposed grievance system requirements, including needing time to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. However, we noted that the absence of a grievance system in FFS HCBS systems poses a substantial risk of harm to beneficiaries. We proposed at § 441.301(c)(7)(viii) that the requirements at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. A 2-year time period after the effective date of the final rule for States to implement these requirements reflected our attempt to balance two competing challenges: (1) the fact that there is a gap in existing regulations for FFS HCBS grievance processes related to important HCBS beneficiary protection issues involving person-centered planning and HCBS settings requirements; and (2) feedback from States and other interested parties that it could take 1 to 2 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in the proposed rule (88 FR 27971 through 27995) as whole. We solicited comments on overall burden for States to meet the requirements of this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (1 year to 18 months) or longer timeframe (3 to 4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal at § 441.301(c)(7)(viii) that the requirement at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. However, one commenter, stating that these grievance protections will be vital to HCBS beneficiaries, recommended that States be required to come into compliance within 18 months after the effective date of the regulations.

A few commenters expressed concerns about the burden they believe will be associated with developing a grievance system, particularly in States that do not already have grievance processes in place. Commenters believed that it would take significant resources to help beneficiaries understand what rights they can claim under the grievance system. Commenters also described costs or activities such as: funding and statutory change requests to State legislatures; administrative rulemaking; IT and administrative system design and development, which may include vendor procurement; collaboration with other State agencies or agency divisions; partnering with providers for implementation; hiring and training new staff; and approval of implementation advance planning documents by CMS. These commenters suggested alternative effective dates ranging from 3 to 5 years. One commenter also suggested an effective date of 4 years after CMS releases relevant subregulatory guidance.

Response: We appreciate the fact that States will have to expend resources in developing the grievance system, particularly States that do not currently have grievance systems for Medicaid beneficiaries receiving services under section 1915(c), (i), (j) and (k) authorities through a FFS delivery system. Because of the activities that some States will have to perform to develop the grievance system shared by commenters, we agree that requiring an earlier timeframe of 18 months is not realistic. We also appreciate, and agree with, the sense of urgency expressed by commenters. We believe it is important to prioritize giving beneficiaries the opportunity to have their concerns heard. In this final rule, we have provided States with as much flexibility as possible to build on or retain existing grievance systems and have kept specific information systems requirements to a minimum. We have also reduced some potential initial

administrative challenges by not finalizing a formal expedited resolution requirement and by allowing States to decide whether, and how, to implement such a policy. After consideration of public comments received as discussed herein, we are finalizing the substance of § 441.301(c)(7)(viii) as proposed, but with minor modifications to correct erroneous uses of the word “effective” and retitle the requirement as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(7)(viii) to specify that **States must comply with** the requirements at § 441.301(c)(7) **beginning** 2 years from the effective date of this final rule, rather than stating that this requirement is effective 2 years after the date of enactment of the final rule. (New text in bolded font). We are finalizing § 441.301(c)(7)(viii) with a technical modification to specify that the applicability date applies to the requirements at § 441.301(c)(7).

Comment: A few commenters requested enhanced FMAP to support implementation and operationalization of the grievance process. Two commenters recommended that, in addition to providing 90 percent FFP for information systems improvements, we should offer 75 percent FFP for all quality-related activities, including operational costs associated with a grievance system. The commenters suggested this would create parity between the States whose service delivery systems are largely FFS and the States with managed care services that can receive 75 percent FFP for External Quality Review (EQR) activities.

Response: We note that enhanced FMAP is available for certain activities related to administering the Medicaid program and designing, developing, implementing, and operating certain IT systems.⁶⁰ However, Federal matching rates are established by Congress and CMS does not have the authority to change or increase them, nor do we have the authority to add additional activities not specified in statute into the scope of an existing enhanced FMAP. We also do not agree that providing broader enhanced match for the FFS grievance system would create parity with managed care, as we believe this is an inaccurate characterization of payments

⁶⁰ For a current list of activities eligible for this enhanced FMAP, refer to: MACPAC, “Federal Match Rates for Medicaid Administrative Activities,” last access: October 22, 2023. <https://www.macpac.gov/federal-match-rates-for-medicaid-administrative-activities/>.

related to the managed care grievance systems. While commenters are correct that States can receive 75 percent enhanced match for EQR activities, which are listed at § 438.358, these activities are primarily validation and review of data on performance measures; the operation of a grievance system is not listed as an EQR activity. We also note that the associated administrative costs for MCOs, PIHPs, and PAHPs are variable and negotiated with the State as part of their contracts.

After consideration of public comments received, we are finalizing the substance of § 441.301(c)(7)(viii) as proposed, but with minor modifications to correct erroneous uses of the word “effective” and retitle the requirement as Applicability date (rather than Effective date). We are also modifying the language at § 441.301(c)(7)(viii) to specify that States must comply with the requirements at § 441.301(c)(7) beginning 2 years from the effective date of this final rule, rather than stating that this requirement is effective 2 years after the date of enactment of the final rule. (New text in bolded font.) We are finalizing § 441.301(c)(7)(viii) with a technical modification to specify that the applicability date applies to the requirements at § 441.301(c)(7).

h. Application to Other Authorities

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options also must comply with the HCBS Settings Rule and with similar person-centered planning and service plan requirements, we proposed to include these grievance requirements within the applicable regulatory sections. Specifically, we proposed to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively.

Also, consistent with our proposal for section 1915(c) waivers, we proposed to apply the proposed grievance requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries and our authority at section 2402(a)(3)(B)(ii) of the Affordable Care Act to require a complaint system for beneficiaries. We stated that the same arguments for applying these requirements for section 1915(c) waivers are equally applicable to these other HCBS authorities. We requested comment on the application of the grievance system provisions to section 1915(i), (j), and (k) authorities. We also noted that, in the language added to § 441.464(d)(2)(v), the proposed grievance requirements apply when self-directed personal assistance services authorized under section 1915(j) include services under a section 1915(c) waiver program.

As described in the proposed rule (88 FR 27978), we did not propose to apply these requirements to section 1905(a) services. Specifically, we considered whether to also apply the proposed requirements to section 1905(a) “medical assistance” in the form of State plan personal care services, home health services, and case management services, but did not propose these requirements apply to any section 1905(a) State plan services because section 1905(a) services are not required to comply with HCBS settings requirements and because the person-centered planning and service plan requirements for most section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We solicited comment, seeing the value in discussing and seeking public input, on whether we should establish grievance requirements for section 1905(a) State plan personal care services, home health services and case management services.

We received public comments on these proposals. The following is a summary of the comments and our responses.

Comment: A few commenters supported the proposal to apply the grievance system provisions proposed for section 1915(c) at § 441.301(c)(7) to sections 1915(i), (j) and (k) authorities. They agreed with the goal of aligning the different HCBS program authorities and promoted consistency with managed care.

Response: We thank commenters for their support.

Comment: One commenter supported the application of the grievance requirements to self-directed personal assistance services under section 1915(j) of the Act as well. This commenter noted that, during the pandemic, there was no clear way to file a grievance with Medicaid concerning a lack of access to direct care workers, for example.

One commenter, on the other hand, questioned the operationalization of the grievance process for self-directed personal care service models under sections 1915(j) and (k), where the beneficiary acts as the employer for purposes of hiring, training, supervising, and firing, their provider, if necessary. This commenter was concerned that allowing beneficiaries to file grievances against their provider would erode a beneficiary's responsibilities as the employer. Another commenter, while supporting application of the grievance process to section 1915(j) self-directed services, did suggest that implementing this requirement in self-directed models may require additional time and guidance.

Response: We believe it would be inappropriate to exclude beneficiaries enrolled in self-directed services delivery models from the grievance system and decline to do so in this final rule. As noted by other commenters, beneficiaries enrolled in self-directed services may experience systemic challenges with their services; they may also interact with other providers in addition to their self-directed service provider (such as the entity providing financial management services). We also note that the grievance system is a venue for expressing concerns about violations of the HCBS settings requirements, which may be relevant to some beneficiaries in self-directed programs. We do not believe that additional time needs to be granted specifically for inclusion of beneficiaries using self-directed services.

Comment: Several commenters responded to our request for comment on whether we should establish grievance requirements for section 1905(a) State plan personal care services, home health services and case management services. A few commenters supported the proposal not to extend the requirements to section 1905(a) services on the basis that these services are not subject to the same person-centered planning and HCBS settings rules. Additionally, several commenters also believed the expansion of these requirements to section 1905(a) State plan services would pose additional challenges to State Medicaid and operating agencies. One commenter noted that, in States that deliver section 1905(a) State plan services and section 1915(c) services through different agencies or agency divisions, implementation could prove challenging and costly. A few commenters stated that States should be encouraged (but not required) to implement the proposed provisions to their section 1905(a) State plan services.

However, a few commenters supported extending the grievance system requirements to section 1905(a) services. Among these commenters, a few commenters recommended that CMS apply the grievance system requirements specifically to mental health rehabilitative services delivered under section 1905(a) services. These services, some commenters stated, are delivered to large numbers of Medicaid beneficiaries, particularly those with mental health needs. These commenters elaborated on concerns that, otherwise, there would be disparities between individuals receiving similar services from the same State Medicaid agency under different authorities, and that many Medicaid recipients with mental health disabilities receiving services under the section 1905(a) authority would not have recourse if their rights were violated. One commenter also suggested that mental health rehabilitative services are considered “home- and community-based services” under the broader definition enacted by Congress in the American Rescue Plan Act of 2021.

Response: At this time, we are not requiring inclusion of section 1905(a) services in the State grievance system. That said, we are not convinced by the argument that including section 1905(a) services would simply be too much work, as we do believe it is critical that beneficiaries

have access to mechanisms to claim their rights and have their concerns heard. Rather, we note that there are statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. We would need to consider how to define the nature of the grievances that would be filed for section 1905(a) services, given that they do not have the same person-centered planning and HCBS settings rule requirements at § 441.301(c)(1) through (6). As we discussed extensively in this section, the bases for a grievance are providers' and States' performance of the requirements at § 441.301(c)(1) through (6). We believe this definition of grievance provides clear parameters for matters that would be the subject of grievances. We note that person-centered service planning requirements are established for section 1915(j) services in § 441.468, for section 1915(k) services in § 441.540, and for section 1915(i) services at § 441.725. While person-centered service planning might be part of some specific 1905(a) services, it is not a required component of all section 1905(a) services.

Similarly, the HCBS settings requirements at § 441.301(c)(3) through (6) that apply to section 1915(c) services have counterparts for section 1915(k) services at § 441.530 and for 1915(i) services at § 441.710. (For more discussion of the application of the HCBS settings rule's application to section 1915(c), (i), and (k) services, we refer readers to the final rule published in 2014 at 79 FR 2948.) Section 1915(j) services offered through a section 1915(c) waiver (as specified, for instance, at § 441.452(a)) would also be subject to the HCBS settings requirements at § 441.301(c)(3) through (6). There is not a similar application of the HCBS settings rule to section 1905(a) services.

If we are to apply a grievance process to 1905(a) services, it is likely we would weigh proposing a grievance process for all section 1905(a) services versus for only specific section 1905(a) services. These services are diverse, are offered in diverse settings, and lack the clear regulatory framework that we were able to use in constructing the bases for grievances in section 1915 services. We believe this requires additional consideration and discussion with the public beyond what could be finalized in this current rule.

Though we are not finalizing inclusion of section 1905(a) services in the State grievance system in this rule, we acknowledge that many beneficiaries, including those receiving mental health services, are served by section 1905(a) services and encourage States to consider development of grievance processes to address these beneficiaries' concerns. We appreciate the commenters' suggestions. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

After consideration of public comments, we are finalizing the application of the grievance system requirements for section 1915(c) waivers, as finalized in this rule at § 441.301(c)(7), to the other HCBS authorities under sections 1915(j), 1915(k), and 1915(i). However, after further review, we determined it is necessary to make modifications to our regulations for these other HCBS authorities to clarify this intention. Our proposed regulation text for these HCBS authorities did not accurately reflect or effectuate our proposal to require States to implement and maintain a grievance system, in accordance with § 441.301(c)(7), for these HCBS authorities as well. We are finalizing the regulation text we proposed at §§ 441.464 (for section 1915(j)), 441.555 (for section 1915(k)), and 441.745 (for section 1915(i)) with modification to more clearly specify that a State must implement and maintain a grievance system in accordance with the requirements we are finalizing at § 441.301(c)(7) for HCBS programs they administer under these authorities.

For application to section 1915(j) services, we are not finalizing the amendment we proposed at § 441.464(d)(2)(v), but rather finalizing this new requirement for a grievance system at § 441.464(d)(5). We will retain the current language at § 441.464(d)(2)(v), which indicates that States must include grievance processes, generally, among the support activities about which States provide information, counseling, training, and assistance. At § 441.464(d)(5), we are finalizing with modification for clarity and precision that the State must implement and maintain

a grievance process in accordance with § 441.301(c)(7), rather than the language we proposed at § 441.464(d)(2)(v) (Grievance process, as defined in § 441.301(c)(7) when self-directed PAS include services under a section 1915(c) waiver program). We are also finalizing § 441.464(d)(5) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

For application to section 1915(k) services, we are not finalizing the amendment we proposed at § 441.555(b)(2)(iv), but rather finalizing this new requirement for a grievance system at § 441.555(e). We will retain the current language at § 441.555(b)(2)(iv), which indicates that States must include grievances processes, generally, among the support activities about which States provide information, counseling, training, and assistance. At § 441.555(e), we are finalizing with modification for clarity and precision that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7), rather than the language we proposed at § 441.555(b)(2)(iv) (Grievance process, as defined in § 441.301(c)(7)). We are also finalizing § 441.555(e) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

For application to section 1915(i) services, we are finalizing the amendment we proposed at § 441.745(a)(1)(iii) with modifications. As proposed, § 441.745(a)(1)(iii) had indicated that a State must provide beneficiaries receiving section 1915(i) services with the opportunity to file a grievance. To clarify that the State must maintain a grievance process in accordance with § 441.301(c)(7) for beneficiaries receiving HCBS under section 1915(i), we are finalizing § 441.745(a)(1)(iii) to specify that the State must implement and maintain a grievance process in accordance with § 441.301(c)(7). We note that several requirements being finalized at § 441.301(c)(7) (such as § 441.301(c)(7)(iii)(A), (B)(2), and (C)(1), discussed in section II.B.2.b. of this final rule) require States to provide the beneficiary with the opportunity to file grievances

in the grievance system. We are also finalizing § 441.745(a)(1)(iii) with a technical modification to clarify that the grievance system must meet the requirements of § 441.301(c)(7), but that references therein to section 1915(c) of the Act are instead references to section 1915(i) of the Act. Additionally, as we are finalizing a new § 441.745(a)(1)(iii) in this rule, we are redesignating the current § 441.745(a)(1)(iii) as § 441.745(a)(1)(iv).

We also note that while we are finalizing these amendments to regulations under section 1915(j), (k) and (i) authorities, we are not suggesting that States that provide HCBS through multiple authorities must operate a separate grievance process for each program. As discussed earlier in II.B.2. of this preamble, while States are allowed to maintain multiple grievance processes (so long as each process complies with § 441.301(c)(7)), we strongly encourage States to maintain a single, integrated grievance system for all HCBS beneficiaries.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the proposals at § 441.301(c)(7) as follows:

- We are finalizing the requirement describing the grievance system purpose at § 441.301(c)(7)(i) with technical modifications to specify that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's **performance of** (rather than **compliance with**) the activities described in paragraphs (c)(1) through (6) of § 441.301(c)(7). (New language identified in bold.) We are also adding language to § 441.301(c)(7)(i) stating that the State may contract with other entities to perform activities described in § 441.301(c)(7) but retains responsibility for ensuring performance of and compliance with these provisions. The finalized requirement at § 441.301(c)(7)(i) will read:
Purpose. The State must establish a procedure under which a beneficiary may file a grievance related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. The State may

have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions.

- We are finalizing the definition of grievance at § 441.301(c)(7)(ii) with a technical modification, conforming with the modification at § 441.301(c)(7)(i), to specify that a grievance will mean an expression of dissatisfaction or complaint related to the State's or a provider's performance of (rather than **compliance with**) the activities described in paragraphs (c)(1) through (6), regardless of whether remedial action is requested. (New language identified in bold.) We are finalizing the definition of grievance system at § 441.301(c)(7)(ii) as proposed.

- We are finalizing the process requirement at § 441.301(c)(7)(iii)(A) as proposed, with the following exceptions. We are finalizing § 441.301(c)(7)(iii)(A)(1) with modification to specify that another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. The finalized requirement at § 441.301(c)(7)(iii)(A)(1) will read: Another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative. We are finalizing § 441.301(c)(7)(iii)(A)(2) as proposed.

- We are finalizing the process requirement at § 441.301(c)(7)(iii)(B) as proposed.

- We are finalizing § 441.301(c)(7)(iii)(B)(1) with a modification to correct an erroneous reference to subchapter by replacing subchapter with paragraph (c)(7).

- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(2) with a modification to specify that States must provide beneficiaries with reasonable assistance in ensuring grievances are appropriately filed with the grievance system. We are also finalizing § 441.307(c)(7)(iii)(B)(2) with modifications to change the term "individuals who are limited English proficient" to "individuals with Limited English Proficiency." We are also finalizing

with modification to clarify that auxiliary aids and services are to be available where necessary to ensure effective communication. As finalized, § 441.301(c)(7)(iii)(B)(2) specifies that States must provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system, completing forms, and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and to provide meaningful access to individuals with Limited English Proficiency, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services where necessary to ensure effective communication, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

- We are finalizing the process requirement at § 441.301(c)(7)(iii)(B)(3) with modifications to require that States ensure that punitive or retaliatory action (rather than just punitive actions) is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf. The finalized requirement at § 441.301(c)(7)(iii)(B)(3) will read: Ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance **or who has had a grievance filed on their behalf**. (New language identified in bold.)

- We are finalizing the process requirement § 441.301(c)(7)(iii)(B)(4) with a modification to remove the reference to expedited grievances. The finalized requirements at § 441.301(c)(7)(iii)(B)(4) will read: Accept grievances and requests for extension of timeframes from the beneficiary.

- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(5) with a modification to change mention of individuals who are limited English proficient to individuals with Limited English Proficiency.

- We are finalizing the process requirements at § 441.301(c)(7)(iii)(B)(6) and (7) as proposed.

- We are finalizing the requirements at § 441.301(c)(7)(iii)(C)(4) and (5) with a modification to replace the reference to § 441.301(c)(7)(v)(B)(1) and (2) and adding a reference to § 441.301(c)(7)(v). We are also finalizing § 441.301(c)(7)(iii)(C)(5) with a modification to change the reference to 45 CFR 164.510(b) to a broader reference to the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E).

- Aside from the modifications noted previously to § 441.301(c)(7)(iii)(C)(4) and (5), we are finalizing § 441.301(c)(7)(iii)(C) as proposed, with minor formatting changes.

- We are finalizing the filing timeframe requirement at § 441.301(c)(7)(iv) with modifications by removing the expedited resolution requirement at § 441.301(c)(7)(iv)(B) and redesignating § 441.301(c)(7)(iv)(A) as § 441.301(c)(7)(iv). The finalized requirement at 441.301(c)(7)(iv) will read: *Filing timeframes*. A beneficiary may file a grievance at any time.

- We are finalizing the resolution and notification requirement at § 441.301(c)(7)(v)(A) with a modification to require that the State resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition (instead of health, safety, and welfare) requires. The finalized requirement at § 441.301(c)(7)(v)(A) will read: *Basic rule*. The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

- We are not finalizing the expedited resolution timeframe at § 441.301(c)(7)(v)(B)(2). Instead, we are redesignating § 441.301(c)(7)(v)(B)(1) as § 441.301(c)(7)(v)(B) and retitling § 441.301(c)(7)(v)(B) as "Resolution timeframes." We are also removing the word "standard" from § 441.301(c)(7)(v)(B). The finalized requirement at § 441.301(c)(7)(v)(B) will read: *Resolution timeframes*. For resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.

- We are finalizing the timeframe extension requirement at § 441.301(c)(7)(v)(C) and (D) without substantive changes. We are finalizing § 441.301(c)(7)(v)(C) with a technical modification to redesignate paragraphs (C)(1)(i) and (C)(1)(ii) as (C)(1) and (C)(2), respectively. We are finalizing § 441.301(c)(7)(v)(D) as proposed, but with a technical modification to change the periods at the end of § 441.301(c)(7)(v)(D)(1) and (2) to semi-colons, and adding “and” at the end of § 441.301(c)(7)(v)(D)(2).

- We are finalizing the notice format requirement at § 441.301(c)(7)(vi)(A) without substantive modification. However, we are not finalizing the proposal relating to the expedited resolution process at § 441.301(c)(7)(vi)(B). Therefore, we are redesignating § 441.301(c)(7)(vi)(A) as § 441.301(c)(7)(vi).

- We are finalizing the recordkeeping requirements at § 441.301(c)(7)(vii) without substantive modifications. However, we are finalizing § 441.301(c)(7)(viii)(B)(1) through (5) with semi-colons rather than periods at the end of each paragraph, and with the word “and” at the end of § 441.301(c)(7)(vii)(B)(5).

- We are finalizing the applicability date requirements at § 441.301(c)(7)(viii) to specify that States must comply with the requirement at paragraph (c)(7) beginning 2 years from the effective date of this final rule.

Additionally, we are finalizing the application of the grievance process requirements at § 441.301(c)(7) to section 1915(j), (k) and (i) authorities as follows:

- For application to section 1915(j) services, we are not finalizing a reference at § 441.464(d)(2)(v), as we had proposed, but rather finalizing a new requirement at § 441.464(d)(5) that specifies that States must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

- For application to section 1915(k) services, we are not finalizing a reference at § 441.555(b)(2)(iv), as we had proposed, but rather finalizing a new requirement at § 441.555(e)

that specifies that States must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

- For application to section 1915(i) services, we are finalizing a new § 441.745(a)(1)(iii) with modification to clarify that the State must maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act. We are redesignating the existing § 441.745(a)(1)(iii) as § 441.745(a)(1)(iv).

3. Incident Management System (§§ 441.302(a)(6), 441.464(e), 441.570(e), 441.745(a)(1)(v) and 441.745(b)(1)(i))

Section 1902(a)(19) of the Act requires States to provide safeguards as may be necessary to assure that eligibility for care and services will be determined, and that such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients. Section 1915(c)(2)(A) of the Act and current Federal regulations at § 441.302(a) require that States have in place necessary safeguards to protect the health and welfare of individuals receiving section 1915(c) waiver program services. Further, as discussed previously in section II.B.1. of this rule, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁶¹ Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and oversight of a system to qualify and monitor providers.

⁶¹ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at <https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf>.

As noted earlier in section II.B.1. of this rule, we released guidance for section 1915(c) waiver programs included in the 2014 guidance⁶², which noted that States should report on State-developed performance measures to demonstrate that they meet six assurances, including a Health and Welfare assurance for States to demonstrate that they have designed and implemented an effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance highlighted, related to the Health and Welfare assurance, the following:

- The State demonstrates on an ongoing basis that it identifies, addresses, and seeks to prevent instances of abuse, neglect, exploitation, and unexplained death;
- The State demonstrates that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible;
- The State’s policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed; and
- The State establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.

Consistent with the expectations for other performance measures, the 2014 guidance noted that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their Health and Welfare performance measures.

Despite States implementing these statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and States’ adherence to related subregulatory guidance, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. For example, a 2018 report, “Ensuring

⁶² Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.

Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight,”⁶³ (referred to as the Joint Report, developed by ACL, OCR, and the OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm.

In addition, in 2016 and 2017, OIG released several reports on their review of States’ compliance with Federal and State requirements regarding critical incident reporting and monitoring.^{64, 65, 66} OIG found that several States did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving individuals receiving HCBS through waivers. In particular, the reports indicated that:

- Critical incidents were not reported correctly;
- Adequate training to identify appropriate action steps for reported critical incidents or reports of abuse or neglect was not provided to State staff;
- Appropriate data sets to trend and track critical incidents were not accessible to State staff; and
- Critical incidents were not clearly defined, making it difficult to identify potential abuse or neglect.

In 2016, we conducted three State audits based at least in part on concerns regarding health and welfare and media coverage on abuse, neglect, or exploitation issues.⁶⁷ We found that these three States had not been meeting their section 1915(c) waiver assurances, similar to findings reported by the OIG. In two cases, for the incidents of concern, tracking and trending of

⁶³ Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Health and Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at <https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf>.

⁶⁴ HHS OIG. “Connecticut did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.” May 2016. Accessed at <https://oig.hhs.gov/oas/reports/region1/11400002.pdf>.

⁶⁵ HHS OIG. “Massachusetts did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries.” July 2016. Accessed at <https://oig.hhs.gov/oas/reports/region1/11400008.pdf>.

⁶⁶ HHS OIG. “Maine did not comply with Federal and State requirements for critical incidents involving Medicaid beneficiaries with developmental disabilities.” August 2017. Accessed at <https://oig.hhs.gov/oas/reports/region1/11600001.pdf>.

⁶⁷ Presentation by CMS for Advancing States: Quality in the HCBS Waiver – Health and Welfare. See: <http://www.nasuad.org/sites/nasuad/files/Final%20Quality%20201.pdf>.

critical incidents were not present. Further, in at least two of the States, staffing at appropriate levels was identified as an issue.

In January 2018, the United States Government Accountability Office (GAO) released a report on a study of 48 States that covered assisted living services.⁶⁸ The GAO found large inconsistencies between States in their definition of a critical incident and their system's ability to report, track, and collect information on critical incidents that have occurred. States also varied in their oversight methods, as well as the type of information they were reviewing as part of this oversight. The GAO recommended that requiring States to report information on incidents (such as the type and severity of incidents and the number of incidents) would strengthen the effectiveness of State and Federal oversight.

In July 2019, we issued a survey to States that operate section 1915(c) waivers, requesting information on their approach to administering incident management systems. The goal of the survey was to obtain a comprehensive understanding of how States organize their incident management system to best respond to, resolve, monitor, and prevent critical incidents in their waiver programs. The survey found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and

⁶⁸ Government Accountability Office. "Medicaid assisted living services – improved Federal oversight of beneficiary health and welfare is needed." January 2018. Accessed at <https://www.gao.gov/assets/690/689302.pdf>.

- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Additionally, during various public engagement activities conducted with interested parties over the past several years, we have heard that ensuring access to HCBS requires that we must first ensure health and safety systems are in place across all States, a theme underscored by the Joint Report.

a. Incident Management System Requirements (§ 441.302(a)(6))

Based on these findings and reports, under the authorities at sections 1902(a)(19) and 1915(c)(2)(A) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we proposed a new requirement at § 441.302(a)(6) to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. This proposal is intended to ensure standardized requirements for States regarding incidents that harm or place a beneficiary at risk of harm and is based on our experience working with States as part of the section 1915(c) waiver program and informed by the incident management survey described previously in this section of the final rule. In the absence of an incident management system, people receiving section 1915(c) waiver program services are at risk of preventable or intentional harm. As such, we believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We proposed similar requirements for section 1915(i), (j) and (k) HCBS programs at §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and 441.745(b)(1)(i); these are discussed further in section II.B.3.i of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal at § 441.302(a)(6) to require States to provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. Additionally, these commenters noted that the proposed requirements for this incident management system can ensure States standardize data and processes for critical incident monitoring, identify trends, and influence timely oversight of responses to incidents to minimize health and safety risks for beneficiaries receiving HCBS.

Several commenters stated that establishing an incident management system, including requirements for data-driven analytics and trend reporting, would help to better inform States and providers by creating new collaborative models to measure improvements to better ensure quality of life for HCBS beneficiaries. In the same vein, one commenter noted that States should use the data and information collected on critical incidents to develop strategies to reduce or eliminate the risk of abuse, neglect, or exploitation; to enable discovery of root cause for occurrence of critical incidents; and to identify actions to influence critical incidents proactively, instead of reactively.

Response: We appreciate the support for our proposal and agree that requiring States to provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents will ensure that States are better informed and more able to identify root causes for the occurrence of critical incidents, enabling them to act more proactively to influence and prevent the occurrence of such incidents.

Comment: A few commenters requested we clarify how States can fully address critical incidents for dually eligible beneficiaries who are enrolled in managed care plans, when the managed care plan does not have access to Medicare claims data. In the same vein, they were also concerned that States would require extensive resources to utilize the Medicare claims data.

These commenters also requested clarification on the feasibility of reporting across Medicare and Medicaid in dual eligible special needs plan (D-SNP) contracts.

Response: Since 2011, we have provided States access to Medicare data for dually-eligible beneficiaries, including for beneficiaries in different categories of dual eligibility, free-of-charge via the Medicare-Medicaid Data Sharing Program.⁶⁹ Information on the Medicare-Medicaid Data Sharing Program, including how to request data and the standard data sharing agreements, is available through the State Data Resource Center.⁷⁰

We proposed that the incident management system requirements, as specified at § 441.302(a)(6) and as finalized in this rule, will apply to section 1915(c)(i), (j), and (k) services delivered through managed care plans. We also note that dually eligible beneficiaries enrolled in managed care plans known as fully integrated dual eligible special needs plans (FIDE SNP) and highly integrated dual eligible special needs plans (HIDE SNP), are subject to the incident management requirements at § 441.302(a)(6) as finalized. We will provide technical assistance regarding the application of these requirements to beneficiaries in different categories of dual eligibility.

Comment: A few commenters expressed concern that the requirements we proposed for this incident management system generally seemed to be more focused on documentation of critical incidents, rather than impacting quality and outcomes for HCBS participants to ensure optimal health and welfare. One commenter recommended that States should assure that resolution of critical incidents focuses on preventing harm to the HCBS participant(s) involved in the critical incident. This commenter also suggested that States should take actions to not only prevent further harm to HCBS participant(s) involved in a critical incident, but actions based on the critical incident should be taken to prevent further harm to all HCBS participants.

⁶⁹ See Medicare-Medicaid Data Sharing Program at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/StateAccessToMedicareData>.

⁷⁰ See State Data Resource Center at <https://www.statedataresourcecenter.com/home/contact-us>.

Response: We believe the requirements we proposed at § 441.302(a)(6), and as finalized in this rule, give States the flexibility to decide how to design and implement their incident management system. We encourage States to consider implementing quality improvement processes as part of their incident management systems, as quality improvement processes can help States to promote the health and welfare of beneficiaries by addressing systemic issues in their HCBS programs. We also note that the purpose of tracking and trending critical incidents is to assist States in understanding patterns that require interventions to promote improvement and prevent the recurrence of harm to beneficiaries.

We also refer readers to the requirements currently set forth at § 438.330(b)(5)(ii) that MCOs, PHIPs, and PAHPs participate in efforts by the State to prevent, detect, and remediate critical incidents, consistent with assuring beneficiary health and welfare as required in § 441.302 and § 441.703(a). Further, as noted herein, the six assurances and related subassurances for section 1915(c) waiver programs, including the Health and Welfare assurance, as set forth in the 2014 guidance, continue to apply. In addition, as discussed in section II.B.8. of this final rule, the HCBS Quality Measure Set reporting requirements include requirements for States to implement quality improvement strategies in their HCBS programs; while the HCBS Quality Measure Set requirements being finalized in this rule are distinct and severable from the incident management requirements being finalized at § 441.302(a)(6), we believe the HCBS Quality Measure Set requirements support the quality improvement objectives described by this commenter.

After consideration of these public comments, we are finalizing our proposal to require at § 441.302(a)(6) that States must provide an assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents as proposed.

b. Critical Incident Definition (§ 441.302(a)(6)(i)(A))

At § 441.302(a)(6)(i)(A) through (G), we proposed new requirements for States' incident management systems. Specifically, at § 441.302(a)(6)(i)(A), we proposed to establish a standard definition of a critical incident to include, at a minimum, verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

We proposed the Federal minimum standard definition of a critical incident at § 441.302(a)(6)(i)(A) to address the lack of a standardized Federal definition for the type of events or instances that States should consider a critical incident that must be reported by a provider to the State and considered for an investigation by the State to assess whether the incident was the result of abuse, neglect, or exploitation, and whether it could have been prevented. The definition we proposed at § 441.302(a)(6)(i)(A) is based on internal analyses of data and information obtained through a CMS survey of States' incident management systems, commonalities across definitions, and common gaps in States' definitions of critical incidents (for instance, that many States do not consider sexual assault to be a critical incident).

We also requested comment on whether there are specific types of events or instances of serious harm to section 1915(c) waiver participants, such as identity theft or fraud, that would not be captured by the proposed definition and that should be included, and whether the inclusion of any specific types of events or instances of harm in the proposed definition would lead to the overidentification of critical incidents.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed minimum standard definition of a critical incident. Commenters expressed that the proposed requirements at § 441.302(a)(6)(i)(A)

establish a minimum Federal definition of a critical incident which would help to standardize practices across States and HCBS programs to better serve and prevent harm or risk of harm for beneficiaries. A few commenters noted the standardized Federal minimum definition of a critical incident will increase consistency across States, section 1915(c) waivers, and HCBS programs. A few commenters suggested CMS further explain the critical incident definition to minimize misinterpretation, stating that explanations of definitions for each type of critical incident could ensure reporting is uniform and consistent across all State programs and services. These commenters stated that without a uniform understanding of each type of critical incident, critical incidents could be over or under reported. Similarly, several other commenters suggested that the definition of critical incident we proposed is overly broad, expressing it could impede the State's coordination with other agencies and interested parties. These commenters indicated that more explanation of the definitions of critical incident at § 441.302(a)(6)(i)(A) could help to address varying interpretations in implementation of the proposed requirements, noting that each State Medicaid agency or interested parties could independently establish meaning.

Response: We disagree with commenters that the proposed definition of critical incident is overly broad. We believe that the proposed requirements at § 441.302(a)(6)(i)(A) provide States with a comprehensive minimum standard definition of a critical incident. We recommend that States view the definition as a minimum Federal standard. States may consider expanding the definition to include other health and safety concerns based on the unique needs of their HCBS populations and the specific characteristics of their HCBS programs. We plan to provide technical assistance, as needed, to States if they have questions about the types of incidents that should be included in the standardized definition, and how this definition relates to existing critical incident definitions already in use.

Comment: Commenters responded to our request for comment on whether there were specific types of events or instances of serious harm that would not be captured by the proposed critical incident definition and should be included. A few commenters suggested that we

broaden the definition of critical incident and suggested that the following types of incidents be included in the proposed definition of critical incident at § 441.302(a)(6)(i)(A): abuse between HCBS waiver housemates; expression of racism, sexism, homophobia, or transphobia by a provider toward a beneficiary; lack of direct care workers; physical or emotional harm suffered by participant; falls with severe or moderate injury/illness; missed or delayed provision of services identified in the person-centered plan; refusal of service; self-neglect; and a range of harmful things beneficiaries may experience.

Alternatively, a few commenters recommended that CMS not expand the minimum definition of critical incident further, indicating the critical incident definition offers flexibility to States to expand their critical incident definition to fit the HCBS program and population served by the State. Commenters expressed that CMS should provide technical assistance, for all States, including for States that already have an incident management system with critical incident definitions and policies and programs in place.

Response: We appreciate commenters sharing these suggestions. We note that many of these types of events would be captured by the minimum standard definition. For instance, we would consider abuse between HCBS waiver housemates to fall under verbal, physical, sexual, psychological, or emotional abuse. Similarly, expressions of racism, sexism, homophobia, or transphobia by a provider toward a beneficiary may be considered a critical incident. If a lack of direct care workers, a refusal of service, or missed or delayed provision of services identified in the person-centered service plan results in harm or risk of risk from the failure of a provider to deliver needed services, we would expect a State to consider those events as instances of neglect. Physical or emotional harm suffered by a participant as a result of one or more types of events included in our definition of critical incidents or that results in death would also be captured as a critical incident. Falls with severe or moderate injury/illness may be considered critical incidents depending on whether they occur as a result of an event included in our definition of critical incidents. They would also be considered critical incidents if they result in death. Some of these

events, such as missed or delayed provision of services identified in the person-centered service plan, could also meet the definition of a grievance and be appropriate for consideration under the grievance system, which we are finalizing as part of a separate provision in § 441.301(c)(7) (discussed in section II.B.2 of this rule.)

We decline to include refusing a service or self-neglect in the minimum standard definition because we intend this definition to focus on incidents that occur during the course of service delivery. However, States may include these events in their own definitions.

We are unsure what the commenter intended by “range of harmful things beneficiaries may experience” and are unable to respond directly to that recommendation.

We appreciate these comments and will take this feedback into consideration when developing resources for States on the incident management system’s requirements.

Comment: One commenter stated that we should consider whether what constitutes a critical incident might differ between adult and child beneficiaries and recommended that pediatricians could assist States in development and implementation of incident management requirements, including critical incident requirements. This commenter also stated that data and information for children receiving HCBS and housed in pediatric health systems should be linked with the State electronic critical incident system proposed at § 441.302(a)(6)(i)(B).

Response: As previously discussed, our proposal is to establish a minimum Federal definition, and States may consider expanding the definition to include other health and safety concerns based on the unique needs of their HCBS populations. We also encourage States to include input from interested parties, including experts in children receiving HCBS, when developing and implementing their incident management systems and policies and procedures to meet the proposed requirements. We discuss requirements for data and information sharing and electronic systems in more detail below in this section II.B.3. of the rule.

Comment: Several commenters provided feedback about the inclusion of medication errors resulting in a telephone call to or a consultation with a poison control center in the

proposed critical incident definition at § 441.302(a)(6)(i)(A)(5). One commenter expressed support for the reporting of a medication error resulting in a telephone call to or a consultation with a poison control center, and agreed they should be reported by the provider to the State. Another commenter expressed that beneficiaries receiving HCBS are encouraged to be independent and have the right to self-determination, and completing investigations on medication errors could be infringing upon HCBS beneficiaries' self-determination. One commenter requested we consider that managed care plans do not typically receive member data from poison control centers unless they are contracted with the managed care plan to provide this notification, making it difficult to track incidents that result in a consultation with the poison control center unless this data is captured elsewhere in member claims data. One commenter expressed concern that including a medication error in the definition of critical incidents could be problematic since not all providers who serve HCBS beneficiaries are clinical staff who can render a professional clinical determination of medication error, which could result in medication errors being over or under reported and skew data reports.

Response: We plan to provide States with technical assistance to help address issues raised by providers in reporting any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services, including medication errors resulting in a telephone call to or a consultation with a poison control center. Because we also are finalizing § 441.302(a)(6)(i)(C) as described in II.B.3.d. of this rule, we confirm that States must require providers to report to them any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. As such, a provider would be expected to report a medication error resulting in a contact with a poison control center if the medication error occurred during the delivery of services or a result of the failure to deliver services. We believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm

during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving HCBS.

Comment: One commenter requested that CMS clarify that in addition to audio-only telephone, that the use of audio or video technology be made acceptable to satisfy the requirement proposed at §441.302(a)(6)(i)(A)(5) that the State adopt the minimum standard definition for critical incident for a medication error resulting in contact with a poison control center.

Response: We do not have the authority to define additional communication types or consultation methods for poison control centers. We decline to add “use of audio or video technology” to the requirement proposed at §441.302(a)(6)(i)(A)(5). We encourage States to collaborate with their State and local poison control centers to understand the types of consultation that are acceptable and make requests for additional communication types or consultation methods for poison control centers.

Comment: Several commenters responded to our solicitation to comment on whether the proposed critical incident definition at § 441.302(a)(6)(i)(A) should include other specific types of events or instances of serious harm to beneficiaries receiving HCBS, such as identity theft or fraud. Most commenters responding to the request for comment recommended that CMS not expand the critical incident definition to include identity theft or fraud, noting it could create duplication of existing investigative and reporting processes. Alternatively, a few commenters supported the inclusion of identity theft and fraud in the critical incident definition. One commenter recommended that CMS provide additional guidance on identity theft or fraud in the context of exploitation, including financial exploitation if added to the minimum critical incident definition. One commenter expressed concern with including identity theft or fraud in the proposed critical incident definition, except when the individual has been formally and legally judged incompetent to make relevant decisions.

Response: We agree with commenters that expanding the critical incident definition at § 441.302(a)(6)(i)(A) to include identity theft or fraud could create duplication of existing Federal investigative agencies and reporting processes. Therefore, we have not identified a compelling reason to add other types of incidents, such as identity theft or fraud, to the standardized minimum definition of critical incidents we proposed and are finalizing in this rule.

Comment: One commenter specifically responded to the request for comment soliciting whether the proposed critical incident definition at § 441.302(a)(6)(i)(A) includes any specific types of events or instances of harm that would lead to the overidentification of critical incidents. The commenter supported the proposed definition, noting it would not result in overidentification of critical incidents. This commenter noted that, although the events included in the critical incident definition they use are not the same as those in the proposed critical incident definition at § 441.302(a)(6)(i)(A), they believed that the proposed definition would not cause overidentification of critical incidents because their policies require any incident, not solely those that are defined, to be reported.

Response: We appreciate the support for our proposal.

After consideration of these public comments, we are finalizing § 441.302(a)(6)(i)(A) as proposed with the following minor modifications: a minor formatting modification at § 441.302(a)(6)(i)(A)(3) to correct an improper italicization; a minor technical modification at § 441.302(a)(6)(i)(A)(5) to correct missing punctuation; and a minor formatting modification to conclude § 441.302(a)(6)(i)(A)(6) with a semi-colon.

c. Electronic Critical Incident Systems (§ 441.302(a)(6)(i)(B))

At § 441.302(a)(6)(i)(B), we proposed that States must have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We also solicited comment on the burden associated with requiring States to have electronic critical incident systems and whether there is specific functionality, such as unique identifiers, that should be

required or encouraged for such systems. As part of our proposal, we also encouraged, but did not propose to require, States to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the Interoperability Standards Advisory (ISA).⁷¹

We received public comments on these proposals. Below is a summary of the public comments we received and our responses.

Comment: Several commenters supported the proposed requirements at § 441.302(a)(6)(i)(B), that a State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. A few commenters expressed concern about the impact of the proposed requirements on States that already have multiple incident management systems, including electronic systems, for different programs, administered by different operating agencies. Commenters requested that we allow States flexibility to design the electronic critical incident systems, which we proposed to require at § 441.302(a)(6)(i)(B), by taking into account existing State incident management systems and processes which fit their unique program and systems structures. A few commenters were especially concerned about the impact on States that already enable electronic collection of critical incidents and questioned whether a single incident management system is required to be implemented across all waivers and authorities, or whether a separate system can be implemented for each waiver or program. Commenters expressed concern about having to consolidate current incident management systems, designed based on State infrastructure, into a single electronic system.

Response: We acknowledge that some States currently have electronic incident management systems in place for HCBS, and it is not our intent for States to abandon these systems. We encourage States to build upon existing incident management system infrastructure

⁷¹ Relevant standards adopted by HHS and identified in the ISA include the USCDI (<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>), eLTSS (<https://www.healthit.gov/isa/documenting-care-plans-person-centered-services>), and Functional Assessment Standardized Items (<https://www.healthit.gov/isa/representing-patient-functional-status-and-or-disability>).

and protocols to meet the electronic critical incident systems requirements we proposed at § 441.302(a)(6)(i)(B) and are finalizing in this rule.

We believe that a single electronic critical incident system may best enable the State to prevent the occurrence of critical incidents and protect the health and safety of beneficiaries across their lifespan. For example, in the absence of a single electronic critical incident system, States may have more difficulty developing and implementing a comprehensive plan to address and resolve critical incidents across HCBS programs and authorities. A single electronic incident management system could also better enable the State to track critical incidents for providers that deliver services in multiple HCBS programs or under different HCBS authorities, identify systemic causes of critical incidents, or detect patterns of preventable critical incidents and, in turn, implement strategies to more effectively prevent critical incidents.

We assume that some States may need to make at least some changes to their existing systems to fully comply with the requirements at § 441.302(a)(6)(i)(B). We have attempted to provide the State with as much flexibility as possible in the design of their incident management system. As such, the State may opt to maintain multiple systems that comply with the requirements at § 441.302(a)(6).

We encourage each State to consider developing a single electronic critical incident system for all of their HCBS programs under section 1915(c), (i), (j), and (k) authorities.

However, if a State chooses to implement multiple systems, we strongly encourage the State to share data among those systems to enable the development and implementation of a comprehensive plan to address and resolve critical incidents for HCBS beneficiaries and track and trend incidents for specific providers. We note that the State is responsible for ensuring compliance with the requirements of applicable Federal or State laws and regulations governing confidentiality, privacy, and security of certain information and records.

Comment: Several commenters recommended that CMS consider providing additional funding opportunities to assist States in the development and implementation of electronic critical incident systems we proposed to require at § 441.302(a)(6)(i)(B).

Response: As noted in the proposed rule (88 FR 27979), in Medicaid, enhanced Federal financial participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.⁷² Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.⁷³ However, we reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.⁷⁴

Comment: A few commenters supported CMS encouraging States to advance the interoperable exchange of HCBS data by adopting standards in the Interoperability Standards Advisory (ISA), and requested we further promote, support, and incentivize the development of better interoperability infrastructure to facilitate more seamless data sharing between States, providers, and managed care plans.

Response: While we did not propose any specific requirements related to interoperability for the electronic incident management system, States should ensure the advancement of the interoperable exchange of HCBS data, to further improve the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries to support quality improvement activities that can help promote the health and safety of HCBS beneficiaries. We clarify that, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health

⁷² See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

⁷³ See section 1903(a)(3)(B) and § 433.15(b)(4).

⁷⁴ See § 433.112 (b), 80 FR 75841; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C>.

information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the Interoperability Standards Advisory (ISA)⁷⁵ to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities that can help promote the health and safety of HCBS beneficiaries.

Comment: A few commenters recommended CMS not require States to include additional specific functionalities, including unique identifiers.

Response: We agree with commenters to not require or encourage a specific functionality, such as unique identifiers.

After consideration of public comments received, we are finalizing our proposal to require at § 441.302(a)(6)(i)(B) that States use an information system, meeting certain requirements, for electronic data collection, tracking, and trending of critical incident data, as proposed, with minor modifications. We are finalizing § 441.302(a)(6)(i)(B) with the addition of the word “enables” and striking “enables” from § 441.302(a)(6)(i)(B)(1) so that it applies to all paragraphs in § 441.302(a)(6)(i)(B). We are finalizing minor formatting changes to conclude paragraphs (a)(6)(i)(B)(2) and (3) with semi-colons.

d. Provider Critical Incident Reporting – During Delivery of or Failure to Deliver Services (§ 441.302(a)(6)(i)(C))

At § 441.302(a)(6)(i)(C), we proposed that States must require providers to report to the State any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant’s person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. We believe that this

⁷⁵ Relevant standards adopted by HHS and identified in the ISA include the USCDI (<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>), eLTSS (<https://www.healthit.gov/isa/documenting-care-plans-person-centered-services>), and Functional Assessment Standardized Items (<https://www.healthit.gov/isa/representing-patient-functional-status-and-or-disability>).

proposed requirement will help to specify provider expectations for reporting critical incidents and to ensure that harm that occurs because of the failure to deliver services will be appropriately identified as a critical incident.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the requirement we proposed at § 441.302(a)(6)(i)(C) that a State must require providers to report to the State any critical incidents that occur during the delivery of services as specified in a beneficiary's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. One commenter expressed that requiring providers to report on any critical incidents that occur during service delivery, or as a result of the failure to deliver authorized services, encourages better, more transparent reporting and provides a more accurate reflection of the prevalence and types of critical incidents occurring in HCBS delivery. Another commenter noted missed or delayed services, especially a pattern of missed or delayed service appointments, can lead to poor health outcomes for beneficiaries.

Response: We appreciate the expressions of support for our proposal.

Comment: A few commenters raised concerns with the requirement we proposed at § 441.302(a)(6)(i)(C) that States require providers to report to them any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or as a result of the failure to deliver services authorized under a section 1915(c) waiver program and as specified in the waiver participant's person-centered service plan. One commenter expressed that this requirement would require reviewers of critical incidents to draw conclusions about the service provider's role, without taking into account a beneficiary's right to privacy, decision making, personal preferences, and autonomy, especially for beneficiaries who live in their own home and/or receive care from different providers. Another commenter expressed concern that, even after a thorough

investigation, it is often impossible to definitively substantiate certain allegations of abuse or neglect or determine whether a negative outcome, such as a hospitalization, was the direct result of a critical incident that occurred during the delivery of services or as a result of the failure to deliver services as authorized. A commenter expressed concern that the requirement for providers to report to States any critical incidents that are a result of the failure to deliver authorized services is too broad and could cause critical incident reporting to be ineffective and inconsistent.

Response: We proposed requirements for States regarding the reporting of critical incidents by providers that we believe are important for identifying and addressing incidents of abuse, neglect, exploitation, or other harms that occur during the course of service delivery or as a result of the failure to deliver services. We note that the reporting of a critical incident does not necessarily mean that an action should be taken by the State in response to the critical incident. Further, even if no action is warranted or it is not possible to substantiate an allegation of abuse or neglect, it is still important to have the critical incident reported, and investigation conducted if appropriate, in case, for instance, a pattern later emerges that indicates systemic causes of critical incidents or that warrants action by the State.

Comment: A few commenters suggested we modify § 441.302(a)(6) to specify that critical incident records be collected in accordance with applicable privacy laws, such as HIPAA and its implementing regulations.

Response: In consideration of public comments received, we have not identified a compelling reason, and therefore decline, to add a reference to specific privacy laws to the requirements at § 441.302(a)(6). We note that States have existing obligations to comply with applicable Federal and State laws and regulations governing confidentiality, privacy, and security of information, records, and data obtained and maintained in a critical incident system. We note that this regulatory requirement does not modify these obligations to comply with applicable laws.

Comment: One commenter suggested we require States to accept critical incident reports, and acknowledge receipt of the report, directly from beneficiaries or other interested parties, establish a process to accept such reports, and allow reports to be made orally or in writing. The commenter recommended that we should require that punitive action is neither threatened nor taken against any individual who makes a report in good faith.

Response: We decline to modify our proposal to broaden the requirements related to critical incidents we proposed at § 441.302(a)(6)(i)(C) in this final rule. Although we proposed to only require providers to report critical incidents at § 441.301(a)(6)(i)(C), the State is not precluded from accepting the reporting of critical incidents from others, who are not providers, including beneficiaries or other interested parties. We believe that our proposal that the State assure a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery, or as a result of the failure to deliver services, is in the best interest of, and necessary for, protecting the health and welfare of beneficiaries receiving HCBS in section 1915(c) waiver programs and under section 1915(i), (j) and (k) State plan services.

We encourage States to include in their policies and procedures that beneficiaries would not be prohibited from reporting critical incidents and, in doing so, would be free from any punitive action when reporting a critical incident to the State. We have provided States with flexibility to establish their own policies and procedures related to addressing punitive actions against beneficiaries involved in the critical incident process.

After consideration of these public comments, we are finalizing our proposal at § 441.302(a)(6)(i)(C) with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the

beneficiary's (instead of waiver participant's) person-centered service plan. (New language identified in bold.) We are also finalizing § 441.302(a)(6)(i)(C) with minor formatting changes to conclude § 441.302(a)(6)(i)(C) with a semi-colon.

e. Data Sources to Identify Unreported Critical Incidents (§ 441.302(a)(6)(i)(D))

At § 441.302(a)(6)(i)(D), we proposed to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. We believe that such data can play an important role in identifying serious instances of harm to waiver program participants, which may be unreported by a provider, such as a death that occurs as a result of choking of an individual with a developmental disability residing in a group home, or a burn that occurs because a provider failed to appropriately supervise someone with dementia and that results in an emergency department visit.

We solicited comment on whether States should be required to use these data sources to identify unreported critical incidents, and whether there are other specific data sources that States should be required to use to identify unreported critical incidents.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal at § 441.302(a)(6)(i)(D). One commenter noted that these data sources could help establish pathways at the beneficiary and systems levels for reporting, tracking, and addressing issues with person-centered planning and provider noncompliance, and they will also advance efforts to ensure States' ongoing compliance with the HCBS Settings Rule. Another commenter approved of the requirement that States use data sources to identify unreported critical incidents, including claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult

Protective Services or Child Protective Services to the extent permissible under applicable State law, expressing that implementation of this requirement could result in a more accurate reflection of the prevalence and types of critical incidents occurring in HCBS delivery, in working with managed care plans and providers.

Response: We appreciate the support for our proposal.

Comment: Two commenters requested that collaboration with police and law enforcement be included in the data sources under § 441.302(a)(6)(i)(D). One commenter noted CMS should require providers to report to law enforcement in a timely manner any reasonable suspicion of a crime committed against a beneficiary receiving HCBS. Another commenter recommended CMS require providers to report suspicion of a crime to law enforcement. A commenter also questioned whether an investigative agency includes law enforcement. Additionally, a few commenters also recommended that collaboration with the designated Protection & Advocacy (P&A) system for the State be included in the data sources under § 441.302(a)(6)(i)(D), citing that P&A systems have the authority to investigate incidents of abuse and neglect of individuals with developmental disabilities if the incidents are reported to the system or if there is probable cause to believe that the incidents occurred.

Response: While we intend that § 441.302(a)(6)(i)(D) establishes the minimum requirements for States to use certain data sources to detect unreported critical incidents, States retain flexibility to use additional data sources, such as police and law enforcement data and P&A systems, to identify critical incidents that are unreported by providers. However, we decline to include additional data sources in the regulation at this time. We are concerned that it would be difficult for States to use non-Medicaid data sources, such as data from P&A systems and law enforcement records, to effectively identify unreported critical incidents for Medicaid beneficiaries and that such requirements would be administratively and operationally burdensome for States to implement. At § 441.302(a)(6)(i)(D), we proposed to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies to

the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, identifying Adult Protective Services or Child Protective Services as examples of State agencies. We encourage the State to include additional State agency data sources to detect unreported critical incidents as defined at § 441.302(a)(6)(i)(D) as appropriate.

Comment: A couple commenters stated that CMS should direct States to take definitive enforcement actions to address provider compliance with the incident management requirements. One commenter proposed to penalize HCBS providers that do not timely report critical incidents by imposing monetary penalties or suspension from the Medicaid program. Another commenter recommended that we allow States to implement an escalation of remedies to address provider reporting, up to and including a separate investigation with sanctions, if necessary.

Response: We reiterate that States already have broad authority to create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program.

After consideration of public comments we received, we are finalizing our proposal at § 441.302(a)(6)(i)(D), with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the **beneficiary's** (instead of waiver participant's) person-centered service plan. (New language identified in bold.) We are also finalizing § 441.302(a)(6)(i)(D) with minor formatting changes to conclude § 441.302(a)(6)(i)(D) with a semi-colon.

f. Critical Incident Data Sharing (§ 441.302(a)(6)(i)(E))

At § 441.302(a)(6)(i)(E), we proposed States share information, consistent with the regulations in 42 CFR part 431, subpart F on the status and resolution of investigations. We set the expectation that data sharing could be accomplished through the use of information sharing agreements with other entities in the State responsible for investigating critical incidents if the State refers critical incidents to other entities for investigation.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended CMS provide technical assistance related to the data sharing requirements. Commenters noted data sharing barriers in and between the State, agencies, and divisions within in the same agency, influencing successful implementation of the proposed requirements at § 441.302(a)(6)(i)(G).

Response: We appreciate these comments identifying the need for technical assistance related to data and information sharing agreements. We will take this feedback into consideration when developing resources for States on the incident management system requirements.

Further, we generally note that the State is responsible for ensuring its critical incident system(s) comply with all applicable Federal and State laws and regulations governing confidentiality, privacy, and security of records obtained, maintained, and disclosed via this incident management system.

After consideration of public comments, we are finalizing the proposed § 441.302(a)(6)(i)(E) as proposed, with a minor technical modification to clarify that mention of critical incident in § 441.302(a)(6)(i)(E) refers to critical incidents as defined in paragraph (a)(6)(i)(A) of this section (meaning § 441.302).

g. Separate Investigation of Critical Incidents (§ 441.302(a)(6)(i)(F))

At § 441.302(a)(6)(i)(F), we proposed to require the State be required to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. These proposed requirements are intended to

ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents, particularly where there could be evidence of serious harm or a pattern of harm to a section 1915(c) waiver program participant for which a provider is responsible.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed serious concerns about the requirements we proposed at § 441.302(a)(6)(i)(F), that the State is required to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. Commenters recognized the importance of cross-agency collaboration but identified that the timeframes for investigations by investigative agencies, such as Adult Protective Services and Child Protective Services, can be prolonged. Further, opening a separate concurrent investigation at the State level, if the investigative agency fails to report the resolution of an investigation within State-specified timelines, could compromise the integrity of both investigations. Some commenters questioned the feasibility of the requirements at § 441.302(a)(6)(i)(F) due to State statutory provisions around investigative agency responsibilities and allowable data sharing.

Response: These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State Medicaid agency's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents to protect the health and welfare of HCBS beneficiaries. We believe that requiring the State to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes will strengthen the ability of the State Medicaid agency to act quickly and/or separately if investigations by Adult Protective Services, Child Protective

Services, or other State agencies are taking longer to address and resolve. Further, it will ensure that the State has the information it needs to take action to protect beneficiary health and safety if a provider is responsible (intentionally or unintentionally) for causing harm to beneficiaries or putting beneficiaries at risk of harm. Additionally, we note that the State Medicaid agency may have the authority to take certain actions against the provider (such as suspend their Medicaid enrollment) that other State agencies, such as Adult Protective Services or Child Protective Services, are unable to take.

We have provided States with flexibility to establish State-specified timelines to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation and encourage States to take into account specific nuances that may impact the timelines.

After consideration of public comments, we are finalizing the proposed § 441.302(a)(6)(i)(F) as proposed.

h. Reporting (§§ 441.302(a)(6)(i)(G) and 441.302(a)(6)(ii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at section 1902(a)(6) of the Act, we proposed to modernize the health and welfare reporting by requiring all States to report on the same Federally prescribed quality measures as opposed to the State-developed measures, which naturally vary State by State. Specifically, at § 441.302(a)(6)(i)(G), we proposed to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We discuss these reporting requirements in our discussion of proposed § 441.311(b)(1). Further, under our authority at sections 1915(c)(2)(A) and 1902(a)(19) of the Act, we proposed to codify a minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6). Specifically, at § 441.302(a)(6)(ii), we

proposed to require that States demonstrate that: an investigation was initiated, within State-specified timeframes, for no less than 90 percent of critical incidents; an investigation was completed and the resolution of the investigation was determined, within State-specified timeframes, for no less than 90 percent of critical incidents; and corrective action was completed, within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action. This minimum performance level strengthens health and welfare reporting requirements while taking into account that there may be legitimate reasons for delays in investigating and addressing critical incidents.

In the proposed rule (88 FR 27980), we considered whether to allow good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent. We opted not to propose good cause exceptions because the minimum 90 percent performance level accounts for various scenarios that might impact a State's ability to achieve these performance levels, and there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters expressed concern about implementing the performance levels at the 90 percent threshold at § 441.302(a)(6)(ii). Alternatively, one commenter recommended the performance level should instead be 100 percent to protect the health and welfare of HCBS beneficiaries, since the minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6) should gauge State performance by how efficiently they conduct critical incident investigations.

Response: We believe the performance levels at the 90 percent threshold sets a high, but achievable standard, for complying with the requirements at § 441.302(a)(6)(ii). Our intention in proposing minimum performance requirements at § 441.302(a)(6)(ii) was to provide a standard

by which we could oversee, and hold States accountable, for complying with the requirements for an incident management system that we are finalizing at § 441.302(a)(6). Further it, was intended to strengthen the critical incident requirements while also recognizing that there may be legitimate reasons why critical incident processes occasionally are not completed timely in all instances. However, it is our expectation that States make reasonable efforts to ensure every critical incident is investigated, resolved, and (if necessary) subject to corrective action within State-specified timeframes.

Comment: A few commenters suggested CMS include a good-cause exception to the incident management performance level for certain instances that fall outside of the specified performance standards for appropriate reasons, such as for resource challenges or when the investigating agency requests that the State refrain from contact due to an ongoing and active investigation. Alternatively, a few commenters supported the approach in the proposed rule to not allow good-cause exceptions to the incident management performance level, observing that the 90 percent minimum performance level already gives States leeway for unexpected occurrences.

Response: We reiterate our belief that the 90 percent minimum performance level sets a high, but achievable standard for States' incident management systems. We underscore that the minimum 90 percent performance level accounts for various scenarios that might impact the State's ability to achieve these performance levels, and there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. The 90 percent minimum performance level is intended to strengthen incident management system requirements. We also recognize that there may be legitimate reasons why incident management processes occasionally are not completed timely in all instances. We reiterate that our expectation is that States make reasonable efforts to ensure every critical incident is investigated, resolved, and (if necessary) subject to corrective action within State-specified timeframes.

After consideration of public comments, we are finalizing our proposals at §§ 441.302(a)(6)(i)(G) and 441.302(a)(6)(ii) as proposed.

i. Applicability Date

We proposed at § 441.302(a)(6)(iii) to provide States with 3 years to implement these requirements in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed concerns about the burden they believe will be associated with the proposed provision to implement the incident management requirements at § 441.302(a)(6) within 3 years following the effective date of the final rule. Commenters stated that implementation of the incident management requirements as proposed at § 441.302(a)(6)(i)(B) could require potential State statute and regulatory amendments, lead time for securing additional technology resources, and operational and workflow changes. Commenters requested CMS consider alternative effective dates for the incident management system ranging from 4 to 7 years, with the most frequent suggestions at 4 to 5 years to address these concerns.

Response: We believe that 3 years for States to comply with the requirements at § 441.302(a)(6) is realistic and achievable for most of the incident management provisions. However, we agree that the proposed 3-year implementation timeframe for States to comply with the electronic incident management requirements at § 441.302(a)(6)(i)(B) could create hardships for States. We agree that States and managed care plans may require a timeframe longer than 3 years to address funding needs, policy changes, IT procurements, and other systems changes,

necessary to implement an electronic incident management system as required at

§ 441.302(a)(6)(i)(B), which may necessitate 5 years.

After consideration of public comments, we are finalizing § 441.302(a)(6)(iii) with minor modifications to correct erroneous uses of the word “effective.” We are retitling the requirement at § 441.302(a)(6)(iii) as Applicability date (rather than Effective date). We are also modifying the applicability date to require that States must comply with the requirements in paragraph (a)(6) beginning 3 years from the effective date of this final rule, except for the requirement at paragraph (a)(6)(B) of this section, with which the State must comply beginning 5 years from the effective date of the final rule. In addition, we are making a technical correction to clarify that the applicability dates in § 441.302(a)(6)(iii) apply only to the requirements in § 441.302(a)(6). Additionally, we are also finalizing with modification the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy at § 441.302(a)(6)(iii).

j. Application to Other Authorities

At § 441.302(a)(6)(iii), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems. Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We proposed that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to

achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because of the importance of assuring health and welfare for other HCBS State plan options, we proposed to include the incident management requirements at § 441.302(a)(6) within the applicable regulatory sections, including section 1915(j), (k), and (i) State plan services at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v), respectively. We note that a conforming reference to § 441.745(b)(1)(i), although not discussed in preamble of the proposed rule, was included in the proposed rule (88 FR 28086); the reference supports the application of incident management requirements to section 1915(i) services. Consistent with our proposal for section 1915(c) waivers, we based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries. We believe the same arguments for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the requirements at § 441.302(a)(6)(iii), expressing that States must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both in FFS and managed care delivery systems, noting there is no meaningful difference between abuse, neglect, or exploitation perpetrated by a provider paid through a managed care plan or by a provider paid through a FFS delivery system. One commenter recommended we assist States in developing instructions for State incident management systems for work with Medicaid managed care plans and contracted providers in implementing the requirements in § 441.302(a)(6).

Response: We appreciate the support for our proposal. We will take this feedback into consideration when developing technical assistance and other resources for States on the incident management system requirements.

After consideration of public comments received, we are finalizing the proposal at § 441.302(a)(6)(iii) for HCBS delivered under both FFS and managed care delivery systems.

Comment: Several commenters supported the proposal to apply the incident management system requirements at § 441.302(a)(6) to sections 1915(i), (j) and (k) authorities. Commenters expressed that equally applicable requirements for States across waiver authorities can ensure better access, equity, quality, and reporting for HCBS beneficiaries.

Response: We appreciate the support for our proposal.

Comment: A few commenters responded to our request for comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care, home health, and case management services. Several commenters supported the proposal not to extend the incident management requirements at § 441.302(a)(6) to section 1905(a) services and expressed that applying these requirements to State plan benefits would pose critical challenges for State Medicaid and other operating agencies, due to varying levels of HCBS provided and different data reporting infrastructure States have for 1905(a) services. A few commenters recommended that CMS apply the incident management system requirements to mental health rehabilitative services delivered under section 1905(a) State plan authority. A couple of commenters suggested that mental health rehabilitative services are considered home- and community-based services under the broader definition enacted by Congress in the American Rescue Plan Act of 2021. They also indicated that many Medicaid beneficiaries with mental health disorders and disabilities receiving services under the section 1905(a) authority would benefit from the beneficiary protections afforded through the incident management system requirements at § 441.302(a)(6).

Response: At this time, we are not mandating inclusion of section 1905(a) services in the State requirements for incident management systems, due to the statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act. That said, we are not persuaded by the argument that including section 1905(a) services would simply be

too much work, as we do believe it is critical that Medicaid beneficiaries have protections for freedom from harm. We acknowledge that many beneficiaries, particularly those receiving mental health services, are served by section 1905(a) services, and encourage States to consider development of critical incident processes to address protections for beneficiaries from harm or events that place a beneficiary at risk of harm.

After consideration of public comments, we are finalizing application of the requirements at § 441.302(a)(6) to other HCBS program authorities within the applicable regulatory sections, including section 1915(j), (k), and (i) State plan services. We are finalizing the requirements at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v) and (b)(1)(i) as proposed, with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

k. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at §§ 441.302(a)(6), as follows:

- We are finalizing § 441.302(a)(6)(i)(A) as proposed with the following minor modifications: a minor formatting modification at § 441.302(a)(6)(i)(A)(3) to correct an improper italicization; a minor technical modification at § 441.302(a)(6)(i)(A)(5) to correct missing punctuation; and a minor formatting modification to conclude § 441.302(a)(6)(i)(A)(6) with a semi-colon.
- We are finalizing § 441.302(a)(6)(i)(B) as proposed with the following minor modifications: adding the word “Enables” to § 441.302(a)(6)(i)(B) and striking it from § 441.302(a)(6)(i)(B)(1); and minor formatting modifications to conclude § 441.302(a)(6)(i)(B)(2) and (3) with a semi-colon.
- We are finalizing the requirements at § 441.302(a)(6)(i)(C) with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of

the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan. We are also finalizing § 441.302(a)(6)(i)(C) with a minor formatting change so that it concludes with a semi-colon.

- We are finalizing the requirements at § 441.302(a)(6)(i)(D), with a modification to require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan. We are also finalizing § 441.302(a)(6)(i)(D) with a minor formatting change so that it concludes with a semi-colon.

- We are finalizing the requirement at § 441.302(a)(6)(i)(E) with a minor formatting modification to change a reference to § 441.302(a)(6)(i)(A) to paragraph (a)(6)(i)(A).

- We are finalizing the requirements at § 441.302(a)(6)(i)(F) and (G) and (a)(6)(ii) as proposed.

- We are finalizing the requirement at § 441.302(a)(6)(iii) with modifications to specify that States must comply with the requirements in paragraph (a)(6) beginning 3 years from the effective date of this final rule; except for the requirement at paragraph (a)(6)(B) of this section, with which the State must comply beginning 5 years after the date that is the effective date of this final rule; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 3 years from the effective date of this final rule, except for the requirement at paragraph (a)(6)(B) of this section, with which the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 5 years from the effective date of this final rule.

- We are finalizing the requirements at §§ 441.464(e), 441.570(e), and 441.745(a)(1)(v) and (b)(1)(i) with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

4. Reporting (§ 441.302(h))

As discussed earlier in section II.B.1. of this rule, section 2402(a)(3)(A) of the Affordable Care Act requires HHS to promulgate regulations to ensure that States develop HCBS systems that are designed to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. We also believe that standardizing reporting across HCBS authorities will streamline and simplify reporting for providers, improve States' and CMS's ability to assess HCBS quality and performance, and better enable States to improve the quality of HCBS programs through the availability of comparative data. Further, section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

To avoid duplicative or conflicting reporting requirements at § 441.302(h), we proposed to amend § 441.302(h) by removing the following language: “annually”; “The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on -”; and by removing paragraphs (1) and (2) under § 441.302(h). Further, we proposed to add “, including the data and information as required in § 441.311” at the end of the new amended text, “Assurance that the agency will provide CMS with information on the waiver's impact.” By making these changes, we proposed to consolidate reporting expectations in one new section at proposed § 441.311, described in section II.B.7. of the proposed rule, under our authority at section 1902(a)(6) of the Act and section 2402(a)(3)(A) of the Affordable Care Act. As noted

earlier in section II.B.1. of the proposed rule, this reporting will supersede existing reporting for section 1915(c) waivers and standardize reporting across section 1915 HCBS authorities.

We did not receive specific comments on this proposal.

We are finalizing our proposed amendment of § 441.302(h) as proposed.

We did receive comments on proposed § 441.311, described in section II.B.7. of this rule, which establishes a new Reporting Requirements section. Comments on this proposal and our responses are summarized in section II.B.7. of this final rule.

5. HCBS Payment Adequacy (§§ 441.302(k), 441.464(f), 441.570(f), 441.745(a)(1)(vi))

Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Access to most HCBS generally requires hands-on and in-person services to be delivered by direct care workers. Direct care workers are referred to by various names, such as direct support professionals, personal care attendants, and home health aides, within and across States. They perform a variety of roles, including nursing services, assistance with activities of daily living (such as mobility, personal hygiene, and eating) and instrumental activities of daily living (such as cooking, grocery shopping, and managing finances), behavioral supports, employment supports, and other services to promote community integration for older adults and people with disabilities. We discuss the definition of direct care workers in more detail below in the context of our proposed definition of direct care workers.

Direct care workers typically earn low wages and receive limited benefits^{76, 77, 78} contributing to a shortage of direct care workers and high rates of turnover in this workforce, which can limit access to and impact the quality of HCBS. Workforce shortages can also reduce the cost-effectiveness of services for State Medicaid agencies that take into account the actual cost of delivering services when determining Medicaid payment rates, such as by increasing the reliance on overtime and temporary staff, which have higher hourly costs than non-overtime wages paid to permanent staff. Further, an insufficient supply of HCBS providers can prevent individuals from transitioning from institutions to home and community-based settings and from receiving HCBS that can prevent institutionalization. HCBS is, on average, less costly than institutional services,^{79, 80} and most older adults and people with disabilities prefer to live in the community. Accordingly, limits on the availability of HCBS lessen the ability for State Medicaid programs to deliver LTSS in a cost-effective, beneficiary friendly manner.

Shortages of direct care workers and high rates of turnover also reduce the quality of HCBS. For instance, workforce shortages can prevent individuals from receiving needed services and, in turn, lead to poorer outcomes for people who need HCBS. Insufficient staffing can also make it difficult for providers to achieve quality standards.⁸¹ High rates of turnover can reduce quality of care,⁸² including through the loss of experienced and qualified workers and by

⁷⁶ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

⁷⁷ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

⁷⁸ We recognize that there are workforce shortages that may impact access to other Medicaid-covered services aside from HCBS. We are focusing in this rule on addressing workforce shortages in HCBS and continue to assess the feasibility and potential impact of other actions to address workforce shortages in other parts of the health care sector.

⁷⁹ Reaves, E.L., & Musumeci, M.B. December 15, 2015. *Medicaid and Long-Term Services and Supports: A Primer*. Kaiser Family Foundation. Accessed at <https://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/>.

⁸⁰ Kim, M-Y, Weizenegger, E., & Wysocki, A. July 22, 2022. *Medicaid Beneficiaries Who Use Long-Term Services and Supports: 2019*. Chicago, IL: Mathematica. Accessed at <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/lts-user-brief-2019.pdf>.

⁸¹ American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

⁸² Newcomer R , Kang T , Faucett J . Consumer-directed personal care: comparing aged and non-aged adult recipient health-related outcomes among those with paid family versus non-relative providers. *Home Health Care Serv Q*. 2011;30(4):178– 97.

reducing continuity of care for people receiving HCBS,⁸³ which is associated with the reduced likelihood of improvement in function among people receiving home health aide services.⁸⁴

While workforce shortages have existed for years, the COVID-19 pandemic exacerbated the problem, leading to higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID-19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in retail and other jobs that tend to draw from the same pool of workers.^{85, 86, 87} Further, demand for direct care workers is expected to continue rising due to the growing needs of the aging population, the changing ability of aging caregivers to provide supports, the increased provision of services in the most integrated community setting rather than institutional services, and a decline in the number of younger workers available to provide services.^{88, 89, 90}

Section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide coordination for and support each person's full engagement in community life, and achieve a more consistent and coordinated approach to the

⁸³ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

⁸⁴ Russell D, Rosati RJ, Peng TR, Barrón Y, Andreopoulos E. Continuity in the provider of home health aide services and the likelihood of patient improvement in activities of daily living. *Home Health Care Manage Pract.* 2013;25(1):6–12.

⁸⁵ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

⁸⁶ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

⁸⁷ American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

⁸⁸ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

⁸⁹ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

⁹⁰ Centers for Medicare & Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at <https://www.medicare.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf>.

administration of policies and procedures across public programs providing HCBS.⁹¹ In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS, while section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure a sufficient number of qualified direct care workers to provide self-directed personal assistance services. To comply with sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, and, specifically, a sufficient number of qualified direct care workers to provide self-directed personal assistance services. We proposed requirements across section 1915(c), (i), (j) and (k) HCBS programs to further this outcome.

a. Assurance of Sufficient Rates (§ 441.302(k))

Consistent with section 1902(a)(30)(A) of the Act and sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, we proposed to require at § 441.302(k) that State Medicaid agencies provide assurance that payment rates for certain HCBS authorized under section 1915(c) of the Act are sufficient to ensure a sufficient direct care workforce (defined and explained later in this section of the rule) to meet the needs of beneficiaries and provide access to services in accordance with the amount, duration, and scope specified in the person-centered service plan, as required under § 441.301(c)(2). We believe that this proposed requirement supports the economy, efficiency, and quality of HCBS authorized under section 1915(c) of the Act, by ensuring that a sufficient portion of State FFS and managed care payments for HCBS go directly to compensation of the direct care workforce.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

⁹¹ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at <https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf>.

Comment: A significant number of commenters raised the issue of State Medicaid rates for homemaker, home health aide, and personal care services. Many commenters suggested that requiring that a sufficient portion, or even requiring a specific percent, of Medicaid payments be spent on compensation for direct care workers will not address rate sufficiency, which they regard as the underlying cause of low wages for direct care workers. Even commenters who were supportive of § 441.302(k) generally or the proposed minimum performance level at § 441.302(k)(3) (discussed further below) acknowledged that the policies may be more successful if they coincided with rate increases to ensure that providers' service operations remain fully supported. Many commenters recommended that as an alternative to (or in addition to) this proposal, we create requirements that States regularly review and update or increase their rates.

Several commenters were concerned that wages for direct care workers will not increase if the underlying Medicaid payment rates for the services remain low and are not increased. However, one commenter suggested that if a State's Medicaid rates are low, this places even greater importance on ensuring that as much of the rate as possible is going to compensation for direct care workers.

A few commenters expressed the belief that the accountability and transparency created by the proposal, in addition to the associated reporting requirement we proposed at § 441.311(e) (discussed further in section II.B.7. of this rule), would encourage providers to pass more of their Medicaid payments along to direct care worker wages. A few commenters offered anecdotal observations that, when their State allocated additional funds to HCBS providers, the commenters believed the increased funding was not passed along to direct care worker wages. One commenter noted that a permanent payment adequacy requirement is preferable to the temporary pass-through policies that have been enacted for one-time rate increases, because a permanent requirement would not be dependent on rate increases.

Response: While section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate-setting methodologies, section 1902(a)(30)(A) of the Act does provide us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. We did not propose to establish, and are not finalizing, specific payment rates for HCBS under the Medicaid program. Instead, we reiterate that under section 1902(a)(30)(A) of the Act payments must be sufficient to recruit and retain enough providers to ensure care and services are available to beneficiaries; we proposed to implement this requirement by specifying a percentage of Medicaid payments be spent on compensation to direct care workers. We believe this policy will also promote, and be consistent with, economy, efficiency, and quality of care.

Broadly speaking, we also do not believe that simply increasing rates alone, without setting guardrails for how the payments are allocated, would ensure that direct care workers' wages will increase. Rather, we agree with commenters who believed that, regardless of the underlying Medicaid rate, requiring a certain amount of Medicaid payments be spent on compensation will help ensure that Medicaid payments are distributed in a way that supports direct care workers, including their recruitment and retention, to the greatest extent possible. While we did not propose, and are not finalizing, a requirement that State Medicaid agencies increase their rates, we anticipate that States will examine their rates to assure they are sufficient to support the direct care workforce to comply with the policy we proposed and are finalizing with modifications, as discussed further herein. We also direct commenters to the proposals discussed in section II.C. of this final rule, which includes a number of provisions related to rate transparency that are intended to support FFS rate sufficiency.

Comment: One commenter recommended that we revise § 441.302(k) to specify that rates must be sufficient to ensure a sufficient number of providers, including members of the

direct care workforce. The commenter stated that this revision would match the broader term “provider” in section 1902(a)(30)(A) of the Act while highlighting the importance of the direct care workforce.

Response: We appreciate the commenter’s feedback, but we decline to make the recommended revision. At this time, we want to make the focus of the requirement explicitly on the individuals who are part of the direct care workforce, whether they act as individual providers (such as by working as an independent contractor), are employed by a provider entity, or otherwise. We agree with the commenter that section 1902(a)(30)(A) of the Act requires that Medicaid payments must be sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent that such care and services are available to the general population in the geographic area. We note that section 1902(a)(30)(A) of the Act also requires that States assure that payments are consistent with efficiency, economy, and quality of care. We agree that enrolling sufficient numbers of providers is critical to Medicaid service delivery, and that providers in turn may not be able to deliver services if they do not have a sufficient number of direct care workers. As noted in a previous response, we proposed to implement these requirements by specifying a percentage of Medicaid payments be spent on compensation to direct care workers. We believe this policy will promote, and be consistent with, economy, efficiency, and quality of care, as required by statute at section 1902(a)(3)(A) of the Act.

Comment: One commenter requested clarification on whether the payment adequacy requirement applies only to the voluntary, nonprofit sector or whether it also applies to State-operated services.

Response: Given the varied nature of HCBS programs, we specifically proposed for the payment adequacy requirement to apply broadly to compensation paid to direct care workers by providers receiving payments for furnishing homemaker, home health aide, or personal care services from the State; we did not propose to apply these requirements to only certain types of

providers or their ownership arrangements. We specifically proposed at § 441.302(k)(1)(ii)(G) (which we are finalizing at § 441.302(k)(1)(ii) as discussed later in this section) that a direct care worker, to whom this requirement would apply, may be employed by or contracted with a Medicaid provider, State agency, or third party or delivering services under a self-directed service model. The requirements we proposed, and are finalizing in this section II.B.5, under § 441.302(k) require States to assure that payment rates are adequate to ensure a sufficient direct care workforce by, in turn, ensuring that providers spend a certain percentage of their total payments for certain HCBS on compensation for direct care workers furnishing those HCBS.

After consideration of the comments received, we are finalizing the assurance requirement at § 441.302(k) with modifications as discussed in this section II.B.5 of this final rule. We are finalizing the language we proposed in the introductory paragraph at § 441.302(k) with technical modifications so that it is clear that the reference to person-centered service plans is to beneficiaries' person-centered service plans. The finalized language at § 441.302(k) will read: *HCBS payment adequacy*. Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans.

b. Minimum Performance Requirement and Flexibilities (§ 441.302(k)(2), (3), (4), (5), and (6))

Our proposal at § 441.302(k)(2) and (3) was designed to affect the inextricable link between sufficient payments being received by the direct care workforce and access to and, ultimately, the quality of HCBS received by Medicaid beneficiaries. We believe that this proposed requirement would not only benefit direct care workers but also individuals receiving Medicaid HCBS because supporting and stabilizing the direct care workforce will result in better qualified employees, lower turnover, and a higher quality of care. The direct care workforce must be able to attract and retain qualified workers in order for beneficiaries to access providers of the services they have been assessed to need and for the direct care workforce to be comprised of workers with the training, expertise, and experience to meet the diverse and often complex

HCBS needs of individuals with disabilities and older adults. Without access to a sufficient pool of direct care workers, individuals are forced to forgo having their needs met, or have them addressed by workers without sufficient training, expertise, or experience to meet their unique needs, both of which could lead to worsening health and quality of life outcomes, loss of independence, and institutionalization.^{92,93,94,95} Further, we believe that ensuring adherence to a Federal standard of the percentage of Medicaid payments going to direct care workers is a concrete step in recruitment and retention efforts to stabilize this workforce by enhancing salary competitiveness in the labor market. In the absence of such requirements, we may be unable to support and stabilize the direct care workforce because we would not be able to ensure that the payments are used primarily and substantially to pay for care and services provided by direct care workers. Therefore, at § 441.302(k)(3)(i), we proposed to require that at least 80 percent of all Medicaid payments, including but not limited to base payments and supplemental payments, with respect to the following services be spent on compensation to direct care workers: homemaker services, home health aide services, and personal care services.⁹⁶

While many States have already voluntarily established such minimums for payments authorized under section 1915(c) of the Act,⁹⁷ we believe a Federal standard would support ongoing access to, and quality and efficiency of, HCBS. Our proposal was based on feedback

⁹² MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

⁹³ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

⁹⁴ American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

⁹⁵ Chong, N., I. Akorbirshoev, J. Caldwell, H.S. Kaye, and M. Mitra. 2021. The relationship between unmet need for home and community-based services and health and community living outcomes. Disability Health Journal. Accessed at <https://www.sciencedirect.com/science/article/abs/pii/S1936657421001953>.

⁹⁶ We note that section 2402(a) of the Affordable Care Act applies broadly to all HCBS programs and services funded by HHS. Further, section 2402(a) does not include limits on the scope of services, HCBS authorities, or other factors related to its use of the term HCBS. Therefore, we believe that there is no indication that personal care, homemaker, and home health aide services would fall outside the scope of section 2402(a).

⁹⁷ For instance, as part of their required activities to enhance, expand, or strengthen HCBS under ARP section 9817, some States have required that a minimum percentage of rate increases and supplemental payments go to the direct care workforce. See <https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html> for more information on ARP section 9817. See <https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html> for more information on ARP section 9817.

from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP⁹⁸ or other State-led initiatives. We refer readers to our proposed rule for more specific discussion of the feedback we received from States regarding their implementation of similar requirements (88 FR 27984).

We focused our proposed requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers. These services are comprised of individualized supports for Medicaid beneficiaries delivered by direct care workers and generally have low equipment or supply costs relative to other services. Further, these are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We requested comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for homemaker services, home health aide services, and personal care services: (1) 75 percent; (2) 85 percent; and (3) 90 percent. If an alternate minimum percentage was recommended, we requested that commenters provide the rationale for that minimum percentage.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Many commenters (regardless of whether they supported the overall proposal itself) applauded our acknowledgement of, and efforts to address, HCBS workforce shortages, which many commenters characterized as a “crisis.” Many commenters appeared to agree that wages to direct care workers are generally low, and that these low wages contribute to overall workforce challenges. Both providers and beneficiaries submitted comments detailing struggles they have had in hiring and retaining qualified direct care workers. Some of these commenters

⁹⁸ Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on Medicaid.gov at <https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html>.

described the frustration of having to constantly recruit and train new direct care workers. Some commenters described having to turn away new clients due to staff shortages, and beneficiaries reported experiencing delays or reductions in their services due to difficulty in finding direct care workers to provide the services. Many direct care workers also submitted personal examples of the hardships caused by financial strain due to inadequate pay, including having to work long hours at multiple jobs to earn extra income, missing time with their own families, struggling to pay bills, risking exposure to (or contracting) COVID-19, and experiencing burnout and psychological stress. A few of these commenters indicated they had left the direct care workforce due to low wages.

Several commenters stated that the proposed minimum performance requirement, if finalized, would likely lead to increases in wages for direct care workers and strengthen the workforce, which in turn could improve the quality of HCBS. In particular, a number of commenters noted the potential for the proposal to have a positive impact on workers who are Black, other people of color, and women, who are disproportionately represented in the direct care workforce – groups that have historically experienced low wages due to discrimination.

Commenters were able to draw anecdotal connections between wages and worker retention. A few providers, for instance, noted that they had made efforts to increase their workers' wages, and observed that the increase in wages had a positive impact on their staff retention and the number of beneficiaries the providers were able to serve.

A few other commenters noted that there are other factors that may contribute to worker shortages, and recommended that we continue to partner with the Administration for Community Living and other Federal agencies to promote a comprehensive, integrated campaign that addresses multiple facets of the workforce shortage, including promotion of and improvement of social valuation of this work, support of workforce pipelines, changes to immigration policy, and creative strategies for atypical workforce development.

Response: We thank commenters for sharing their personal experiences and perspectives on how they have been affected by the direct care workforce shortage and the low wages paid to many direct care workers. We share the belief that this requirement will create a foundation of support for the direct care workforce, which we believe is fundamental to HCBS delivery. We focused in this proposal on compensation for direct care workers because, as we noted above and many commenters confirmed anecdotally, many direct care workers have been paid low wages for a long time.^{99,100} We recognize that other factors also play important roles in worker retention and shortages. While we will continue to partner with other Federal agencies to address these issues, some of the factors affecting the workforce lie outside of our regulatory purview and are outside of the scope of this proposal.

Comment: A significant number of commenters provided feedback on the idea of having a national minimum performance level (separate from providing comment on what the percentage should be). One commenter, representing several State agencies, supported the intent of the proposal and indicated that the proposed requirements could “improve recruitment, retention and economic security of the HCBS direct care workforce.” While offering cautions, the commenter indicated that many States generally support a single national minimum performance requirement, but they also recommended that we consider providing States with flexibility related to the requirement based on provider size, rural/urban status, and risk of closure.

Many commenters expressed concerns that a single national minimum performance level could fail to take into account various factors that might affect the percent of Medicaid payments that is spent on compensation for direct care workers including substantial differences among HCBS waiver programs, such as size, services, populations, service area, and staffing needs; State requirements for providers, such as differences in business operations requirements,

⁹⁹ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

¹⁰⁰ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America’s direct care workforce. Bronx, NY: PHI <http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf>.

licensure costs, staff training requirements, or whether States require providers to maintain physical office space; and local economic environments, including cost of living, taxes, and wage laws. Many commenters requested that we not finalize a minimum performance level, so that providers may be allowed flexibility to allocate their Medicaid payments as they determine to be appropriate. One commenter, while acknowledging a workforce crisis, noted that Area Agencies on Aging and provider organizations are taking steps to improve recruitment and retention and that a Federal mandate such as the 80 percent minimum performance level proposed in the rule is unnecessary, may have unintended consequences, and may complicate State and local efforts currently underway.

Response: After consideration of public comments as described in this section II.B.5 of this rule, we are finalizing a national minimum performance level in this final rule. We believe that not doing so would fail to help address the chronic shortages in the HCBS direct care workforce. In this context, the status quo amounts to minimal oversight over how much of the Medicaid payment is going to support the direct care workers who are performing the core activities of homemaker, home health aide, and personal care services. While some States have already implemented initiatives to ensure that a certain percentage of Medicaid payments or rate increases are going to direct care worker compensation, as noted above, we believe a Federal requirement is necessary and would be more effective to promote consistency and transparency nationwide.

We agree that there may be State or local circumstances that impact the percent of Medicaid payments that is spent on compensation for direct care workers. Where possible, we have built flexibilities into this requirement as discussed further in this section II.B.5 to ensure that it addresses certain differences among HCBS programs and providers. Specifically, as we discuss in detail later in this section, we are modifying the policy we proposed at § 441.302(k) by: (1) adding a definition of excluded costs at § 441.302(k)(1)(iii) to ensure certain costs are not included in the minimum performance level calculation of the percentage of Medicaid

payments to providers that is spent on compensation for direct care workers; (2) revising the definition of direct care worker proposed at § 441.301(k)(1)(ii) to clarify that clinical supervisors are included in the definition of direct care workers; (3) revising § 441.302(k)(3)(ii) to allow States to set a separate minimum performance level for small providers; (4) adding a new provision at § 441.302(k)(4) to provide an option for States to develop reasonable, objective criteria to identify small providers to meet a small provider minimum performance level set by the State; (5) adding a new provision at § 441.302(k)(5) to allow States to develop reasonable, objective criteria to exempt certain providers from meeting the minimum performance level requirement; and (6) adding a new provision at § 441.302(k)(7) to exempt the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements at § 441.302(k). The specific modifications and the rationale for these modifications are discussed in greater detail in this section II.B.5. of the final rule.

Further, we are modifying the policy we proposed at § 441.302(k) to require States to comply with this HCBS payment adequacy policy beginning 6 years after the effective date of this final rule, rather than the 4 years we proposed. (We discuss this modification to § 441.302(k)(4), being redesignated as § 441.302(k)(8), in section II.B.5.h., of this rule.) We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k).

Ultimately, while we agree that providers generally have flexibility to determine how to spend their Medicaid payments, we believe it is important to reiterate the parameters for payment rates required under section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that payment rates must be economic and efficient; they must not be so high as to be uneconomic or inefficient. This provision also requires payment rates to be consistent with quality of care and sufficient to enlist enough providers to ensure a specified level of access to services for beneficiaries; rates must not be so low as to impermissibly limit beneficiaries' access to care or the quality of care they receive. The Supreme Court in *Armstrong v. Exceptional*

Child Center, Inc., in considering this provision, recognized that Congress was “explicitly conferring enforcement of this judgment-laden standard upon the Secretary[,] . . . thereby achieving ‘the expertise, uniformity, widespread consultation, and resulting administrative guidance that can accompany agency decision-making.’”¹⁰¹ We believe that implementing this statutory requirement includes some degree of oversight into how providers are allocating the Medicaid payments that they receive for delivering HCBS to beneficiaries. For example, if providers are spending a high proportion of their Medicaid payments on compensation to direct care workers but beneficiaries have difficulty accessing services and quality is compromised due to an insufficient number of direct care workers, then the payment rate may be too low to satisfy section 1902(a)(30)(A). Conversely, if concerns about access to and quality of services were not present and providers were spending a low proportion of their Medicaid payments on compensation to direct care workers, then the Medicaid payment rate may exceed a level that is economic and efficient, contributing to overhead spending and/or operating margin at levels higher than needed to ensure access and quality.

Comment: While several commenters agreed that a national minimum performance level is authorized by section 1902(a)(30) of the Act, a few other commenters disagreed that this policy is authorized by section 1902(a)(30) of the Act. These latter commenters noted that section 1902(a)(30)(A) of the Act requires each State plan for medical assistance to provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. As such, these commenters contended that this statutory provision applies to State plans, not to CMS, and speaks to the adequacy of payments to Medicaid-enrolled healthcare providers, not the providers’ workforce. They stated

¹⁰¹ *Armstrong v. Exceptional Child Center, Inc.*, 575 U.S. 320, 328-29 (2015) (internal citations omitted).

that section 1902(a)(30)(A) of the Act cannot be read to delegate authority to us to prescribe specific wage pass-through requirements that States must impose upon providers.

Response: We believe that the statutes we cited support the components of our proposal. Regarding the applicability of section 1902(a)(30)(A) of the Act, we refer readers to our prior discussion of section 1902(a)(30)(A) of the Act in section II.B.5.a. of this rule. As we noted in that discussion, section 1902(a)(30)(A) of the Act provides us with authority to oversee that States assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. We did not propose to establish, and are not finalizing, specific payment rates. Instead, we proposed that States demonstrate that payments are sufficient to ensure care and services are available to beneficiaries by specifying a percentage of Medicaid payments that States must ensure is spent on compensation to direct care workers. We believe this policy will also promote, and be consistent with, economy, efficiency, and quality of care. We also disagree that section 1902(a)(30)(A) of the Act speaks only to provider enrollment. We believe that setting a performance level at which States support their State plan assurance that payments are consistent with efficiency, economy, and quality of care is an appropriate use of our oversight authority under section 1902(a)(30)(A) of the Act.

Comment: A few commenters agreed that sections 2402(a)(1) and 2402(a)(3) of the Affordable Care Act authorize the creation of a national minimum performance requirement to support the direct care workforce. However, a few commenters disagreed with this application of section 2402(a)(1) of the Affordable Care Act. These commenters noted that section 2402(a)(1) of the Affordable Care Act requires the Secretary of the Department of Health and Human Services (HHS) to promulgate regulations to ensure that all States develop service systems that are designed to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving non-institutionally-based long-term services and

supports and that provides strategies for beneficiaries receiving such services to maximize their independence, including through the use of client-employed providers. Commenters stated that, although this provision speaks to HHS's authority to promulgate regulations, those regulations must pertain to ensuring that States develop systems to appropriately allocate resources to the types of services their beneficiaries need. These commenters contended that section 2402 of the Affordable Care Act allows HHS to, for example, require States to assess whether they should provide services such as delivering healthy meals to certain populations or allow beneficiaries to hire a family member to assist them (and fund the wages), but it does not provide HHS the authority to require States to impose upon providers wage pass-through requirements that are set at a specific minimum performance level.

Response: We disagree with commenters' interpretation of section 2402(a)(1) of the Affordable Care Act. Section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS. As discussed throughout this section, one of the most fundamental ways that HCBS programs meet the needs of beneficiaries is by having a sufficient direct care workforce to provide the services beneficiaries have been assessed to need. Without an adequate supply of workers, beneficiaries may not be able to access all the services that they need and that fully reflect their choices or preferences. We believe that setting a benchmark that helps measure whether Medicaid payments are being allocated in a way that is responsive to the HCBS workforce shortage and supports essential aspects of HCBS delivery is an appropriate application of our authority under section 2402(a)(1) of the Affordable Care Act.

Comment: One commenter did not agree that section 2402(a)(3)(B)(iii) of the Affordable Care Act authorized the application of a minimum performance requirement. The commenter noted that section 2402(a)(3)(B)(iii) of the Affordable Care Act requires the Secretary of HHS to promulgate regulations to ensure that all States develop service systems that are designed to improve coordination among, and the regulation of, all providers of such services under

Federally and State- funded programs in order to oversee and monitor all service system functions to assure an adequate number of qualified direct care workers to provide self-directed personal assistance services. The commenter stated that this statutory provision both bestows authority upon HHS to promulgate regulations and specifically references the need to ensure an adequate number of direct care workers. However, the commenter noted that, like section 2402(a)(1) of the ACA, section 2402(a)(3)(B)(iii) specifies that HHS's role—and its authority to promulgate such regulations—is limited to ensuring that States develop service systems that assure an adequate number of qualified direct care workers to provide self-directed personal assistance services. The commenter also stated that this statutory provision applies only to the self-directed service delivery model and does not authorize HHS to promulgate wage pass-through requirements with respect to services delivered by provider agencies. The commenter stated, generally, that the Medicaid program's fundamental premise is to allow each State or Territory the ability to tailor its program to reflect its unique needs, and that this is at odds with a requirement for States to direct providers' behavior.

Response: We generally disagree with the commenter's analysis of section 2402(a)(3)(B)(iii) of the Affordable Care Act that it does not authorize the application of a minimum performance requirement. Section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure there is a sufficient number of qualified direct care workers to provide self-directed personal assistance services. We believe that, to comply with this statutory requirement, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries (regardless of delivery model), and, specifically, States must have a sufficient number of qualified direct care workers to provide self-directed personal assistance services. In other words, an insufficient direct care workforce generally will impact whether a State has a sufficient number of qualified direct care workers to provide self-directed personal assistance services in compliance with this requirement. However, we do agree that section

2402(a)(3)(B)(iii) of the Affordable Care Act speaks specifically to self-directed services. We cited this authority for the purposes of supporting our inclusion of self-directed services in this proposal.

As noted in prior responses, we believe that section 1902(a)(30)(A) of the Act and 2402(a)(1) of the Affordable Care Act authorize us to set parameters or benchmarks for HCBS expenditures (both including and in addition to expenditures for self-directed personal care services). Section 1902(a)(30)(A) of the Act provides us with authority to oversee that States assure that Medicaid payments for services are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area. Section 2402(a)(1) of the Affordable Care Act requires HHS to ensure States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS. States retain flexibility in how they construct their HCBS systems. Rather, we believe the minimum performance requirement we proposed, and are finalizing with modifications in this section II.B.5, sets a benchmark to help us determine whether States are ensuring that their HCBS systems are allocating sufficient resources to support the direct care workforce to ensure there are sufficient providers so that care and services are available to beneficiaries and that these services are consistent with efficiency, economy, and quality of care. We believe that setting such a benchmark that helps measure whether Medicaid payments are being allocated in a way that is responsive to the HCBS workforce shortage and supports essential aspects of HCBS delivery is an appropriate application of our authority under section 2402(a)(1) of the Affordable Care Act and applies to other HCBS in addition to the self-directed personal care services specifically addressed in section 2402(a)(iii)(B).

Comment: A number of commenters stated that we did not provide enough data to support the proposal for an 80 percent minimum performance level. One commenter suggested

that by not providing sufficient data to support the proposal, we have not fulfilled our obligations under the Administrative Procedure Act.

A number of commenters recommended we collect more data before finalizing a certain percent for the national minimum performance level. Some commenters suggested that a State-by-State analysis of rates and the potential impact of a minimum performance level would need to be performed before setting a minimum performance level. A few of these commenters suggested that helpful data could be collected from States' rate studies, HCBS waiver rates, provider cost reports, or the data we proposed in the proposed rule to be reported to us (including our proposals at § 441.311(e) and § 447.203, which we discuss in sections II.B.7. and II.C. of this rule, respectively). One commenter suggested using the electronic visit verification (EVV) system¹⁰² as a tool for gathering relevant data. Several commenters also suggested that any additional data collection performed to support a national minimum performance level be used to assess unintended consequences of such a level.

A few commenters questioned the specific data relied on for the proposal of an 80 percent minimum performance level. They noted concerns including:

- A lack of support for the claim in the proposed rule that some States have set wage pass-through requirements as high as 90 percent;
- Use of data on the American Rescue Plan Act of 2021 section 9817 funds by a few States to increase worker wages, which have only been relatively recently distributed, and thus reflect limited data;
- State wage pass-through requirements as part of their activities to enhance, expand, or strengthen HCBS under section 9817 the American Rescue Plan Act of 2021 were generally only applied to temporary rate increases, not entire rates; and

¹⁰² Section 12006 of the 21st Century Cures Act (Pub.L. 114-255) requires States to have EVV systems for Medicaid personal care services and home health care services.

- Minnesota and Illinois, two States that have wage pass-through requirements, have their requirements set at 72 percent and 77 percent, respectively, and both use different definitions of compensation or direct care worker than what was proposed.

Response: As discussed in the proposed rule (88 FR 27982), we based our proposal on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP¹⁰³ or other State-led initiatives. For example, as noted by commenters, Minnesota has established a minimum threshold of 72.5 percent,¹⁰⁴ while Illinois has implemented a minimum threshold of 77 percent, for similar requirements for HCBS payments as we proposed.¹⁰⁵ To further clarify the data that we used to inform our proposal, which was referenced in footnote 81 in the proposed rule (88 FR 27983 to 27984), we note the following examples of different types of States' wage pass-through requirements that States added to spending plans for ARP section 9817:

- Indiana announced a Direct Service Workforce Investment Grant in which 95 percent of the grant funds must be spent on direct service professionals.¹⁰⁶
- Massachusetts required that HCBS providers use 90 percent of a rate increase to support their direct care workers.¹⁰⁷
- North Carolina required that 80 percent of its rate increases for certain HCBS be spent on direct care worker wages.¹⁰⁸

¹⁰³ Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on Medicaid.gov at <https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html>.

¹⁰⁴ See <https://www.revisor.mn.gov/statutes/cite/256B.85/pdf> for more information.

¹⁰⁵ See <https://casetext.com/regulation/illinois-administrative-code/title-89-social-services/part-240-community-care-program/subpart-t-financial-reporting/section-2402040-minimum-direct-service-worker-costs-for-in-home-service> for more information.

¹⁰⁶ Indiana Family and Social Services Administration, "HCBS Enhanced FMAP Spending Plan: Direct Service Workforce Investment Grant Program," <https://www.in.gov/fssa/ompp/hcbs-enhanced-fmap-spending-plan/>

¹⁰⁷ Massachusetts Executive Office of Health and Human Services, "Strengthening Home and Community Based Services and Behavioral Health Services Using American Rescue Plan (ARP) Funding," <https://www.mass.gov/info-details/strengthening-home-and-community-based-services-and-behavioral-health-services-using-american-rescue-plan-arp-funding>.

¹⁰⁸ North Carolina Department of Health and Human Services, North Carolina "January 2023 Quarterly Report for the Implementation of the American Rescue Plan Act of 2021, Section 9817 – 10% FMAP Increase for HCBS" <https://medicaid.ncdhhs.gov/hcbs-spending-plan-narrative-january-2023/download?attachment>

- West Virginia set different wage pass-through requirements (ranging from 50 percent to 100 percent) for the amount of the rate increase that would be allocated to direct care workers providing services to beneficiaries in several of the State’s waiver programs.¹⁰⁹

We acknowledge that we are unable to present a State-by-State study of the impact of a specific minimum performance level on all State Medicaid programs and providers. The variability among HCBS programs (including staffing requirements, service definitions, and rate methodologies) poses challenges to performing and presenting a multi-State analysis of the allocation of Medicaid payments to direct care workers using existing available data, such as rate studies or cost reports. We also note that information from EVV system reporting would only pertain to use of personal care services or home health aide services (not homemaker services) and would not speak to rates. We agree that the reporting requirement we proposed, and are finalizing in this rule, at § 441.311(e) may generate standardized data that is more amenable to national comparisons.

We also believe that the reporting requirement at § 441.311(e) may yield important data that will support transparency around the portion of Medicaid payments being shared with direct care workers; such transparency in and of itself may well encourage States and providers to look critically at their rates and how they are allocated. Further, we believe that gathering and sharing data about the amount of Medicaid dollars that are going to the compensation of workers is a critical step in understanding the ways we can enact policies that support the direct care workforce and thereby help advance access to high quality care for Medicaid beneficiaries. However, we believe that a reporting requirement alone will not be as effective at stabilizing the direct care workforce.

We believe that compensation levels are a significant factor in the creation of a stable workforce, and that a stable workforce will result in better qualified employees, lower turnover,

¹⁰⁹ West Virginia Department of Health and Human Resources, “Spending Plan for Implementation of American Rescue Plan Act of 2021, Section 9817.”
<https://dhhr.wv.gov/bms/News/Documents/WV%20State%20ARP%20HCBS%20Spending%20Plan.pdf>

and safer and higher quality care. If individuals are attracted to the HCBS workforce and incentivized to remain employed in it with sufficient compensation, the workforce is more likely to be comprised of workers with the training, knowledge, and experience to meet the diverse and often complex needs of individuals with disabilities and older adults receiving HCBS. A stable and qualified workforce will also enable beneficiaries to access providers of the services they have been assessed to need. As noted in an earlier comment summary, commenters almost unanimously agreed that the direct care workforce shortage is posing extensive challenges to HCBS access and quality of care. We believe that setting a minimum performance requirement that we have determined to be reasonable based on available information (and is supported by many commenters) is an appropriate exercise of our responsibility to oversee the sufficiency of Medicaid payments under section 1902(a)(30)(A) of the Act and States' allocation of resources under section 2402(a) of the Affordable Care Act.

We agree that the data from States that implemented wage pass-throughs through activities in their ARP section 9817 spending plans is relatively recent. However, we do not believe that data should be disqualified simply because it was generated recently; such data is likelier to provide a more current snapshot of States' Medicaid rates and the needs of their direct care workforce.

We also agree that States applied wage pass-through requirements to rate increases that they were implementing as part of their ARP section 9817 spending plans and that at least some of these wage pass-through requirements were temporary. As such, these percentages might not be as relevant to the selection of a minimum performance level as a permanent wage pass-through requirement applied to the entire Medicaid rate. That said, we do believe that these data are useful for illustrating that the need to support direct care workers' wages is relevant across the country, and that States and interested parties have not only identified increases in wages for direct care workers as a priority, but they have also identified allocating specific portions of Medicaid rates as an appropriate mechanism for addressing low wages. We echo a comment

summarized earlier that the advantage of establishing a permanent minimum performance requirement is that it creates a stable support for the direct care workforce, rather than intermittent increases in compensation that are dependent on specific actions taken by State or Federal legislatures.

As observed by some commenters, the percent we proposed, at 80 percent, is slightly higher than the wage pass-through requirements set by Minnesota and Illinois. We believe that the 80 percent minimum performance level we are finalizing is informed by the current range of the wage pass-through requirements set by those States, but is set slightly higher to encourage further steps towards improving compensation for workers. We also note that we are not required to replicate precisely what certain States have done.

We continue to believe 80 percent is the feasible performance level to ensure that payments made for Medicaid HCBS are appropriately allocated to direct care workers' compensation to ensure sufficient providers for beneficiaries to access HCBS as approved in their person-centered plans. However, given that the 80 percent minimum performance is higher than what States have currently set in terms of permanent wage pass-through requirements, we will provide States with additional time to come into compliance with the 80 percent performance level. We are finalizing at § 441.302(k)(8) a modification to the applicability date for § 441.302(k) to indicate that States must comply with this requirement at § 441.302(k) beginning 6 years after the effective date of this rule, rather than 4 years as proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k). As discussed in greater detail below, we are also finalizing additional flexibilities that States, at their option, may utilize to apply a different percentage for small providers and exempt certain providers that experience hardships from the State's calculation for meeting these performance levels. We also describe below an exemption of the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements.

Comment: A significant number of commenters stated that an 80 percent minimum performance level, if finalized, would not leave providers enough money for costs associated with administrative tasks, programmatic activities, supervision, technology, office or facility expenses, training, or travel reimbursement. Many commenters noted the 80 percent minimum performance level would result in unintended consequences – namely that affected HCBS providers would cut back on services, limit or stop serving Medicaid beneficiaries, or close altogether. A few commenters expressed concern that our proposal would result in fewer new providers enrolling as Medicaid HCBS providers. Many commenters worried that such reductions in available services or the provider pool would reduce, rather than increase, beneficiaries’ access to high-quality HCBS. A few commenters worried that HCBS provider closures, as a result of the proposed policy, could result in more beneficiaries moving into institutional settings.

Several commenters also expressed the belief that the 80 percent minimum performance level would discourage innovation among providers. One commenter suggested that providers would be penalized if they relied on assistive technology, remote supports, or other technology solutions to support beneficiaries in lieu of human assistance.

Response: We thank commenters for their feedback. As discussed in greater detail later in this section, we are modifying the policy we proposed at § 441.302(k)(3) to establish certain exceptions from the minimum performance level, and to establish a 6-year effective date, rather than the 4 years we had proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when States must comply with § 441.302(k). As discussed in greater detail below, we are also: (1) adding a definition of excluded costs at § 441.302(k)(1)(iii) to exclude certain costs from the minimum performance level calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers; (2) revising the definition of direct care worker proposed at § 441.301(k)(1)(ii) to clarify that clinical supervisors are included in the definition of direct care workers; (3) revising § 441.302(k)(3)(ii)

to allow States to set a separate minimum performance level for small providers; (4) adding a new provision at § 441.302(k)(4) to provide an option for States to develop reasonable, objective criteria to identify small providers to meet a small provider minimum performance level set by the State; (5) adding a new provision at § 441.302(k)(5) to allow States to develop reasonable, objective criteria to exempt certain providers from meeting the minimum performance level requirement; and (6) adding a new provision at § 441.302(k)(7) to exempt the Indian Health Service (IHS) and Tribal health programs subject to 25 U.S.C. 1641 from the HCBS payment adequacy requirements at § 441.302(k).

We believe that these amended requirements will address some commenters' concerns about leaving providers sufficient administrative funds for certain personnel and administrative activities and will meet the needs of providers that are small or experiencing other challenges in meeting the minimum performance level.

We always encourage providers to find innovative ways to deliver services but believe that these services (even if delivered with the assistance of technology or telehealth) at their core require direct care workers to provide them. It is difficult to imagine how strategies that do not aim to stabilize direct care worker wages would improve the efficacy or quality of these services. We do believe, however, that placing a limit on the amount of the Medicaid payment going to expenses other than direct care worker compensation could encourage innovative efforts to improve and streamline administrative activities.

In response to commenters' concerns that this proposal would have the unintended consequence of causing program cuts or provider closures, we do not believe this outcome would be the result from implementing the proposed minimum performance level. We believe that the current environment – in which providers and beneficiaries routinely struggle to find qualified direct care workers, and direct care workers leave the HCBS workforce for better-paying jobs – poses a significant threat to access and community integration because there are an insufficient number of direct care workers to meet beneficiaries' needs. In addition, the direct care worker

shortage threatens beneficiary access to services and community integration as such shortage may lead to provider closures if providers are unable to find enough workers to deliver services. This shortage also threatens service quality through the loss of well-trained and experienced direct care workers, if left unaddressed. Further, we believe that the modifications we are finalizing to this requirement will help to mitigate these concerns.

Comment: Some commenters (including beneficiaries, providers, labor organizations, disability or legal advocacy organizations, and research and policy organizations) agreed that 80 percent was an appropriate or reasonable payment adequacy requirement. A couple of these commenters based their support on personal experience, including a few who indicated that they were providers, and stated that 80 percent was an achievable minimum performance level. A few commenters pointed out that the medical loss ratio (MLR) for managed care is 85 percent. One commenter suggested that the minimum performance level be increased to 85 percent to align with the MLR. One commenter recommended that the 80 percent standard should account for necessary administration of HCBS programs, including training. This commenter stated that, if it does not account for necessary administration, the payment rates that States and managed care programs have established are likely too low. The commenter also recommended that, once the requirement is implemented, we review whether the percentage should be higher than 80 percent.

A number of commenters suggested alternative, lower minimum performance levels. Several commenters (including providers, State Medicaid agencies, a labor organization, and an advocacy organization) suggested minimum performance levels ranging from 70 percent to 75 percent. A few of the commenters who recommended 75 percent self-identified as providers and believed that 75 percent was achievable based on their own experiences and expenditure calculations. One commenter recommended we mandate a 72.35 percent minimum performance level and change the definition of compensation to exclude the 7.65 percent employer share of FICA taxes for direct care workers; the commenter believed this would reduce confusion regarding employers' shares of taxes and align the definition of compensation with that used by

some States. A few commenters recommended 70 percent based on experience with rate studies or provider expenditures in their States.

Several commenters, including providers and commenters representing State agencies, recommended setting a minimum performance level at either 60 percent or 65 percent, based on the commenters' personal experience running a provider agency or overseeing provider agencies. One commenter suggested a minimum performance level of 60 percent based on a hypothetical analysis of one State's HCBS rates and projected expenditures.

While not making specific recommendations, several commenters (mostly providers and State Medicaid agencies) submitted comments that included anecdotal data of what providers spend on compensation; these percentages ranged from 55 to 81 percent.

Response: We thank commenters for engaging in this issue, including sharing their own experiences allocating Medicaid payments. While we found the feedback provided by commenters instructive, both the range of recommendations and the anecdotal nature of information supporting most of the recommendations prevented us from relying on the recommendations to finalize additional modifications to the proposed minimum performance at the provider level requirement at § 441.302(k)(3).

We do not agree that we should increase the minimum performance level upward to match the 85 percent MLR required in managed care as the MLR is a calculation and associated reporting requirement for Medicaid managed care contracts in accordance with § 438.8 and is not specific to HCBS.

Additionally, as discussed previously and in more detailed responses below, we are finalizing some modifications related to the exclusion of certain costs, the inclusion of clinical supervisors in the definition of direct care workers, and options for a small provider minimum performance level and hardship exemptions for some providers that will change somewhat the impact of the minimum performance level. Further, we are modifying the policy we proposed at § 441.302(k) to establish certain exceptions from the minimum performance level proposed at §

441.302(k)(3), and requiring States to comply beginning 6 years after the effective date of this final rule, rather than the 4 years we had proposed. We will continue to use our standard enforcement tools and discretion, as appropriate, when the minimum performance level requirement go into effect. We believe these modifications are necessary to balance the goal of stabilizing the direct care workforce with the operational realities faced by providers of varying sizes and locations.

Comment: A few commenters suggested that the minimum performance level, if finalized, should be applied at the State level, rather than the provider level. Commenters suggested that applying the minimum performance level at the State level would create some flexibility, as this would require only that all providers in the State meet the minimum performance level in aggregate. However, a few other commenters recommended that we clarify that the minimum performance level applies at the provider level.

Response: We clarify that we intended to propose that the minimum performance level policy would apply at the provider level, meaning that the State must ensure that each provider spends Medicaid payments they receive for certain HCBS on direct care worker compensation in accordance with the minimum performance level requirement. As noted previously, we believe it is important for States to hold providers individually accountable for how they allocate their Medicaid payments and are finalizing other policies, discussed below and elsewhere in this section II.B.5. of the final rule, for States to accommodate providers that need additional flexibility. We note that there was an error in the heading of § 441.302(k)(3), which was proposed as “Minimum performance at the State level.” We apologize for any confusion this may have caused; we believe that most commenters, based on their comments, understood the minimum performance requirement to apply at the provider level. Accordingly, we are finalizing § 441.302(k)(3) with modification by revising the heading for § 441.302(k)(3) to read “Minimum performance at the provider level,” as it was originally intended to read.

Additionally, to ensure that it is understood that the minimum performance level that must be met by the State is calculated as the percentage of total payment (not including excluded costs, which are discussed in greater detail in section II.B.5.d. of this final rule) to a **provider** for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by **the provider's** total compensation to direct care workers. (New text in bold font).

Comment: A significant number of commenters worried that a national minimum performance level, regardless of the percentage, would have a disparate impact on providers that are small, new, in rural or underserved areas, or run by/for people from specific underserved communities (such as indigenous people) or individuals for whom English is a second language. Some commenters worried that the proposal favors large providers and would lead to consolidation of providers. A few other commenters worried that this would mean that beneficiaries would have fewer choices of providers and have to work with larger corporate providers. One commenter worried that a national minimum performance level would have a disparate impact on agency providers (which may have more overhead costs), as opposed to providers of self-directed services.

A number of commenters requested that if we finalize a national payment adequacy requirement, we include additional flexibilities to minimize unintended consequences on certain providers, particularly small and rural providers. One commenter suggested that we allow for “hardship exemptions” on a case-by-case basis. One commenter suggested that we allow States to exempt providers that pay workers 200 percent of the Federal Poverty Level. Another commenter suggested that we exempt States from the payment adequacy requirement if the State has a minimum hourly base wage of \$15 per hour applicable to direct care workers delivering the affected services.

Other commenters recommended adjustments to the national minimum performance level, rather than exemptions. A few commenters suggested that we allow for a variable payment

adequacy requirement or for “scaling” of the minimum performance level, adjusted for different provider sizes or different types of services. A few other commenters recommended requiring a range to identify rates, which could vary by provider size, number of Medicaid beneficiaries served, rural or urban status, hardship status (risk of closure), or other characteristics. One commenter suggested the rate could vary by delivery system or service type. A number of commenters recommended that we allow States to set their own payment adequacy requirement.

A small number of commenters raised concerns that requiring a minimum performance level would conflict with 25 U.S.C. 1641, governing how IHS and Tribal health programs (as defined in 25 U.S.C. 1603(25)) may use Medicare and Medicaid funds, and other applicable laws providing for Tribal self-governance and self-determination. One commenter recommended that we exempt IHS and Tribal health programs from the requirement.

Response: We believe that at least some of commenters’ concerns about provider impact may be alleviated by some of the modifications we are finalizing to our proposed policy in this section II.B.5. of the final rule. In particular, we are excluding travel costs from the calculation of the minimum performance level, as increased travel expenses were cited as a primary concern for rural providers. (We refer readers to the discussion of the definition of compensation and excluded costs in section II.B.5.d. of this rule, below.)

We note that the purpose of this proposal is not to set a particular wage for direct care workers, but to ensure that Medicaid payments are being allocated in ways that promote efficiency, economy, and quality of care. We believe that all States are accountable to this requirement and should hold their providers accountable. However, we also agree that some small providers may experience additional challenges in meeting a payment adequacy requirement, as any fixed costs must be covered by a smaller pool of revenues than for larger providers, and small providers have fewer opportunities for administrative efficiencies than larger providers do. We share commenters’ desires that the minimum performance level not have a disparate impact on small providers, new providers that may still be developing their processes,

providers that may, for various reasons, have additional administrative tasks (such as an increased need for interpreter or translation services), or providers that face disparately high costs, such as providers that may have to pay for temporary lodging for direct care workers delivering services to clients in extremely rural areas.

While we are finalizing a minimum performance level at § 441.302(k)(3)(i) as previously discussed that States must apply to most of their providers, we also agreed with commenters' suggestions. We are finalizing our policy with modifications at § 441.302(k)(3)(ii) to provide that States may apply a different minimum percentage to small providers that the States develop in accordance with requirements at § 441.302(k)(4). These modifications at § 441.302(k)(3)(ii) and (k)(4) will allow States the option to require a reasonable number of small providers, as defined using reasonable, objective criteria set by the State through a transparent process that must include public notice and opportunities for comment from interested parties, to meet a different minimum performance level. This separate minimum performance level would also be set by the State based on reasonable, objective criteria through a transparent process that must include public notice and opportunities for comment from interested parties. In order to apply a small provider minimum performance level, States must ensure it is supported by data or other reasonable factors in the State. We also note that States would still need to collect and report data as required in § 441.302(k)(2) and § 441.311(e) (discussed in section II.B.7. of this rule) for providers subject to the small provider minimum performance level.

Further, under our authority at section 1902(a)(6) of the Act, we are finalizing an additional provision at § 441.302(k)(6)(i), to require that States that establish a small provider minimum performance level in accordance with § 441.302(k)(4) must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the following: the State's small provider criteria; the State's small provider minimum performance level; the percent of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider

performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at § 441.302(k)(3)(i) within a reasonable period of time.

We also agree with commenters that some providers may experience hardships with meeting a payment adequacy requirement because, for instance, they are new to serving Medicaid beneficiaries and thus have not had time to develop administrative efficiencies. Additionally, we agree that special attention needs to be paid where a provider may be at risk of closure and could cause beneficiaries to lose access to HCBS in a particular area. We also agree that States are best positioned to identify the nature of the hardships and which providers are experiencing these hardships. As a result, we are finalizing a modification at § 441.302(k)(5) to allow States to develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at § 441.302(k)(3) a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with § 441.302(k)(3). The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, the provider should be excluded from the State's calculation of the minimum performance level at § 441.302(k)(3). We note that we expect that most providers would be subject to a hardship exemption on a temporary basis, and that States would still need to collect and report data as required in § 441.302(k)(2) and § 441.311(e) for providers with hardship exemptions.

Further, under our authority at section 1902(a)(6) of the Act, we are finalizing an additional provision at § 441.302(k)(6)(ii) to require that States that provide a hardship exemption to providers facing extraordinary circumstances must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the State's hardship criteria, the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption, and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time.

We plan to issue guidance on both the small provider performance level and the hardship exemption and encourage States to consult with CMS as they develop their criteria. However, we note that, for States in which a small proportion of providers (less than 10 percent of the total number of providers of services at § 440.180(b)(2) through (4)) qualify for either the small provider performance level or a hardship exemption, CMS may waive the requirements, at § 441.302(k)(6)(i)(D), for States to report on a plan for small providers to meet the minimum performance level at § 441.302(k)(3)(i) within a reasonable period of time, and at § 441.302(k)(6)(ii)(C), for States to report on a plan for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. We are finalizing this waiver at § 441.302(k)(6)(iii).

In addition, we are modifying the date for when States must comply with the requirements at § 441.302(k) to be beginning 6 years after the effective date of the final rule, rather than the 4 years we had proposed. (We refer readers to our discussion in II.B.5.h. of this rule.) We will continue to use our standard enforcement tools and discretion, as appropriate, when the minimum performance level requirement goes into effect.

Finally, we are persuaded by commenters who raised concerns about interactions between statutory requirements for IHS and certain Tribal health programs health programs subject to 25 U.S.C. 1641 and the proposed requirement at § 441.302(k). Congress has already passed laws, such as 25 U.S.C. 1641, specifying how IHS and Tribal health programs (as defined in 25 U.S.C. 1603(25)) are to use their Medicaid collections. Because Congress has already specified how such funds must be used, we are finalizing an exemption at § 441.302(k)(7) to the HCBS payment adequacy requirements at § 441.302(k) for IHS and Tribal health programs subject to 25 U.S.C. 1641.

After consideration of the comments received, we are finalizing § 441.302(k)(3) with modifications, as well as finalizing new requirements at § 441.302(k)(4), (5), and (6). The requirements we are finalizing with modifications are as follows:

We are finalizing § 441.302(k)(3) with several modifications to retitle the requirement as *Minimum performance at the provider level* and clarify the components of the required calculation and the services that fall within this requirement. We also made modifications at § 441.302(k)(3) to clarify that excluded costs are not included in the calculation of the percentage of total payments to a provider that is spent on compensation to direct care workers and to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies. We are also modifying § 441.302(k)(3) to note the exceptions to the minimum performance level that we are adding at (k)(5) (hardship exemption) and (k)(7) (IHS and Tribal health programs subject to 25 U.S.C. 1641). As finalized, § 441.302(k)(3) specifies that, **except as provided in paragraphs (k)(5) and (7)**, the State must meet the following minimum performance level as applicable, calculated as the percentage of total payment (not including excluded costs) *to a provider* for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by the *provider's* total compensation to direct care workers. (New text in bold font).

We are modifying the language at § 441.302(k)(3)(i) to read that the minimum performance level of 80 percent applies to all payments to a provider, except as provided in paragraph (k)(3)(ii). We are finalizing a new requirement at § 441.302(k)(3)(ii) to read that at the State's option, for providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

We are redesignating the applicability date we proposed at § 441.302(k)(4) as § 441.302(k)(8), as discussed further in section II.B.5.f. of this rule. We are finalizing a new § 441.302(k)(4) and adding new paragraphs (i) and (ii) to provide an option for States to develop reasonable, objective criteria through a transparent process to identify small providers to meet

the State-defined small provider minimum performance level; require that the transparent process for developing criteria to identify providers that meet the small provider minimum performance level must include public notice and opportunities for comment from interested parties; and require that the small provider minimum performance level be set based on reasonable, objective criteria the State develops through a transparent process that includes public notice and opportunities for comment from interested parties.

We are finalizing a new § 441.302(k)(5) to allow States to develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at § 441.302(k)(3) a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with § 441.302(k)(3). The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, the provider should be excluded by the State from its calculation of the State's compliance with the minimum performance level at § 441.302(k)(3).

We are finalizing a new provision at § 441.302(k)(6) to require States to report on their development and use of the small provider minimum performance level and hardship exemption. Specifically, at § 441.302(k)(6)(i), States that establish a small provider minimum performance level in accordance with § 441.302(k)(4) must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the following: the State's small provider criteria; the State's small provider minimum performance level; the percent of providers of services at § 440.180(b)(2) through (4) that qualify for the small provider performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at § 441.302(k)(3)(i) within a reasonable period of time. We are also requiring at § 441.302(k)(6)(ii) that States that provide a hardship exemption to providers facing extraordinary circumstances must report to CMS annually, in the form and manner, and at a time, specified by CMS, on the State's hardship criteria, the percentage of providers of services at § 440.180(b)(2)

through (4) that qualify for a hardship exemption, and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. Additionally, we are finalizing a waiver at § 441.302(k)(6)(iii) that specifies that CMS may waive the reporting requirements in paragraphs (6)(i)(D) or (6)(ii)(C), as applicable, if the State demonstrates it has applied the small provider minimum performance level at § 441.302(k)(4)(ii) or the hardship exemption at § 441.302(k)(5) to a small proportion of the State's providers.

Finally, we are finalizing a new § 441.302(k)(7) specifying that the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 are exempt from the requirements at § 441.302(k).

c. Other Services (§ 441.302(k)(3))

We considered whether the requirements we proposed at § 441.302(k)(3)(i) related to the percent of Medicaid payments going to the direct care workforce should apply to other services in addition to homemaker, home health aide, or personal care services (as set forth at § 440.180(b)(2) through (4)), such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness. However, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce. We requested comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities, we requested comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services.

We also requested comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for each specific service that this provision should apply if this provision should apply to other services at § 440.180(b): (1) 65 percent; (2) 70 percent; (3) 75 percent; and (4) 80 percent. Specifically, we requested that commenters respond separately on the minimum percentage of payments for services delivered in a non-residential community-based facility, day center, senior center, or other dedicated physical space, which would be expected to have higher other indirect costs and facility costs built into the Medicaid payment rate than other HCBS. If an alternate minimum percentage is recommended, we requested that commenters provide the rationale for that minimum percentage.

We further clarified that we were requesting comment on a different range of options for the other services at § 440.180(b) than for the services at § 440.180(b)(2) through (4) because we expect that some of the other services at § 440.180(b), such as adult day health and day habilitation services, may have higher other indirect costs and facility costs than the services at § 440.180(b)(2) through (4). We also requested that commenters respond separately on the minimum percentage of payments for facility-based residential services and other facility-based round-the-clock services that have other indirect costs and facility costs that would be paid for at least in part by room and board payments that Medicaid does not cover. If a minimum percentage is recommended for any services, we requested that commenters provide the rationale for that minimum percentage.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter requested additional clarification on how the services we proposed to be included in the requirements at § 441.302(k)(3) were selected. One commenter suggested that we only apply the minimum performance requirement to personal care services. The commenter suggested we could align the requirement with the EVV system reporting

requirement,¹¹⁰ which applies to personal care services, including personal care services delivered as part of habilitation services.

Response: The priority of this proposal is to support the direct care workforce, and to this end we have focused on accountability for services that rely on direct care workers to perform the core activities. As noted in the background discussion of this provision and in previous responses, the services subject to the minimum performance requirement were selected because they are unlikely to have facility costs as part of the rate or as a component of the core service. We also note that the data we reviewed when determining an appropriate minimum performance requirement focused on home-based services, not facility-based services. Additionally, as identified in an analysis performed by CMS, the three services we proposed to be subject to this requirement at § 441.302(k) fall within the taxonomy of home-based services, which are both high-volume and high-cost.¹¹¹ Thus, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of the allocation of Medicaid rates for frequently used services. Given these similarities among homemaker, home health aide, and personal care services, we cannot find a justification for removing homemaker and home health aide services from this requirement.

Comment: A few commenters requested that we provide a more specific definition of personal care services. Commenters noted that States do not always use HCBS taxonomies consistently, and personal care services can be applied to a different constellation of activities in different waivers. Similarly, one commenter noted that the lack of definitions in the proposed rule for homemaker, home health aide, and personal care services is problematic because States do not use these terms consistently and use a variety of different terms to describe these services.

¹¹⁰ Section 12006 of the 21st Century Cures Act (Pub. L. 114-255)

¹¹¹ Centers for Medicare & Medicaid Services. “Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.” <https://www.medicare.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf>. Last access October 2, 2023.

Response: We understand that States have service definitions for homemaker, home health aide, and personal care services that differ from the definition of homemaker, home health aide, and personal care services in the section 1915(c) waiver Technical Guide¹¹² and that States do not always use these terms consistently. However, codifying definitions of homemaker, home health aide, and personal care services would have broad implications for State’s HCBS programs that would extend beyond the HCBS payment adequacy requirements in this final rule. We will provide additional subregulatory guidance and technical assistance to aid in implementation of the HCBS payment adequacy requirements and may consider addressing in future rulemaking.

Comment: Many commenters responded to our solicitation for comment on whether we should include habilitation services in the services subject to the minimum performance requirement. Most commenters who responded did not believe that habilitation services should be included in the requirement. They echoed our concerns that these services are likelier to include at least some activities in a provider-operated facility or residential setting, which changes the expected costs of providing and allocation of the payment for these services.

Much of the public feedback around habilitation services focused on the facility or residential portion of those services. Commenters noted that rent, utilities, property maintenance, and other costs associated with residential or facility-based services can vary significantly. One commenter suggested that if residential habilitation was included in the minimum performance requirement, the minimum performance level for residential habilitation should be set at 75 percent to account for additional administrative costs. A few other commenters suggested that a different minimum performance level should be set for habilitation services, if included, but did not specify a particular percentage.

¹¹² See Centers for Medicare & Medicaid Services, “Application for a § 1915(c) Home and Community Based Waiver: Instructions, Technical Guide and Review Criteria.” January 2019. Available at https://wms-mmml.cms.gov/WMS/help/35/Instructions_TechnicalGuide_V3.6.pdf.

Some commenters also suggested that residential services might require more, or different staffing levels, as well as different types of staff than home-based services, which might change the necessary minimum performance level. Commenters disagreed, however, on whether these staffing differences would necessitate a higher or lower minimum performance level than for in-home services, and commenters did not recommend a percentage to specifically address the perceived differences in staffing. One commenter objected to any discussion of residential settings, out of concern that this would appear to promote congregate settings in violation of the home and community-based settings requirements; the commenter stated that all services should be provided in the community.

Several commenters recommended that we not apply the minimum performance level at § 441.302(k)(3)(i) to habilitation services and encouraged us to collect data on the percent of payments for habilitation services.

Response: We believe that the comments we received affirm our decision not to apply the HCBS payment adequacy policy we are finalizing at § 441.302(k) to habilitation or other facility-based services (in which services are delivered in a provider-operated physical location and for which facility-related costs are included in the Medicaid payment rate) due to the number of additional or variable expenses associated with facility-based services. While outside the scope of this final rule, we refer readers to and our requirements for, and the criteria of, a home and community-based setting at § 441.301(c)(4) and (5).

We agree with commenters that additional data collection on habilitation services would be useful. Please refer to the discussion of § 441.311(e) in section II.B.7. of this rule, below.

Comment: Although not necessarily supporting the inclusion of habilitation services in the minimum performance requirement, commenters worried about the impact on beneficiaries receiving habilitation services, who are largely individuals with intellectual or developmental disabilities or behavioral health needs. Some commenters stated that direct care workers who had been providing habilitation services might switch to working for providers that offer

homemaker, home health aide, or personal care services because they believed that the requirements at § 441.302(k), if finalized, would lead to increased wages paid to these workers or to Medicaid agencies allocating more resources for these services. One commenter speculated that, if a lower minimum performance level was set for residential habilitation, this would encourage more services to be provided in congregate settings because providers would try to take advantage of the lower minimum performance level. Several commenters that provided services to people with intellectual disabilities and people with mental illness suggested we amend § 441.302(k)(3)(i) to specify an exclusion for direct care workers (or direct service professionals) providing services for individuals with intellectual and developmental disabilities or severe mental illness, as they believed that many of these services are delivered as facility-based habilitation services; the commenters were concerned that these providers have additional non-compensation expenses that are not considered by the proposal, and that it was unclear whether facility-based services were already excluded from the proposal.

Response: We agree that, by excluding habilitation services from this requirement, we are excluding services that are used more frequently by certain populations. This was not our intent, and we do not intend to explicitly exclude certain services from this requirement on the basis of the population receiving the service. However, as noted above, because of differences in these services, we do not believe we can set an appropriate minimum performance level for these services at this time. Although we are not requiring that habilitation or other facility-based services (in which services are delivered in a provider-operated physical location and for which facility-related costs are included in the Medicaid payment rate) be included in the minimum performance requirement, States are able to set wage pass-through requirements of their own for such services to promote the stability of the workforce; we also believe that States may naturally adjust rates or wages in other services in response to the implementation of the minimum performance requirement for homemaker, home health aide, and personal care services.

Comment: One commenter expressed a concern that the minimum performance requirement would apply to skilled nursing facilities. Several commenters requested that we clarify in § 441.302(k)(3)(i) that direct care workers would be excluded from the minimum performance requirement if they are providing services in residential settings. One commenter requested that we clarify that assisted living facilities or assisted living services are not included in the minimum performance requirement, while another commenter raised concern about a lack of clarity about whether the requirement applies to assisted living facilities.

Response: The requirements we are finalizing in this section II.B. of this rule only apply to HCBS, and the minimum performance requirement at § 441.302(k)(3) applies specifically to homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4). However, while the minimum performance requirement would not apply to institutional services (because those are not HCBS), we decline to explicitly restrict the application of this requirement on the basis of different community-based settings. As we noted in prior responses, we selected homemaker, home health aide, and personal care services because these are typically services delivered in the home. However, we acknowledge that beneficiaries may live in different residential settings that are considered homes, and that these services may be bundled with other services delivered to beneficiaries in residential settings.

Comment: A number of commenters requested that we add private duty nursing to the services subject to the minimum performance requirement.

Response: We believe that at least some commenters may be referring to private duty nursing as defined at section 1905(a)(8) of the Act and § 440.80 of our regulations. As discussed in greater detail below in section II.B.5.g. of this rule, we are not planning to require that the minimum performance level be applied to services authorized under section 1905(a) at this time. We note that home health aide services, included in § 440.180(b)(3) but authorized as part of a section 1915(c) waiver, are included in the minimum performance requirement. It is possible that some services that commenters are characterizing as “private duty nursing” may fall within the

category of a section 1915(c) home health aide service, even as we acknowledge that Federal requirements for private duty nursing specify that these are skilled care services provided by a registered nurse or licensed practical nurse.

Comment: A few commenters recommended that we apply the minimum performance requirement to a number of other services that are experiencing staffing shortages, including: job supports; respite provided in the community; community habilitation services; in-home cognitive rehabilitation therapy; and in-home physical, occupational and speech therapy services. A few commenters suggested, without specifying which services, that the minimum performance requirement ought to be expanded to other services, or that it would be easier to administer if applied to a broader array of services than just homemaker, home health aide, and personal care services.

Response: We thank the commenters for their suggestions and will take them under consideration for potential future rulemaking. As we noted earlier in this section of the final rule, we selected homemaker, home health aide, and personal care services because they are services for which we expect that the vast majority of payment to be comprised of compensation for direct care workers. Further, they are high-volume and high-cost services,¹¹³ and as a result, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of the allocation of Medicaid rates for frequently used services. We note that States are able to apply wage pass-through requirements to additional services if they choose.

After consideration of the comments received, we are finalizing our proposed language at § 441.302(k)(3) to apply the minimum performance requirement to homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4).

d. Definition of Compensation (§ 441.302(k)(1)(i))

¹¹³ Centers for Medicare & Medicaid Services. “Trends in Rate Methodologies for High-Cost, High Volume Taxonomies.” <https://www.medicaid.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf>. Last access October 2, 2023.

At § 441.302(k)(1)(i), we proposed to define compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 et seq., 29 CFR parts 531 and 778), and benefits (such as health and dental benefits, sick leave, and tuition reimbursement). In addition, we proposed to define compensation to include the employer share of payroll taxes for direct care workers delivering services under section 1915(c) waivers. We considered whether to include training or other costs in our proposed definition of compensation. However, we determined that a definition that more directly assesses the financial benefits to workers would better ensure that a sufficient portion of the payment for services went to direct care workers, as it is unclear that the cost of training and other workforce activities is an appropriate way to quantify the benefit of those activities for workers. We requested comment on whether the definition of compensation should include other specific financial and non-financial forms of compensation for direct care workers.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A couple of commenters noted support for our definition of compensation and encouraged us to finalize the definition as proposed.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that workers' overtime pay would not be considered part of the definition of compensation.

Response: Our definition of compensation as proposed at § 441.302(k)(1)(i)(A) included salary, wages, "and other remuneration as defined by the Fair Labor Standards Act" and its regulations. As the Fair Labor Standards Act includes overtime pay in its definition of wages, overtime pay therefore is included in our definition of compensation as well.

Comment: Many commenters supported the inclusion of health and dental insurance and sick leave in the definition of benefits at § 441.302(k)(1)(i)(B). A few commenters requested that life insurance, disability insurance, and retirement contributions also be added to this definition.

Several commenters also requested clarification as to whether paid time off was included in the definition of compensation, and a few suggested that it should be included.

One commenter noted that our definition of compensation was too broad, particularly the use of the term “such as” when describing the inclusion of benefits. The commenter expressed concern that employers could over-include items in compensation by calling them “benefits.” One commenter worried that if too many benefits were included in compensation, this would reduce workers’ take-home pay.

One commenter expressed concerns that it will be difficult for State Medicaid agencies to quantify benefits included in direct care worker compensation.

Response: We believe that all the items identified by these commenters – life insurance, disability insurance, retirement, and paid time off – would be reasonably considered part of compensation. In its glossary, the Bureau of Labor Statistics (BLS) defines compensation as “employer costs for wages, salaries, and employee benefits,” and notes that the National Compensation Survey includes the following categories in employee benefits: insurance (life insurance, health benefits, short-term disability, and long-term disability insurance); paid leave (vacations, holidays, and sick leave); and retirement (defined benefit and defined contribution plans).¹¹⁴ We believe the items suggested by the commenters align with our intent and are reflected by a common understanding of “benefits” as exemplified in the BLS glossary.

To help clarify what is meant by “benefits,” we are modifying the language we proposed at § 441.302(k)(1)(i)(B) in this final rule. We are retaining “health and dental benefits” but also are adding to the list “life and disability insurance.” We note that the definition used by BLS simply refers to health benefits, life insurance, and different types of disability insurance collectively as “insurance,” but we believe that spelling out examples of types of insurance is useful here. In the context of our definition, “insurance” listed by itself might be unclear (since it could be confused with other types of insurance that would not be considered compensation,

¹¹⁴ See BLS “Glossary” at <https://www.bls.gov/bls/glossary.htm>.

like employers' liability insurance), and we wish to make it clear that the benefits must benefit the employee directly. We are also modifying "sick leave" to the broader term "paid leave," as this should be understood to cover any time for which the employee is paid, whether it be for sick leave, holidays, vacations, and so forth. We also are adding retirement, which we believe is also a useful blanket term for different types of retirement plans or contributions on the employee's behalf. After consideration of public comments, we are finalizing § 441.302(k)(1)(i)(B) with modification to specify that compensation includes benefits, such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

When proposing that benefits be included in the definition of compensation, we intentionally included the phrase "such as" to indicate that the examples of benefits provided in the definition is not exhaustive. We did not attempt to list all possible benefits in the regulatory definition, as we believe that would run the risk of creating a definition that is too narrow. We plan to provide technical assistance to States on how to help ensure that providers are applying a reasonable definition of "benefits" and are only counting expenses thereunder that would reasonably be considered an employee benefit.

Comment: Some commenters supported including employers' share of payroll taxes in the definition of compensation at § 441.302(k)(1)(i)(C). However, several commenters recommended that this expense be removed from the definition, as these are not expenses included in employees' take-home pay and are the responsibility of the employer. Several commenters requested that employers' contributions to worker's compensation and unemployment insurance be included in the definition of compensation.

Response: It is our intent to include employers' payroll tax contributions for unemployment insurance and workman's compensation (as well as payments required by the Federal Insurance Compensation Act) under § 441.302(k)(1)(i)(C) and thus as part of our definition of compensation for the purposes of the requirements at § 441.302(k). While not

necessarily paid directly to the workers, these expenses are paid on their behalf. We also note, for instance, that per the BLS, the National Compensation Survey calls these payroll taxes “legally mandated employee benefits” and includes them as part of the definition of “employee benefits” for the purposes of determining compensation.¹¹⁵ We plan to provide technical assistance to States on how to help ensure that providers are including payroll tax contributions for unemployment insurance and workman’s compensation when reporting on compensation to workers.

Comment: Several commenters noted support for including tuition reimbursement in the definition of compensation. Several commenters suggested that costs associated with continuing education should also be included as compensation.

Response: We appreciate the commenters’ support. We believe the term “tuition reimbursement” is broad enough to cover a variety of scenarios in which a provider may choose to reimburse a worker for tuition costs incurred either prior to or during their period of employment.

Comment: A number of commenters supported either including training in the definition of compensation or excluding training from the administrative and other expenses that are not considered compensation under this rule. Some of these commenters noted that certain types of services or programs might involve additional training for staff, such as services delivered to beneficiaries with complex needs. One commenter suggested that raising workers’ wages will not necessarily increase service quality if it is not accompanied by better training for staff. Another commenter worried that providers could decide to cut back on training in order to meet the minimum performance level, which could endanger workers. Commenters cited examples of trainings, including in-service trainings and cardiopulmonary resuscitation trainings, as being critical for caring for beneficiaries. Several commenters suggested that direct care workers who

¹¹⁵ See BLS “Glossary” at <https://www.bls.gov/bls/glossary.htm>.

serve beneficiaries with higher-acuity needs may require additional training than other direct care workers.

Commenters suggested that, if training was included in the definition of “compensation” (or was excluded from administrative and other expenses that are not considered compensation under this rule), training should be defined to include time spent in training, training materials, trainers, and training facilities.

Conversely, one commenter stated that if training was included in the definition of compensation, the minimum performance level should be adjusted further upward (above 80 percent). One commenter stated that if training was included as compensation to direct care workers, this cost should be restricted to the time workers spend in training and not include training materials and payments made to the trainer. One commenter stated that the cost of onboarding new staff should not be considered “training.” One commenter expressed skepticism that training was truly a major cost for providers.

Response: We clarify that the time direct care workers spend in training would already be accounted for in the definition of compensation. We agree with commenters on several points: that training is critical to the quality of services; that training needs might vary across (or even within) States’ Medicaid HCBS programs, depending on the nature of the services or the acuity of the beneficiaries served; that training costs may be difficult to standardize; and that worker training is essential to quality, as well as the health and safety of both the direct care worker and the beneficiary. We do not want to encourage providers to reduce training to cut administrative costs.

However, we are also reluctant upon considering comments to treat all training costs as “compensation” to the direct care worker. Trainings, as commenters noted, are often required as part of the job and may vary depending on the services or the needs of the beneficiaries they serve. We are concerned that including training costs in the definition of compensation could mean that direct care workers with higher training requirements would see more of their

“compensation” going to training expenses, which could cause them to receive lower take-home pay than colleagues with fewer training requirements.

Rather than include training costs in the definition of compensation at § 441.302(k)(1)(i), we are creating a new definition at § 441.302(k)(1)(iii) to define excluded costs for the purposes of the payment adequacy requirement at § 441.302(k)(3). Excluded costs are those that are not included in the State’s calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers required at § 441.302(k)(3). In other words, States would ensure providers deduct these costs from their total Medicaid payments before performing the calculation. We are specifying at § 441.302(k)(3)(iii) that excluded costs are limited to: training costs (such as costs for training materials or payment to qualified trainers); travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and costs of personal protective equipment for direct care workers. This would mean that providers could deduct the total eligible training expenses, travel costs, and personal protective equipment for direct care workers from the total payments they receive for homemaker, home health aide, and personal care services before the compensation percentage is determined for the minimum performance level as required under § 441.302(k)(3).

The training costs that are excluded costs under § 441.302(k)(1)(iii) are limited to those costs associated with the training itself (such as qualified trainers and materials) and are distinct from the compensation paid to a direct care worker participating in the training as part of their employment duties under § 441.302(k)(1)(i).

Comment: One commenter requested clarification as to whether travel expenses were part of the definition of “compensation.” Many commenters stated that travel or transportation expenses should be included in the definition of compensation, or not treated as an administrative expense. Many commenters also expressed the concern that it would be difficult to cover the cost of travel as part of administrative expenses and other expenses that are not considered compensation under this rule, especially in rural areas where direct care workers may

have to travel large distances to visit clients or transport them to appointments. A few commenters worried that if travel were considered an administrative expense, providers would be reluctant to serve beneficiaries outside of a narrow service area to save on travel expenses. A number of direct care workers shared experiences of having to pay for gas out-of-pocket when they transported beneficiaries and having to shoulder the financial burden of wear-and-tear on their cars. One commenter noted that travel costs are frequently included in rate calculations. Several commenters suggested that “travel,” if included in the definition of compensation, should include time workers spent travelling, mileage reimbursement, and public transportation reimbursement.

However, a few commenters specifically noted that travel should not be considered part of the definition of compensation. One commenter noted that due to the variability of travel costs, it would be difficult to include travel in a standardized definition of compensation.

Response: We agree with commenters that certain travel-related expenses should not be considered compensation to direct care workers. Travelling to beneficiaries’ homes or assisting them in the community is an essential function of the job, and thus, travel reimbursement is not for the direct care worker’s personal benefit.¹¹⁶ We also agree that travel costs will vary significantly by region and even by beneficiary. We too are concerned that including travel in the definition of compensation could mean that direct care workers with higher travel demands would see more of their compensation going to travel, which could cause them to receive lower take-home pay than colleagues with lower travel demands.

At the same time, we are aware of the critical importance of travel to the delivery of these services and do not want to create unintended consequences. We are persuaded by commenters’ concerns that counting travel as an administrative expense could induce some providers to stop serving beneficiaries that live outside certain regions. We would also be concerned if direct care

¹¹⁶ See 29 U.S.C. 207(e)(2) (permitting employers to exclude “reasonable payments for traveling expenses” when determining an employee’s regular rate of pay under the FLSA); see also 29 CFR 778.217 (same).

workers were expected to shoulder the financial burden of travel out-of-pocket, as appears to be happening in some cases now.

To preserve beneficiary access to services and avoid burden or disparate impact on beneficiaries, direct care workers, and providers in rural or underserved areas, we are excluding travel costs in this final rule from the calculation of the percent of Medicaid payments for certain services going to compensation for direct care workers. This means that providers can deduct the total travel expenses for direct care workers that providers incur from the total Medicaid payments they receive before the compensation percentage is determined.

In order to reflect the exclusion of travel costs from the payment calculation, we are adding a new § 441.302(k)(1)(iii)(B) that specifies that travel costs (such as reimbursement for mileage or public transportation) may be considered an excluded cost for the purposes of the minimum performance requirement at § 441.302(k)(3). The travel costs that are excluded costs under § 441.302(k)(1)(iii) are limited to those costs associated with the travel itself (such as reimbursement for mileage or public transportation) and are distinct from the compensation paid to a direct care worker for any time spent traveling as part of their employment duties under § 441.302(k)(1)(i). Please refer to our discussion in an earlier response regarding the new definition of excluded costs at § 441.302(k)(1)(iii) and its effect for the calculation required at § 441.302(k)(3).

Comment: Several commenters expressed concerns about covering the cost of vehicle purchases or maintenance as an administrative expense. One commenter suggested that if travel were included in the definition of compensation, it should include the cost of vehicles or vehicle maintenance.

Response: We note that the payment adequacy requirement applies to Medicaid payments for homemaker services, home health aide services, and personal care services. In our experience, it is rare that providers would be purchasing vehicles for these services or that vehicle purchases would be part of the rate. We do not expect that the cost of vehicles would be

part of excludable travel costs, but we plan to provide technical assistance to States on a case-by-case basis.

Comment: Several commenters noted that personal protective equipment (PPE) for staff should be counted as compensation or that these expenses should not count as an administrative expense. Several direct care workers also shared experiences of having to provide their own PPE during the COVID-19 public health emergency (PHE), and the harms caused to them both physically and financially by contracting COVID-19.

Response: We agree, particularly given the recent experience with the COVID-19 PHE, that PPE should not be treated as an administrative expense. Providing direct care workers with adequate PPE is critical for the health and safety of both the direct care workers and the beneficiaries they serve. We also do not believe that direct care workers should have to pay for PPE out-of-pocket or that it is considered part of their compensation.

Similar to our approach with training and travel above, we are excluding the cost of PPE for direct care workers in this final rule from the calculation of the percentage of payments spent on compensation for direct care workers. In order to reflect the exclusion of PPE costs from the payment calculation, we are adding new §§ 441.302(k)(1)(iii) that specifies that PPE costs for direct care workers may be considered an excluded cost for the purposes of the minimum performance requirement at § 441.302(k). Please refer to our discussion in an earlier response regarding the new definition of excluded costs at § 441.302(k)(1)(iii) and its effect for the calculation required at § 441.302(k)(3).

Comment: Several commenters requested clarification as to what activities and costs would not be counted as compensation under this rule. A significant number of commenters described other activities or costs they believed should count as compensation, should not be counted as part of non-compensation costs, or simply would not be affordable if providers were left with only 20 percent of the Medicaid rate for personal care, homemaker, or home health aide services. These included costs associated with:

- Administration, including wages paid to administrative and human resources staff, who perform activities such as billing, payroll processing, contracts management, or scheduling client appointments;

- Other business expenses, such as organization accreditation, liability insurance, and licensure.

- Human resources activities, including recruitment activities or advertising for new staff.

- Background checks, drug screening, and medical screening for employees (such as testing staff for tuberculosis prior to starting service delivery).

- Office space and utilities (especially for providers that are required by State law to have a physical office).

- Office supplies, medical supplies, food, or other out-of-pocket expenses for clients, IT, mobile devices (including those used for electronic visit verification), and staff uniforms.

- Non-cash awards to direct care workers, such as parties, staff retreats, gifts for staff, Employee Assistance Programs, or other wellness programs.

- Recordkeeping and complying with quality measures and other reporting requirements.

Commenters noted that these costs are essential to operating a service organization. Commenters also noted that at least some of these costs, such as office space, are fixed costs, or costs that are beyond providers' control.

Response: We believe that most of the items listed above would qualify as administrative expenses, but some activities may be considered compensation or excluded costs under the definitions we are finalizing at § 441.302(k)(1), depending on the context. We clarify that, by designating activities as administrative and other expenses that are not considered compensation under this rule, we do not suggest that they are inessential. However, we also believe, as has been discussed in prior responses, that a vast majority of the payment for homemaker, home

health aide, and personal care services must be spent supporting core activities that are performed by direct care workers. As noted by commenters in earlier comment summaries, we also do not want States to allow providers to add so many non-cash benefits to a worker's compensation that their take-home pay is excessively reduced. We plan to provide technical assistance to States to help ensure that States understand what are considered administrative and other expenses that are included in the percentage calculation and what are considered excluded costs.

Comment: Several commenters raised concerns that wages spent for staff conducting certain beneficiary support activities would not be considered compensation. These activities include completing person-centered service plans or scheduling client appointments.

Response: We believe that some of the activities described by commenters are activities that would be performed by staff who would classify as direct care workers, as we proposed to define at § 441.302(k)(1)(ii). We refer readers to our discussion of our proposed definition of direct care workers in the next section below. We plan to provide technical assistance to help States appropriately identify direct care workers and, separately, administrative staff, administrative activities, and other costs that are not considered compensation under this rule.

Comment: A few commenters expressed the concern that employers will shift more administrative activities to direct care workers, to avoid having these activities fall under administrative and other costs that are not considered compensation under this rule. The commenter stated that this could increase burnout for direct care workers.

Response: As discussed earlier, the definition of compensation we proposed, and are finalizing with modification, includes all compensation paid to direct care workers for activities related to their roles as direct care workers. States should ensure providers do not count in the percentage calculation at § 441.302(k)(3) compensation for the time that workers spend on administrative or other tasks unrelated to their roles as direct care workers as compensation to direct care workers. We would not view as permissible under this regulation the shifting of

administrative tasks to direct care workers as a way to inflate compensation for direct care workers. However, providers can count as compensation to direct care workers the time that direct care workers spend on tasks, including administrative tasks, such as completing timecards, that are directly related to their roles as direct care workers in providing services to beneficiaries. We plan to provide States with technical assistance on how to accurately capture compensation for workers who provide direct care and perform administrative or other roles. However, we decline to make changes in this final rule based on these comments.

Comment: Several commenters requested clarification on what was included in the denominator of the calculation (in other words, what is meant by “payments” when calculating the percent of payments being spent on compensation for direct care workers). One commenter suggested that rather than requiring 80 percent of Medicaid payments be spent on compensation, we require that 80 percent of all revenue be spent on compensation. One commenter requested clarification about whether, for managed care delivery systems, payment is the State’s capitation payment to the MCO or the MCO’s payment to the home care provider agency. The commenter also recommended that we require States to set a minimum payment rate that MCOs or other entities pay home care agencies and that the minimum rates be set at a level to pay workers the locally required minimum wage and other compensation as defined in the regulation, and for the home care agency to reserve 20 percent overhead.

A few commenters made specific suggestions for parameters of what should be included or excluded in the denominator, such as:

- Only collected revenue (and not billed charges) would be considered as base or supplemental payments;
- Excluding refunded or recouped payments from current or prior years based on program financial audits;
- Excluding chargebacks; and
- Excluding bad debt.

Response: For Medicaid FFS payments in the denominator of the calculation should include base and supplemental payments (as described in SMDL 21-006¹¹⁷). Those base and supplemental payments should only include payments actually collected, or revenue, rather than billed charges. In addition, refunded or recouped payments from current or prior years based on program financial audits, chargebacks, and bad debt should be excluded from those base and supplemental payment amounts. We are available to provide States with technical assistance related to calculating payments for the purpose of determining the percent of all payments that is spent on compensation.

For Medicaid managed care, payments refer to payments from the managed care plan to the provider and not the capitation payment from the State to the managed care plan. Further, for Medicaid managed care, payments in the denominator of the calculation should include only those payments actually collected and exclude refunded or recouped payments from current or prior years based on program financial audits, chargebacks, and bad debt. We note that section 1902(a)(30)(A) of the Act does not provide us with authority to require specific payment rates or rate-setting methodologies.

As discussed throughout this section (II.B.5), we proposed the requirements at § 441.302(k) using our authority under section 1902(a)(30)(A) of the Act, which requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believe section 1902(a)(30)(A) of the Act speaks specifically to Medicaid payments, not to all revenue received by providers (which may be from various sources); thus, we decline to modify the requirement to affect non-Medicaid revenues.

¹¹⁷ CMS State Medicaid Director Letter: SMDL 21–006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at <https://www.medicaid.gov/sites/default/files/2021-12/smd21006.pdf>.

Comment: One commenter requested that revenue from value-based care (VBC) arrangements in managed care be exempt from the calculation so as not to disrupt State or managed care efforts moving toward VBC or to disincentivize providers from pursuing innovative strategies to improve health and financial outcomes such as lowering emergency room visits, inpatient utilization, and admissions from HCBS to inpatient settings such as nursing facilities. The commenter also noted that providers must make numerous additional investments above and beyond typical compensation rates for a VBC or pay-for-performance (PFP) arrangement to work. Additionally, the commenter noted, VBC and PFP programs rely on lengthy cycles of data, tracking, analysis, and reconciliation before additional payments are made. The commenter stated that, if these types of payments are included in the denominator of the calculation, this will prove disruptive to these programs.

Response: We appreciate the commenter raising these concerns and agree that VBC, PFP, and other unique payment arrangements that reward and support quality over quantity are important, and it was not our intention to appear to discourage them or minimize their value. However, given the wide-ranging designs of such payments and that most HCBS are often not included in these arrangements, we are not requiring a specific way to address them in this final rule. We also decline to adopt the commenter's suggestion to exempt revenue from VBC arrangements in managed care from the calculation of the percent of Medicaid payments for certain HCBS that is spent on compensation of direct care workers, as such an exemption would undermine the intent of the proposal and the usefulness of the data for assessing the percentage of all Medicaid payments for certain HCBS that is spent on compensation for direct care workers. We plan to provide States with technical assistance as needed on how to include revenues from VBC, PFP, and other unique payment arrangements in the calculation.

After consideration of the comments received, we are finalizing § 441.302(k)(1)(i) with a modification to clarify at § 441.302(k)(1)(i)(B) that compensation includes benefits, such as

health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement.

We are also finalizing a new definition at § 441.302(k)(1)(iii) to define excluded costs, which are costs that are not included in the calculation of the percentage of Medicaid payments that is spent on compensation for direct care workers. In other words, States must ensure providers deduct these costs from their total Medicaid payments before performing the calculation required at § 441.302(k)(3)). Such costs are limited to: (A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials); (B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies) provided to direct care workers; and (C) Costs of personal protective equipment for direct care workers.

e. Definition of Direct Care Worker (§ 441.302(k)(1)(ii))

At § 441.302(k)(1)(ii), we proposed to define direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating) or instrumental activities of daily living (such as cooking, grocery shopping, managing finances), and provide behavioral supports, employment supports, or other services to promote community integration. Specifically, we proposed to define direct care workers to include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration. We further identified in the preamble of the proposed rule that our definition of direct care worker is intended to exclude nurses in supervisory or administrative roles who are not directly providing nursing services to people receiving HCBS.

Our proposed definition of direct care worker was intended to broadly define such workers to ensure that the definition appropriately captures the diversity of roles and titles across States that direct care workers may have. We included workers with professional degrees, such as nurses, in our proposed definition because of the important roles that direct care workers with professional degrees play in the care and services of people receiving HCBS, and because excluding workers with professional degrees may increase the complexity of reporting, and may unfairly punish States, managed care plans, and providers that disproportionately rely on workers with professional degrees in the delivery of HCBS. We also proposed to define direct care workers to include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. This proposed definition is in recognition of the varied service delivery models and employment relationships that can exist in HCBS waivers. We requested comment on whether there are other specific types of direct care workers that should be included in the definition, and whether any of the types of workers listed should be excluded from the definition of direct care worker.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported finalizing the definition of direct care worker as proposed. However, one commenter opposed the entire definition. The commenter noted that the definition, which resembles a definition of direct care worker used by the Department of Labor, is distinguishable from the definition used by the Bureau of Labor Statistics. The commenter recommended that no definition should be finalized until there has been an interagency workgroup to review and coordinate the different definitions.

Response: As discussed earlier in this section II.B.5.e. of this rule, our proposed definition of direct care worker was intended to capture the diversity of roles and titles across States that direct care workers may have. It was also intended to include individuals in the

varied service delivery models and employment relationships that can exist in HCBS waivers. As discussed later in this section II.B.5.e. of this rule, we are finalizing the definition of direct care worker largely as proposed with a modification to clarify that direct care workers include nurses and other staff providing clinical supervision, as we do not want to discourage clinical oversight that contributes to the quality of services by creating a disincentive for providers to hire clinicians when necessary. We believe that the definition of direct care worker, as finalized, appropriately defines direct care worker for the specific purposes of the requirements in § 441.302(k), and we note that it was subject to interagency review.

Comment: Several commenters supported including clinicians (such as those we proposed at § 441.302(k)(1)(ii)(A)) in the definition of direct care worker. Commenters noted that providers are often required to have clinicians on staff and that such clinicians are critical to ensuring quality of care. A few commenters, however, expressed ambivalence or reservations about including clinicians in the definition of direct care worker. One commenter noted that some States do not include nurses in their State definitions of direct care worker. A few commenters observed that because clinicians (including nurses) generally earn higher wages, providers that employ clinicians will have an easier time reaching the minimum performance level for direct care worker compensation or that the higher wages of clinicians will mask the lower wages of direct care workers who do not have professional degrees and generally earn lower wages.

Response: We continue to believe it is appropriate to include clinicians (such as registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) in the definition of direct care worker and are finalizing the definition in this final rule with these clinicians included. There is a shortage of nurses and other clinicians delivering HCBS, and we believe it is important to support these members of the HCBS workforce (especially as they also work directly with beneficiaries). We echo observations from commenters that some services are required to be delivered or monitored by clinicians. We also would not want to discourage

clinical oversight that contributes to the quality of services by creating a disincentive for providers to hire clinicians when necessary. Therefore, we are clarifying that our definition of direct care worker is intended to include nurses and other staff who directly provide services to beneficiaries or who provide clinical supervision. However, consistent with the proposed rule, our definition is intended to exclude staff who provide administrative supervision. We are finalizing a modification at the end of § 441.302(k)(1)(ii)(F) to specifically include nurses and other staff providing clinical supervision.

Comment: One commenter suggested that if a State requires that a program employ a nurse to perform occasional beneficiary visits, the State should pay the nurses directly, rather than requiring the providers to pay them.

Response: We thank the commenter for this suggestion. While we do not intend to establish specific requirements for how States pay for services provided by nurses, we agree that this could be a solution for States that would prefer for providers to reach the payment adequacy requirement without relying on salaries for clinical staff. We decline to make changes in this final rule based on this comment.

Comment: A number of commenters requested that we include private duty nurses, including registered nurses, licensed practical nurses, and certified nursing assistants, in the definition of direct care worker.

Response: We note that private duty nurses are not necessarily a separate category of worker, but rather registered nurses, licensed practical nurses, or certified nursing assistants who provide services classified and billed as private duty nursing. As a technical matter, we clarify that only registered nurses and licensed practical nurses may provide private duty nursing services authorized under § 440.80. As discussed above, these types of clinicians are included in the definition of direct care worker in § 441.302(k)(1)(i)(A) so long as they are providing one of the three HCBS services specified in the minimum performance requirement (homemaker, home health aide, or personal care services). However, private duty nursing is not one of the services

we have proposed, and are finalizing, for application of this the minimum performance requirement.

Comment: Many commenters recommended that nurse supervisors be included in the definition of direct care workers. Several of these commenters noted that these are required positions for their programs. Some commenters observed that nurse supervisors perform important activities like supervising and training other direct care workers, coordinating beneficiaries' care, or completing documentation and other paperwork specific to beneficiaries' care (as opposed to paperwork related to business administration). Several commenters stated that clinical supervision is critical to the quality of HCBS. A few commenters noted that nurse supervisors sometimes visit beneficiaries or provide direct services when filling in for absent direct care workers.

One commenter noted support for excluding general administrative or supervisory staff from the definition of direct care workers. A few commenters expressed concerns about the exclusion of administrative or supervisory staff who may sometimes also provide services to beneficiaries. Some of these commenters noted that especially during workforce shortages, administrative staff or supervisors may fill in for direct care workers. A couple of commenters requested clarification on how wages for staff who perform both direct care work and administrative or supervisory work should be counted for the purposes of complying with the minimum performance level. One commenter requested clarification on whether first line supervisors of direct support professionals are included in the definition of direct care workers.

Several commenters stated that they opposed the exclusion of supervisory or managerial staff because these are required positions for their programs. Several commenters noted that staff who provide supervision or perform administrative tasks, such as understanding and reviewing compliance and other regulatory requirements, are critical to quality. One commenter expressed the concern that excluding supervisory or managerial staff from the 80 percent minimum performance level would mean that providers would have to lower the salaries of these

positions, and then in turn may have trouble filling these positions. One commenter raised concerns about “wage compression,” with providers reducing wages for higher-skilled jobs or paying these jobs more like entry-level jobs.

Response: We are persuaded that nurses or other staff who provide clinical oversight and training for direct care workers participate in activities directly related to beneficiary care (such as completing or reviewing documentation of care), are qualified to provide services directly to beneficiaries, and periodically interact with beneficiaries should be included in the definition of direct care workers at § 441.302(k)(1)(ii). As noted earlier, we are modifying our definition of direct care worker at § 441.302(k)(1)(ii)(F) to clarify that it includes nurses and other staff providing clinical supervision. However, consistent with the proposed rule, our definition is intended to exclude staff who provide administrative supervision (such as overseeing business operations).

While we acknowledge that administrative staff and administrative supervisors are often required staff and perform essential functions (including quality and compliance reporting and recordkeeping), we believe it is critical for the economic and efficient use of Medicaid funds that the vast majority of Medicaid payment for homemaker, home health aide, and personal care services must go to supporting the core activities of that service; the core activities of homemaker, home health aide, and personal care services are performed by direct care workers. As discussed above, evidence specifically shows that direct care workers are paid low wages and, thus, our priority is ensuring a greater share of Medicaid payments go to direct care workers’ compensation. If there is an insufficient number of direct care workers employed by a provider, then those HCBS cannot be delivered, and beneficiaries may not be able to access the HCBS they need. We will continue to partner with States to help providers find efficient ways to support their administrative and reporting requirements.

Comment: Many commenters expressed concern that direct support professionals were excluded from the definition of direct care worker, as direct care workers are often associated

with provision of services to older adults and people with physical disabilities, while direct service professionals typically provide services to people with intellectual and developmental disabilities.

Response: We note that direct support professionals are explicitly included in the definition of direct care worker at § 441.302(k)(1)(ii)(C), so there is no need to further modify the definition of direct care worker in response to these comments. If someone designated by their State as a direct support professional provides a service that is subject to the minimum performance requirement, their compensation will be included in the calculation for the minimum performance level.

Comment: One commenter suggested that payments to contract employees should not count toward the minimum performance level.

Response: Given the varied nature of HCBS programs, we specifically proposed for the definition of direct care worker at § 441.302(k)(1)(ii)(G) to encompass a broad array of employment relationships. We cannot find sufficient justification for excluding certain types of employment relationships from this requirement and are finalizing our definition of direct care worker to include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model, as proposed. However, we are making a technical modification for clarity to not finalize § 441.302(k)(1)(ii)(G) and to add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii).

Comment: One commenter opposed including workers who deliver services via a self-directed services delivery model in the definition of direct care workers. They noted that including these workers would “chip away at the uniqueness at the heart of the self-direction paradigm,” unintentionally burden self-directed employers and employees, reduce autonomy by introducing a single title for a wide variety of caregiving types, and would not recognize the

flexible and interdependent nature of self-direction or the fact that Medicaid beneficiaries who self-direct their services do not retain the funds that remain in budgets at the end of the year.

Response: We thank the commenter for raising their concerns. We decline to make modifications to the definition of direct care worker to exclude direct care workers providing services in self-directed services delivery models generally. We believe it is important for States to have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, as required by section 2402(a)(1) of the Affordable Care Act, regardless of whether they are receiving services through a self-directed services delivery model or a model that is not self-directed. Further, we believe it is important for States to have a sufficient number of qualified direct care workers to provide self-directed personal assistance services, as required by section 2402(a)(3)(B)(iii) of the Affordable Care Act.

However, we do agree that there are certain self-directed services delivery models for which the minimum performance level at (k)(3) would not be appropriate. We intend to apply the requirements at § 441.302(k)(3) to models in which the beneficiary directing the services is not setting the payment rate for the worker (such as agency-provider models). We do not intend to apply the requirements to self-directed services delivered through models in which the beneficiary sets the payment rate for the worker (such as in individual budget authority models). In the latter scenario, we expect that all or nearly all of that payment rate routinely is spent on the direct care worker's compensation. We are finalizing a new requirement at § 441.302(k)(2)(ii) that clarifies this policy; this requirement is discussed in greater detail in section II.B.5.g. of this final rule.

After consideration of the comments received, we are finalizing the definition of direct care worker at § 441.302(k)(1)(ii) with technical modifications for clarity to change the term, Medicaid-eligible individuals, to the term, Medicaid beneficiaries, in both § 441.302(k)(1)(ii)(A) and (F). We are finalizing § 441.302(k)(1)(ii) with a modification at the end of § 441.302(k)(1)(ii)(F) to provide that direct care workers include nurses and other staff providing

clinical supervision. The finalized revised text at § 441.302(k)(1)(ii)(F) will read: Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving HCBS available under this subpart, including nurses and other staff providing clinical supervision. We are making a technical modification to not finalize § 441.302(k)(1)(ii)(G) and add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii) to clarify that a direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

f. Reporting (§ 441.302(k)(2))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. At § 441.302(k)(2), under our authority at section 1902(a)(6) of the Act, we proposed to require that States demonstrate that they meet the minimum performance level at § 441.302(k)(3)(i) through new Federal reporting requirements at § 441.311(e). We discuss these reporting requirements in our discussion of proposed § 441.311(e) in section II.B.7 of this final rule.

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We also direct the reader to the discussion of § 441.311(e) in section II.B.7. of this final rule for additional comments and responses.

Comment: A number of commenters, while not supporting the minimum performance requirement, did express support for the requirement that States must collect and report data on the percent of Medicaid payments for certain HCBS going to compensation of direct care workers. Commenters noted this reporting could yield important data about the compensation to workers and allow for national comparisons.

Response: We agree with commenters that the reporting requirement proposed at § 441.311(e) will yield important data about compensation to workers that will help support the HCBS direct care workforce and promote better oversight of how Medicaid payments for certain services are used.

We note that, while several commenters encouraged us to finalize the reporting requirement at § 441.311(e) without finalizing the minimum performance requirement at § 441.302(k)(3), no commenter suggested that we finalize the minimum performance requirement without a reporting requirement. We believe that the reference included in § 441.302(k)(2) to the reporting requirement at § 441.311(e) is necessary for CMS to oversee States' compliance with the minimum performance requirement at § 441.302(k)(3); however, the reporting requirement at § 441.311(e) is distinct and severable from the minimum performance requirement at § 441.302(k). As discussed in more detail in section II.B.7, the reporting requirement at § 441.311(e), which we are finalizing with modifications, addresses a broader universe of services than is included in the minimum performance level at § 441.302(k)(3) and has an earlier applicability date than the date we are finalizing at § 441.302(k)(8) (discussed later in this section). While we are finalizing both the minimum performance requirement at § 441.302(k)(3) and the payment adequacy reporting requirement, as amended, at § 441.311(e), these represent distinct policies, and we believe that the reporting requirement can (and will) function independently from the minimum performance requirement.

Comment: Several commenters suggested that we add a requirement to § 441.302(k)(2) that would require States, as part of their assurances of compliance with the minimum percentage requirement, to acknowledge and explain any differences between the actual payment rates for home care services and the rate most recently recommended by the interested parties' advisory group under § 447.203(b)(6) of this final rule and discussed in section II.C. of this rule. The commenters suggested that if the actual rate is lower than the recommended rate, the State would also need to explain why it is sufficient to ensure access to services.

Response: Although the interested parties' advisory group will provide an invaluable perspective on the adequacy of rates, as discussed in greater detail later in this preamble, the role of the group finalized at § 447.203(b)(6) is advisory. States will not be required to follow the recommendations of the group. We believe the policies as we are finalizing strike the right balance of accountability and flexibility for wholly new rate processes. We further note the recommendations of the interested parties' advisory group will be posted publicly for review. Finally, we note that we are also finalizing steps a State must take to demonstrate adequate access to services when proposing a rate reduction or restructuring in circumstances that could result in diminished access to care.

After consideration of the comments received, we are finalizing § 441.302(k)(2) with modifications. For reasons discussed in section II.B.5.g. of this final rule, at § 441.302, we are redesignating paragraph (k)(2) as paragraph (k)(2)(i) to allow for the addition of a new requirement at paragraph (k)(2)(ii) regarding treatment of certain payment data under self-directed services delivery models.

As discussed in section II.B.5.b. of this rule, we are finalizing reporting requirements at § 441.302(k)(6) to ensure accountability in the States' use of the small provider minimum performance level and hardship exemptions. To clarify that States must comply with this requirement, as well as the reporting requirement at § 441.311(e), we are finalizing references to § 441.302(k)(6) in § 441.302(k)(2)(i). We also are finalizing a technical modification for clarity that the State must demonstrate **annually**, consistent with the reporting requirements at §§ 441.302(k)(6) and 441.311(e), that they meet the minimum performance level at § 441.302(k)(3). (New text in bold font).

g. Application to Other Authorities (Proposed at § 441.302(k)(4), Finalized at § 441.302(k)(8); and §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi))

At § 441.302(k)(4), we proposed to apply the HCBS requirements described in the proposed rule to services delivered under FFS or managed care delivery systems. As discussed

earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.302(k) with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because workforce shortages exist under other HCBS authorities, which include many of the same types of services to address activities of daily living or instrumental activities of daily living as under section 1915(c) waiver authority, we proposed to include these requirements within the applicable regulatory sections. Specifically, we proposed to apply the proposed requirements at § 441.302(k) to section 1915 (j), (k), and (i) State plan at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(30)(A) of the Act to ensure payments to HCBS providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believed the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of payment adequacy provisions across section 1915(i), (j), and (k) authorities. As noted earlier in section II.B.4. of the proposed rule, to accommodate the addition of new language at § 441.464(e) and (f), we proposed to renumber existing § 441.464(e) as paragraph (g) and existing § 441.464(f) as paragraph (h). We requested comment on whether we

should exempt, from these requirements, services delivered using any self-directed service delivery model under any Medicaid authority.

We considered whether to also apply these proposed payment adequacy requirements to section 1905(a) “medical assistance” State plan personal care and home health services.

However, we did not propose that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We requested comment on whether we should apply these requirements to section 1905(a) State plan personal care and home health services.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported holding providers delivering care in managed care delivery systems accountable for paying a sufficient amount to direct care workers. A few commenters requested that we clarify how this requirement would apply to MCOs, PIHPs, and PAHPs. One commenter noted that managed care plans do not control the payment rates that contracted providers pay their direct care workers.

A few commenters requested that we clarify managed care plans’ responsibility for tracking and reporting expenditures. A few commenters expressed concern that this proposal would pose particular reporting or accounting burdens for providers that participate in multiple Medicaid managed care plans, serve non-Medicaid clients, or receive bundled payments.

Response: We acknowledge commenters’ broad concerns about how these requirements will apply to managed care plans and will provide technical assistance regarding specific questions as they are raised during implementation. However, we are finalizing our proposal to apply the requirements at § 441.302(k) to both managed care and FFS delivery systems. We

clarify here that the requirements in § 441.302(k) are the ultimate responsibility of States, regardless of whether their HCBS are delivered through an FFS delivery system, managed care delivery system, or both. The minimum performance requirement applies at the provider level, not the managed care plan level. We expect that States will develop an appropriate process with their managed care plans should the State determine that managed care plans have some role in activities such as the data collection or reporting required in § 441.302(k)(2) (being finalized as § 441.302(k)(2)(i)). We agree that managed care plans do not control payment rates that contracted providers pay their direct care workers and reiterate that the focus of § 441.302(k) is on the percentage of the payment to providers that is passed along as compensation to direct care workers.

We plan to provide technical assistance to States with managed care delivery systems to minimize provider reporting and accounting burden and to address questions related to bundled payments that include the affected services (homemaker, home health aide, and personal care services).

Comment: A few commenters specifically noted support for applying the payment adequacy requirement to programs authorized under all section 1915 authorities. One commenter did not support applying this requirement to “all 1915 waiver authorities” but did not provide a specific rationale for their recommendation.

Response: We are finalizing §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) (applying § 441.302(k) to section 1915(j), (k) and (i) services, respectively) with minor technical modifications as noted later in this section II.B.5.g. of this final rule.

Comment: A number of commenters expressed concerns about the application of the minimum performance level to self-directed services authorized under sections 1915(j) and 1915(k) of the Act. A few commenters, while not necessarily suggesting that self-directed services should be excluded from the payment adequacy requirement, believed that it would take more time and additional guidance to implement the requirement for self-directed services.

Some commenters raised concerns about the application of the requirement to specific models of self-direction, particularly the self-directed model with service budget (as defined in § 441.545(b)) (often referred to as the individual budget authority model), in which the beneficiary sets the direct care worker's wages. Some commenters worried that the application of the minimum performance level to such models would put the individual beneficiary in the position of acting as a provider for this purpose. Other commenters were concerned that if the minimum performance level was applied to these self-directed services delivery models, beneficiaries would have to apply a set percent of their budget to compensation of workers and thus would lose the flexibility of determining how their budget was spent or what to pay their direct care workers. One commenter pointed out that beneficiaries in self-directed services delivery models do not personally keep unspent funds and, thus, do not stand to profit by lowering direct care workers' wages. A few commenters also requested clarification of how the payment adequacy requirement would impact the co-employment relationship in self-directed services. One commenter noted that the vast majority of HCBS furnished under self-directed services delivery models are paid so that the entire payment rate goes toward direct care worker's wages and other associated costs such as employer taxes, workers' compensation, and other employer requirements such as State-mandated paid sick leave, while payment for financial management services is paid separately. In these models, nearly 100 percent of the payment rate goes toward the direct care worker's wages and associated costs, which would create an unfair comparison to agency-directed services.

A few commenters noted that it would be undesirable to apply the minimum performance level to HCBS furnished via self-directed services delivery models because these services involve additional activities and costs not associated with other types of services. These commenters noted that services furnished via self-directed services delivery models involve more training and human resources support for the beneficiaries to help them hire and direct their workers. One commenter stated that the proposed minimum performance level of 80 percent

would be too high to accommodate other non-compensation activities included in self-directed services delivery models, such as employment or day activities, case management, and back up supports.

On the other hand, some commenters noted that self-directed services delivery models should be included in the payment adequacy requirements and that it is important to support compensation for direct care workers who provide HCBS via self-directed services delivery models. One commenter noted that most personal care services in the commenter's State are furnished via self-directed services delivery models.

Response: We agree with commenters that the minimum performance requirement may be difficult to apply (and, in fact, may simply be inapplicable) to self-directed services delivery models with service budget authority in which the beneficiary directing the services sets the worker's wages as the payment rate for the service (such as models meeting the definition of § 441.545(b) for section 1915(k) services, or self-directed services typically authorized under the section 1915(j) authority).

We also agree with one commenter who noted that, because of the separate payment of financial management services, nearly all of the payments for personal care, homemaker, and home health aide services furnished via self-directed services delivery models with service budget authority are spent on compensation for direct care workers. We believe that applying the minimum performance requirement to such models would be ineffectual and an unnecessary burden on States.

We believe the minimum performance requirement is appropriate when applied to a Medicaid rate for self-directed services that includes both compensation to direct care workers and administrative activities and in which the beneficiary did not set the payment rate for the worker.

We note that at least some of the "non-compensation activities" identified by one commenter, such as employment or day activities and case management, do not appear to fall

under the specific services to which we proposed, and are finalizing, for the minimum performance requirement to apply, and therefore, they would not likely be subject to the minimum performance requirement as finalized.

To clarify the application of § 441.302(k) to HCBS furnished via self-directed services delivery models, we are finalizing a new requirement at § 441.302(k)(2)(ii), specifying that, if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

We are finalizing the general application of § 441.302(k) to HCBS authorized under section 1915(j), (k), and (i) authorities, with the understanding that some services delivered under these authorities will fall under the exception for self-directed services delivery models being finalized at § 441.302(k)(2)(ii).

We note that the exception at § 441.302(k)(2)(ii) directs States to exclude certain data from the specified excluded self-directed services models when establishing compliance with the minimum performance level or small provider performance level at § 441.302(k)(3). We believe, however, that the regulation text at § 441.302(k) requiring States to assure that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans applies to all self-directed services models offered under all section 1915 authorities.

Comment: Commenters were mixed in their support for excluding section 1905(a) services from the payment adequacy requirement. A few commenters expressed strong support for extending the payment adequacy requirement to services authorized under section 1905(a), particularly commenters writing from States in which larger numbers of beneficiaries receive

section 1905(a) State plan services. One commenter expressed concern that not including section 1905(a) services would disproportionately exclude direct care workers providing services to children or adults with intellectual and developmental disabilities. One commenter noted that section 1902(a)(6) of the Act gives CMS the authority to apply the requirement section 1905(a) services.

However, several commenters did not support applying the requirement to section 1905(a) State plan services. Many of these commenters simply did not support applying the minimum performance requirement to services under any authority. A few commenters agreed with our concerns that applying the payment adequacy requirement to section 1905(a) State plan services would pose a particular burden on States due to differences in how these services are delivered and monitored.

Several commenters expressed concerns about potential unintended consequences of not applying the minimum performance requirement to section 1905(a) State plan services. In particular, some commenters raised concerns that direct care workers would stop working for providers that deliver section 1905(a) services, in favor of working for providers that were subject to the minimum performance requirement. On the other hand, a few commenters worried that providers would stop providing services under section 1915 authorities and switch to providing section 1905(a) services to avoid having to comply with the payment adequacy requirement.

Response: At this time, we are not requiring the application of the HCBS payment adequacy requirements at § 441.302(k) to section 1905(a) services. Given our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will take these comments under consideration for any potential future rulemaking regarding section 1905(a) services.

Comment: One commenter requested clarification as to whether the payment adequacy requirements would apply to services delivered under section 1115 authority.

Response: At § 441.302(k)(4) (which we are finalizing at § 441.302(k)(8)), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems, including those authorized under section 1115(a) of the Act. We are finalizing this requirement in this final rule, with modifications as noted herein, including retaining the application to managed care delivery systems authorized section 1115(a).

After consideration of public comments, and for reasons discussed in sections II.B.5.b. and II.B.5.h. of this rule, we are finalizing § 441.302(k)(4) with modifications to redesignate § 441.302(k)(4) as § 441.302(k)(8) and change the date for States to comply with the requirements at § 441.302(k) from 4 years to 6 years. We are finalizing § 441.302(k)(8) with minor modifications to correct erroneous uses of the word “effective.” We are retitling the requirement at § 441.302(k)(8) as Applicability date (rather than Effective date). We are also modifying the language at § 441.302(k)(8) to specify that States must comply with the requirements in § 441.302(k) beginning 6 years after the effective date of this final rule, rather than stating that § 441.302(k)(8) is effective 6 years after the effective date of the final rule. In addition, we are finalizing technical modifications to the language pertaining to the applicability date for States providing services through managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy.

As finalized, the redesignated § 441.302(k)(8) reads: *Applicability date. States must comply with the requirements set forth in paragraph (k) of this section* beginning 6 years after the effective date of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes **homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4)** in the MCO’s, PIHP’s, or PAHP’s contract, *the first rating period for contracts with the MCO, PIHP, or PAHP beginning* on or after **the date that is** 6 years after the **effective** date of this paragraph. (New language identified in bold.)

After consideration of the comments, as noted above in this section, we are finalizing a requirement at § 441.302(k)(2)(ii) specifying that if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

We are finalizing the application of § 441.302(k) to section 1915(j), (k), and (i) services with minor modifications. We are finalizing a technical modification to clarify that the reference to person-centered service plans in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) is to beneficiaries' person-centered service plans. We are also clarifying in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) that while § 441.302(k) applies to services delivered under these authorities, references to section 1915(c) of the Act are instead references to sections 1915(j), (k), or (i), as appropriate.

Additionally, to ensure application of all relevant requirements of § 441.302(k) to section 1915(i) and (k) authorities, we are also finalizing a modification to §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) to clarify that the reporting requirement at § 441.302(k)(6) applies to section 1915(j), (k) and (i) authorities, respectively. (We note that discussion of the finalization of §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) is in II.B.7. of this final rule.) We note that while we are applying the requirement at § 441.302(k)(6) to section 1915(j), (k), and (i) authorities, States would only be required to comply with this reporting requirement if the State provided services under these authorities described in § 441.302(k)(2)(i) and if the State meets the other criteria set forth in § 441.302(k)(6).

h. Applicability date (Proposed at § 441.302(k)(4), Being Finalized at § 441.302(k)(8))

As noted throughout the HCBS provisions in this preamble, we recognize that many States may need time to implement these requirements, including to amend provider agreements

or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these proposed payment adequacy requirements. We expect that these activities will take longer than similar activities for other HCBS provisions in the rule. Further, we expect that it will take a substantial amount of time for managed care plans and providers to establish the necessary systems, data collection tools, and processes necessary to collect the required information to report to States. As a result, we proposed at § 441.302(k)(4), to provide States with 4 years to implement these requirements in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP, beginning on or after 4 years after the effective date of the final rule to implement these requirements. Similar to our rationale in other sections, this proposed timeline reflects feedback from States and other interested parties that it could take 3 to 4 years for States to complete any necessary work to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered the overall burden of the proposed rule as a whole in proposing the effective date for the payment adequacy provision. We invited comments on the overall burden associated with implementing this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (such as 3 years) or longer timeframe (such as 5 years) to implement the payment adequacy provisions and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal that the minimum performance requirement go into effect four years after the publication of this final rule. One commenter noted that 4 years should be sufficient time for States and providers to make necessary adjustments. A few commenters noted that 4 years was too long, given the urgency of the workforce shortage. One commenter suggested that we require the minimum performance requirement go into effect January 1, 2025, while another commenter suggested a 2-year effective date. One commenter suggested the requirement should go into effect in 3 years, to align with some of the other proposed effective dates in this rule.

Other commenters recommended that we allow for a longer effective date, such as 6 years. Commenters noted that large-scale changes, such as what would be required to comply with the minimum performance requirement, would take time.

Several commenters suggested that compliance with the minimum performance requirement be phased in over time to give providers and States an opportunity to adjust their systems and policies.

Response: While we are sympathetic to commenters' sense of urgency regarding the workforce shortage, we do not believe it is realistic for States to comply with the requirements earlier than the proposed four years. We agree with commenters that, for some States, ensuring that a minimum percent of Medicaid payments go to direct care worker compensation (and tracking compliance with this requirement) will require a period of adjustment. We do expect that providers should already be aware of their Medicaid revenues and what they pay their workers; however, we acknowledge that they may not already be reporting this information to the States and that the States will need to work with their providers to develop an appropriate reporting mechanism. We also understand that some providers will have to adjust how they operate their business in order to meet the required minimum performance level. We also acknowledge that we will need to provide additional subregulatory guidance and technical assistance to aid in implementation.

We agree with commenters that a slightly longer date for States to comply with the requirements is necessary. We believe that the complementary reporting requirement at § 441.311I (discussed in section II.B.7. of this rule) can be leveraged to create a transition period to aid States in their compliance with § 441.302(k)(3). As such, we are finalizing § 441.302(k)(8) with a modification to change the date for States to comply with the requirements from 4 years to 6 years. The data collected as part of § 441.311(e) will give States feedback on how close they are to reaching the minimum performance level and will help CMS develop targeted technical assistance for States that are farther away from attaining compliance. For States electing to create a State-defined minimum performance level for small providers, this period between reporting and performance will also allow States to make any necessary adjustments to their State-defined minimum performance levels. It will also allow States to make any necessary adjustments to their criteria for hardship exemptions and to identify providers who need hardship exemptions. We will continue to use our standard enforcement tools and discretion, as appropriate, when the requirements at §§ 441.302(k) go into effect.

As noted in section II.B.5.b. and II.B.5.h. of this section, we are creating new requirements at § 441.302(k)(4) through (7) and thus are redesignating proposed § 441.302(k)(4) as § 441.302(k)(8) and finalizing § 441.302(k)(8) with the modifications as noted in section II.B.5.b. of this final rule. We are finalizing § 441.302(k)(8) with minor modifications to correct erroneous uses of the word “effective.” We are retitling the requirement at § 441.302(k)(8) as Applicability date (rather than Effective date). We are also modifying the language at § 441.302(k)(8) to specify that States must comply with the requirements in § 441.302(k) beginning 6 years after the effective date of this final rule, rather than stating that § 441.302(k)(8) is effective 6 years after the effective date of the final rule. In addition, we are finalizing technical modifications to the language pertaining to the applicability date for States providing services through managed care delivery systems to improve accuracy and alignment

with common phrasing in managed care contracting policy. i. Summary of Finalized

Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.302(k) as follows:

- We are finalizing the assurance requirement at § 441.302(k) with technical modifications.
- We are finalizing § 441.302(k)(1) with a technical modification.
- The definition of compensation at § 441.302(k)(1)(i) (now also at § 441.311(e)(1)(i)) and finalized as proposed, with the exception of § 441.302(k)(1)(i)(B) (now also at § 441.311(e)(1)(i)(B)), which is revised to read: Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement).
- The definition of direct care worker at § 441.302(k)(1)(ii) (now also at § 441.311(e)(ii)) is finalized with technical modifications to § 441.302(k)(1)(ii)(A) and (F) (now also at § 441.311(e)(1)(ii)(A) and (F)). We are also finalizing the following addition at the end of § 441.302(k)(1)(ii)(F) (now also at § 441.311(e)(1)(ii)(F)), including nurses and other staff providing clinical supervision. The revised text at § 441.302(k)(1)(ii)(F) (now also at § 441.311(e)(1)(ii)(F)) will read as follows: Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision. In addition, we are making a technical modification to not finalize § 441.302(k)(1)(ii)(G) and add language proposed at § 441.302(k)(1)(ii)(G) to the end of § 441.302(k)(1)(ii) to clarify that a direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model.

- A definition of excluded costs is finalized at § 441.302(k)(1)(iii) (now also at § 441.311(e)(1)(iii)) as follows:

Excluded costs means costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Costs of personal protective equipment for direct care workers.

- Section 441.302(k)(2) is finalized with modifications. We are redesignating the language at § 441.302(k)(2) as § 441.302(k)(2)(i). We are finalizing § 441.302(k)(2)(i) to include references to the reporting requirements that are finalized at §§ 441.302(k)(6) and 441.311(e) and the exception finalized at § 441.302(k)(2)(ii). We also made a technical modification for clarity that the State must demonstrate **annually**, consistent with the reporting requirements at §§ 441.302(k)(6) and 441.311(e), that they meet the minimum performance level at § 441.302(k)(3). In addition, we made technical modifications for clarity and precision to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies and to specify that these requirements apply to services authorized under section 1915(c) of the Act, unless excepted under § 441.302(k)(2)(ii).

- We are finalizing a new requirement at § 441.302(k)(2)(ii) that clarifies that if the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State would not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3).

- Section 441.302(k)(3) is finalized with several modifications to retitle the requirement as “*Minimum performance at the provider level*” and clarify the components of the required calculation and the services that fall within this requirement. Section 441.302(k)(3) is also finalized with modifications to clarify that excluded costs are not included in the calculation of the percentage of total payments to a provider that is spent on compensation to direct care workers and to specify the specific services (homemaker, home health aide, and personal care services) to which the payment adequacy requirement applies. We are also modifying § 441.302(k)(3) to note the exceptions to the minimum performance level that we are adding at (k)(5) (hardship exemption) and (k)(7) (IHS and Tribal health programs subject to 25 U.S.C. 1641).

- Section 441.302(k)(3)(i) is finalized with a clarification that the minimum performance level of 80 percent applies to all payments to a provider, except as provided in paragraph (k)(3)(ii).

- Section 441.302(k)(3)(ii) is amended to add an option for States to set a State-defined small provider minimum performance level. As finalized, § 441.302(k)(3)(ii) reads: (ii) At the State’s option, providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) on total compensation for direct care workers who furnish those services.

- An option for States to develop criteria to identify small providers to meet the State-defined small provider minimum performance level is added at new § 441.302(k)(4).

- An option for States to provide some providers with a hardship exemption is added at new § 441.302(k)(5).

- Reporting requirements are finalized at § 441.302(k)(6), establishing reporting requirements for States that utilize the small provider minimum performance level and hardship

exemption options finalized at § 441.302(k)(4)(ii) and (k)(5), as well as a waiver of these requirements that may be granted under certain circumstances.

- An exemption from the requirements at § 441.302(k) is finalized for IHS and Tribal health programs subject to 25 U.S.C. 1641 at § 441.302(k)(7).
- Section 441.302(k)(4) is renumbered as § 441.302(k)(8) and is finalized, with other technical modifications, to specify that States must comply with the requirements set forth at § 441.302(k)(8) beginning 6 years from the effective date of this final Rule.
- We are finalizing §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) with technical modification to clarify that the references to person-centered service plans in §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi) are to beneficiaries' person-centered service plans. We are also finalizing modifications to clarify that § 441.302(k) applies to services delivered under these authorities, except that references to section 1915(c) of the Act are instead references to sections 1915(j), (k), or (i) of the Act, as appropriate.
- We are finalizing a modification to §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) to clarify that the reporting requirement at § 441.302(k)(6) applies to section 1915(j), (k) and (i) authorities, respectively.

6. Supporting Documentation Required (§ 441.303(f)(6))

As discussed in the proposed rule (88 FR 27986), States vary in whether they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services. This can overestimate the number of people who need Medicaid-covered HCBS because the waiting lists may include individuals who are not eligible for

services. According to the Kaiser Family Foundation, over half of people on HCBS waiting lists live in States that do not screen people on waiting lists for eligibility.¹¹⁸

We have not previously required States to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI¹¹⁹ discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists. In addition, we have found, over the past several years in particular, that some States are operating waiting lists for their section 1915(c) waiver programs despite serving fewer people than their CMS-approved enrollment limit or cap, even though States are expected to enroll individuals up to their CMS-approved enrollment limit or cap before imposing a waiting list. However, because we do not routinely collect information on States' use of waiting lists and the number of people on waiting lists, we are unable to determine the extent to which States are operating such unauthorized waiting lists or to work with States to address these unauthorized waiting lists.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Based on the authority found at section 1902(a)(6) of the Act, we proposed to require information from States on waiting lists to improve public transparency and processes related to States' HCBS waiting lists and ensure that we are able to adequately oversee and monitor States' use of waiting lists in their section 1915(c) waiver programs. To address new proposed requirements at § 441.311(d)(1), described in section

¹¹⁸ Burns, A., M. O'Malley Watts, M. Ammula. A Look at Waiting lists for Home and Community-Based Services from 2016 to 2021. Kaiser Family Foundation. <https://www.kff.org/47f8e6f/>.

¹¹⁹ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

II.B.7. of this rule, on State reporting on waiting lists, we proposed to amend § 441.303(f)(6) by adding a sentence to the end of the existing regulatory text to require that if the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

We received public comments on these proposals. The following is a summary of the comments we received and our responses. We also received a number of comments on the related reporting requirement at § 441.311(d). Those comments are addressed in section II.B.7.

Comment: A few commenters shared local data and anecdotal experiences about States' waiting lists, which some described as containing thousands of people and requiring beneficiaries to wait for long periods of time, even years, before accessing services. One commenter observed that as demand for HCBS grows, the waiting lists will also grow. A few commenters expressed concerns that the long waiting times may result in beneficiaries having to enter institutional care. Commenters also noted that beneficiaries and their families experience confusion regarding waiting lists, including how long they will have to remain on the waiting list before receiving services; commenters noted that this confusion or lack of transparency can make it difficult for beneficiaries to make informed decisions or plan for future care needs.

A few commenters specifically supported our proposed amendment to § 441.303(f) that would require States to report information on waiting lists for section 1915(c) waiver programs, which commenters believed would contribute to transparency and provide additional data to help make future changes within HCBS programs. Commenters believed that a requirement to report this information would improve CMS's ability to provide oversight and to hold States accountable for waiting list practices. A few commenters believed that creating reporting requirements for waiting lists is a necessary step toward the larger goal of reducing HCBS waiting lists through expansion of HCBS programs. A few commenters noted this information is critical when requesting additional appropriations from State legislatures to expand HCBS programs.

Response: We thank the commenters for their support and for sharing their experiences and perspectives. We agree that collecting and reporting data on waiting lists is a critical step in identifying unmet needs among beneficiaries and can support the efficient administration and expansion of HCBS programs.

Comment: A few commenters expressed opposition to adding a reporting requirement for section 1915(c) waiver programs. Commenters noted concerns that this requirement would necessitate changes in States' data collection processes and IT systems.

Response: We address commenters' concerns in more detail in the discussion of § 441.311(d) in section II.B.7. of this rule. As we note in that section, we have designed the reporting requirement to minimize administrative burden on States while still generating valuable data about waiting lists needed to support transparency and accountability. We plan to offer States technical assistance as needed to help align their current data collection practices with what will be needed to comply with this reporting requirement.

After consideration of the public comments, we are finalizing the requirements at § 441.303(f) as proposed. We note that specific recommendations regarding the reporting requirement are addressed in section II.B.7. as part of the discussion of § 441.311(d).

7. Reporting Requirements (§§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. As discussed in section II.B.1. of the proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we requested States to report on State-developed performance measures across several domains, as part of an overarching HCBS waiver quality strategy. The 2014 guidance established an expectation that States conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures. Under our authority at

section 1902(a)(6) of the Act, we proposed requirements at § 441.311, in combination with other proposed requirements identified throughout the proposed rule, to supersede and fully replace the reporting metrics and the minimum 86 percent performance level expectations for States' performance measures described in the 2014 guidance.

The reporting requirements we proposed in the proposed rule represented consolidated feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties on improving and enhancing section 1915(c) waiver performance to integrate nationally standardized quality measures into the reporting requirements, address gaps in existing reporting requirements related to access and the direct service workforce, strengthen health and welfare and person-centered planning reporting requirements, and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. The intent of the proposed reporting requirements was to allow us to better assess State compliance with the statutory and regulatory requirements for section 1915(c) waiver programs. As indicated at the end of this preamble section, we proposed that the reporting requirements at § 441.311 also apply to State plan options authorized under section 1915(i), (j) and (k) of the Act, as well as to both FFS and managed care delivery systems, unless otherwise indicated.

We proposed, at § 441.311(a), a regulation setting forth the statutory basis and scope of the reporting requirements in § 441.311.

We did not receive comments on § 441.311(a). Based on further consideration, we are finalizing § 441.311(a) with a modification for clarity to remove "simplification" and make a minor formatting change to ensure § 441.311(a) aligns directly with the statutory requirement at section 1902(a)(19) of the Act.

We also note that, consistent with statements we made in the introduction of sections II. and II.B. of this final rule regarding severability, we intend that each provision in § 441.311 of this final rule is, as finalized, distinct and severable to the extent it does not rely on another final

policy or regulation that we proposed. While we intend that each of the provisions being finalized within § 441.311, and policies and regulations being finalized elsewhere in this rule, present a comprehensive approach for our oversight of States' Medicaid programs and improving HCBS, we also intend that each reporting requirement within § 441.311 is distinct and severable from one another and from other policies and regulations, being finalized in this rule as well as those rules and regulations currently in effect, to the extent applicable.

Specifically, we proposed, and are finalizing, various reporting requirements in § 441.311 to provide mechanisms for us to oversee States' compliance with other policies being finalized in this rule, such as reporting requirements at § 441.311(b)(1) through (2) for incident management system and critical incident requirements under § 441.302(a)(6), as well as to collect data to support future policy considerations to address the direct care worker shortage at § 441.311(e). While we intend them to be distinct and severable, we are finalizing these reporting requirements in § 441.311 to consolidate them in one place in regulation so they are easier to find. They are not interdependent to the extent each does not rely on another final policy or regulation that we proposed and are finalizing in this rule. We believe that the reporting requirements being finalized herein at § 441.311(b)(1) through (4), (c), (d)(1) and (2), and (e) are each valuable on their own and would provide critical data and oversight even in a circumstance where individual provisions within § 441.311 were not finalized or implemented; however, we note that in this final rule, we are finalizing all reporting requirements in § 441.311, albeit some with modifications, as discussed in this section.

a. Compliance Reporting

(1) Incident Management System Assessment (§ 441.311(b)(1) and (2))

As noted earlier in section II.B.3. of this rule, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. This is despite State efforts to implement statutory and regulatory requirements to protect the health and welfare of individuals

receiving section 1915(c) waiver program services, and State adoption of related subregulatory guidance. In addition, a July 2019 survey of States that operate section 1915(c) waivers found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Based on these findings and reports, as well as feedback obtained during various public engagement activities conducted with interested parties over the past several years to standardize and strengthen health and welfare reporting requirements, we proposed new requirements for States' incident management systems at § 441.302(a)(6), as discussed in section II.B.3. of this preamble. We also proposed new reporting requirements that will allow us to better assess State compliance with the requirements at § 441.302(a)(6).

Relying on our authority at section 1902(a)(6) of the Act, at § 441.311(b), we proposed to establish new compliance reporting requirements. Specifically, at § 441.311(b)(1)(i), we proposed to require that States report every 24 months on the results of an incident management system assessment to demonstrate that they meet the requirements at § 441.302(a)(6) that the State operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents, including that:

- The State define critical incidents to meet the proposed minimum standard definition at § 441.302(a)(6)(i)(A);

- The State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents as proposed at § 441.302(a)(6)(i)(B);

- The State require that providers report any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(C);

- The State use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(D);

- The State ensure records being used as part of the incident management system are handled in compliance with 45 CFR 164.510(b), and records with protected health information are obtained and used with beneficiary consent at § 441.302(a)(6)(i)(E);

- The State share information on reported incidents, the status and resolution of investigations, such as through the use of information sharing agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation, as proposed at § 441.302(a)(6)(i)(E); and

- The State separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes as proposed at § 441.302(a)(6)(i)(F).

Given the risk of preventable and intentional harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect

among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believed the proposed requirement for States to report every other year on the results of an incident management system assessment is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. In the absence of such a reporting requirement, we believed that we are unable to determine whether States have effective systems in place to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery; ensure that States are protecting the health and welfare of individuals receiving section 1915(c) waiver program services; and safeguard people receiving section 1915(c) waiver program services from preventable or intentional harm.

In proposing an every 24-month timeframe for reporting, we were attempting to take into account the likely frequency of State changes to policies, procedures, and information systems, while also balancing State reporting burden and the potential risk to beneficiaries if States have incident management systems that are not compliant with the proposed requirements at § 441.302(a)(6). We believed an every 24-month timeframe for reporting is sufficient to detect substantial changes to policies, procedures, and information systems and ensure that we have accurate information on States' incident management systems. We also proposed, at § 441.311(b)(1)(ii), to allow States to reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined to meet the requirements at proposed § 441.302(a)(6). We invited comments on whether the timeframe for States to report on the results of the incident management system assessment is sufficient or if we should require reporting more frequently (every year) or less frequently (every 3 years). We also invited comment on whether we should require reporting more frequently (every 3 years or every 4 years) for States that are determined to have an incident management system that meets the requirements at § 441.302(a)(6). If an alternate timeframe is recommended, we requested that commenters provide the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the incident management system requirements. Those comments and our responses are in section II.B.3. of this final rule.

Comment: A few commenters generally supported the proposed incident management requirements being finalized at § 441.302(a)(6), which are the subject of the reporting requirement at § 441.311(b)(1). One commenter questioned how these reporting requirements would interact with current State reporting requirements related to critical incidents or other waiver reporting requirements.

Response: We thank commenters for their support. We expect to implement new reporting forms for the new reporting requirements that we are finalizing in this final rule, including the critical incident reporting requirements. We also expect to modify existing reporting forms, particularly to remove the reporting requirements in the 2014 guidance¹²⁰ that are being superseded and fully replaced by the requirements in this final rule. We note that some components of the existing reporting forms may remain in effect to the extent that they cover other requirements that remain unchanged by the requirements that we are finalizing in this final rule. States and interested parties will have an opportunity to comment on the new reporting forms and the revised forms through the Paperwork Reduction Act notice and comment process. Further, we expect that States will be able to build on existing systems to comply with the requirements being finalized in this rule at §§ 441.302(a)(6) and 441.311(b)(1) (discussed in sections II.B.3. and II.B.7. of this rule, respectively.) We plan to provide technical assistance to specific State questions, as needed, about how these requirements can align and interact with current practices.

¹²⁰ We note that, although States will no longer be expected to meet the reporting requirements and 86 percent minimum performance level in the 2014 guidance, the six assurances and related subassurances in the 2014 guidance continue to apply.

Comment: A few commenters requested clarification on the assessment that is mentioned in § 441.311(b)(1)(i). Commenters requested more information on the contents of the assessment States must perform of their incident management systems and how States should report the results of the assessment. A few commenters requested more detail on the reporting template and when the report would need to be submitted. A few commenters expressed the hope that the reporting timing could be aligned with waiver years or other administrative deadlines. One commenter inquired if States were expected to pay for the assessment. One commenter requested clarification on the deadline for when this assessment must be completed. A few commenters noted that the assessment was required to be performed annually.

Response: The assessment that States perform of their systems will include review of the elements being finalized at § 441.302(a)(6). The requirements we are finalizing in § 441.302(a)(6) is discussed in detail in section II.B.3. of this final rule. The assessment results will be collected as part of the overall data collection activities associated with the reporting requirements in § 441.311. Per § 441.311(f), as finalized herein (and discussed below in this section II.B.7.), States will be required to comply with the reporting requirement for § 441.311(b)(1) beginning 3 years after the effective date of this final rule. This means that States will be required to submit the assessment results to CMS in three years; thus, assessments should be performed in time for States to meet this timeframe. We will be making the required assessment and reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance.

We anticipate that the costs that States incur to conduct and report on the results of the assessment will be eligible for Federal match as an administrative activity. Current Medicaid Federal matching funds are available for State expenditures on the design, development, and installation (including enhancements), and for operation, of mechanized claims processing and information retrieval systems. Under section 1903(a)(7) of the Act, Federal matching funds are

available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan. This may include the costs that States incur to conduct and report on the results of the incident management assessment.

We also clarify that there is not a requirement that the incident management assessment be performed annually. As discussed in greater detail below, §§ 441.311(b)(1)(i) and (ii) require that States must submit an incident management assessment every 24 months unless CMS determines the system meets the requirements at § 441.302(a)(6), at which point the assessment must be made every 60 months. Assessments of the incident management system need to be performed as part of this assurance schedule. However, States are welcome to perform assessments more frequently than this schedule requires.

Comment: A few commenters requested that we require States to assess whether the State system tracks the reporting of critical incidents to the designated State Protection and Advocacy system at the same time the incident was reported to the State.

Response: We are declining to make modifications to requirements for States system assessments. We note that commenters made a similar request to add this requirement to the system requirements proposed at § 441.302(a)(6). We also declined to add the requirement to § 441.302(a)(6). We refer readers to section II.B.3. of this rule for the related discussion. However, States are welcome to add other factors to their system assessment beyond the requirements we are finalizing in this rule.

Comment: One commenter requested clarification on the consequences of a State's incident management system being found to be non-compliant with § 441.302(a)(6).

Response: Corrective actions or other enforcement actions will be determined on a case-by-case basis, using our standard enforcement authority, for States with incident management systems that are determined by the assessment to not be compliant with the requirements at § 441.302(a)(6). Additionally, States that do not have compliant systems will be required to perform assessments every 24 months, as required by § 441.311(b)(1)(i) until CMS determines

that the system meets the requirements of § 441.302(a)(6) and the State can reduce reporting frequency to every 60 months, as provided by § 441.311(b)(1)(ii). We are not making any changes in this final rule based on this comment.

Comment: A few commenters supported the proposals at § 441.311(b)(1)(i) and (ii) that States must provide the required assessment every 24 months and, if the system is determined to be compliant, every 60 months. One commenter encouraged us to reduce the frequency in § 441.311(b)(1)(i) to one year. One commenter suggested that States should provide assessments on their systems every 1 to 2 years, and if the State's system has been deemed to be in compliance, the assessment should be provided every 3 to 4 years.

A few commenters, however, believed that the reporting frequency should be increased. One commenter recommended this reporting should occur every three years. A few commenters worried that 24 months would not be sufficient time for States to submit the assessment to CMS, and implement any system changes, which might require IT systems updates and acquiring additional funding from State legislatures. One commenter suggested that the assessment should be submitted every 5 years to align with the waiver renewal cycle.

One commenter noted that requiring an assessment every 24 months will create an unnecessary duplication of work. The commenter agreed with the need for an initial assessment but contended that the ongoing assessments were unnecessary, as States could independently monitor ongoing operations and make quality improvements and system updates as needed.

Response: We continue to believe that 24 months (and, for compliant systems, 60 months) is an appropriate frequency that ensures accountability without being overly burdensome. We refer readers to our prior response regarding situations in which we determine, based on the State's assessment, that its system does not meet the requirements finalized at § 441.302(a)(6).

We do not agree that requiring a regular schedule of system review is duplicative. If a State is already conducting regular system reviews as part of a quality improvement process, that

review can form the basis for the every 24-month or, as appropriate, every 60-month assessment. We believe that for States that may not already have such processes in place, some regular schedule of review is necessary to ensure that over time, systems do not fall out of compliance. We also would encourage States to use these assessments as opportunities to conduct more comprehensive audits or reviews to identify opportunities for system improvements.

After consideration of the comments received, we are finalizing the reporting frequency in § 441.311(b)(1)(i) with a technical modification for clarity that the State must report on the results of an incident management system assessment, every 24 months, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are finalizing § 441.311(b)(1)(ii) as proposed.

(2) Critical Incidents (§ 441.311(b)(2))

As discussed earlier in section II.B.4. of the proposed rule, at § 441.302(a)(6)(i)(A), we proposed to require States to define critical incidents at a minimum as verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

Based on the same rationale as discussed previously in section II.B.7.a.(1) of this preamble related to the proposed incident management system assessment reporting requirement, at § 441.311(b)(2), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States report annually on the number and percent of critical incidents for which an investigation was initiated within State-specified timeframes; number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes; and number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed

within State-specified timeframes. We intended to use the information generated from the proposed reporting requirements at § 441.311(b)(2)(i) through (iii) to determine if States meet the requirements at § 441.302(a)(6)(ii).¹²¹ Given the risk of harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believed the proposed requirement at § 441.311(b)(2) for States to report annually on critical incidents is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We invited comments on the timeframe for States to report on the critical incidents, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the minimum performance requirements for critical incident investigations proposed in § 441.302(a)(6), which form the basis of the reporting requirement at § 441.311(b)(2). These comments and our responses are in section II.B.3. of this final rule.

Comment: A few commenters generally supported our proposal at § 441.311(b)(2). One commenter observed that the current lack of standardized incident management systems across all States puts beneficiaries at risk and believed that the critical incident reporting requirements will help to prevent adverse experiences, increase accountability for States, and provide beneficiaries with an avenue of redress when they experience harm.

Response: We thank commenters for their support.

¹²¹ We note that there was a typographical error in the NPRM at 88 FR 27987, incorrectly identifying the proposed reporting requirements at § 441.311(b)(2)(ii) through (iv), rather § 441.311(b)(2)(i) through (iii).

Comment: A few commenters opposed the reporting requirement at § 441.311(b)(2). One commenter believed that building the necessary IT systems to complete the reporting will impose an extraordinary cost to States and take years to develop, test, and implement. Another commenter expressed concerns that the reporting requirements would necessitate a restructuring of some States' critical incident management, including revising policies, procedures, trainings, and processes.

Response: As discussed in the proposed rule (88 FR 27978), since 2014, States operating section 1915(c) waiver programs have been expected to demonstrate on an ongoing basis that they identify, address, and seek to prevent instances of abuse, neglect, exploitation, and unexplained death, and demonstrate that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible. While we acknowledge that some States may have to make some adjustments to their systems, we expect that most will be able to build on existing systems to achieve this reporting. We plan to offer States technical assistance as needed to support questions they may have about adjustments they need to make to existing policies, tracking, and reporting systems. We decline to make any changes in this final rule based on these comments.

Comment: A few commenters requested that we share more details about the reporting template and when the report would need to be submitted. A few commenters expressed the hope that the reporting timing could be aligned with waiver years or other administrative deadlines.

Response: The reporting requirement at § 441.311(b)(2) will be collected as part of the overall data collection activities associated with the reporting requirements in § 441.311. Per § 441.311(f), as finalized herein and discussed in this section II.B.7. of the rule, States must comply with the reporting requirement at § 441.311(b)(2) beginning 3 years from the effective date of this final rule]. Prior to that applicability date, we will be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance.

Comment: One commenter requested clarification on whether the reporting was statewide or could be submitted for each program. The commenter noted that for States operating multiple critical incident systems, or tracking critical incidents at the program level, reporting of data at an aggregate statewide level will not only prove operationally challenging, but it could also limit the ability to identify and address program-specific issues.

Response: States are expected to report aggregated statewide data for this requirement. We believe that a State could track critical incidents by program at the State level and then aggregate this data for the purposes of the reporting requirement at § 441.311(b)(2). We plan to offer technical assistance to States, as needed, that have decentralized critical incident systems to facilitate the aggregated statewide reporting. We also note that States will be able to provide input into the reporting instrument when it is shared for public comment during the Paperwork Reduction Act notice and public comment process.

Comment: One commenter was critical of the proposed reporting metrics at § 441.311(b)(2), believing that the focus of the metrics was too much on timeliness: timely initiation of investigations, timely resolutions, and timely corrective action. The commenter did not believe that there was sufficient focus on the substance of the incidents. A few commenters recommended that we add the following metrics to § 441.311(b)(2): the number of critical incidents in each year, categorized by type of incident and extent of injury or by severity; whether corrective action was needed; whether corrective action was performed; whether any corrective action addressed the needs of current participants or future participants (or both); and whether corrective action adequately addressed participants' needs.

One commenter stated that the information should be reported to the public, although in a format that protects the anonymity of the beneficiary and filer. The commenter also suggested that a separate section of the public report should provide information on substantiated critical incidents by provider, including the service provider's owner and the name under which they are doing business.

Response: We disagree that the metrics in § 441.311(b)(2) focus only on timeliness. Inherent in these metrics is the expectation that States will promptly investigate and resolve critical incidents, which we believe is the essential purpose of the critical incident system. We developed the reporting requirement at § 441.311(b)(2) to strike a balance between collecting enough information to enable Federal oversight of the States' system designed to investigate and resolve critical incidents and imposing as minimal an administrative burden on States and providers as possible. We believe it is important for States to have flexibility in how they design their system to identify, report, triage, investigate, resolve, track, and trend critical incidents as set forth in the proposed requirements at § 441.302(a)(6), which we are finalizing as discussed in section II.B.3. We also believe that requiring a broad, national reporting requirement for States to report critical incident timeliness data will provide a mechanism to assess whether States are complying with their own timeframes for investigating, resolving, and implementing corrective actions, and to ensure States are complying with their own established processes for reviewing and addressing critical incidents.

We did not propose, and are not finalizing, specific requirements for how States must use this data. We will likely include promising practices related to data collection and analysis, including methods of capturing qualitative data from the records, in technical assistance for States to aid in implementation.

We note that the data required in § 441.311(b)(2) is included in the public posting requirement we are finalizing at § 441.313 (discussed in greater detail in II.B.9. of this final rule). We are not requiring that States publicly report specific information about critical incidents, including the names of providers involved in critical incidents. We believe that some public disclosures may not be suitable or appropriate in every instance, and it would be difficult to tailor a meaningful requirement to anticipate all of these circumstances. We are concerned that, for example, in States with smaller HCBS populations, it may be difficult to truly anonymize information about critical incidents. While we agree that, over time, qualitative data

about trends in critical incidents could be useful to both States and other interested parties in promoting systemic improvements in their HCBS programs, we defer to States to determine when and how to make this information public, in accordance with applicable laws governing confidentiality of such information, and for what purpose.

Comment: A few commenters supported the proposal that this data should be reported on an annual basis. A few commenters recommended less frequent reporting, such as every two years, to reduce burden.

One commenter, while not necessarily recommending a different reporting frequency, noted that reporting requirements must take into account the unique factors that impact the length of time it could take to complete an investigation or conduct corrective action. The commenter noted that depending on the nature of the corrective action and when the corrective action process begins in a reporting year, annual reporting may result in misleading data about the number of resolved critical incidents or completed corrective actions.

Response: Given the importance and time-sensitive nature of critical incident investigations, resolutions, and corrective actions, we believe it is necessary to collect this data on an annual basis so we may monitor these systems. We also clarify that the reporting is not intended to track how many critical incidents were investigated, resolved, or resulted in completed corrective actions in a reporting year; the requirement is to report how many critical incidents were investigated, resolved, or resulted in completed corrective actions within State-specified timeframes during the reporting period. Thus, even if the reporting period falls in the middle of a critical incident resolution or corrective action, these incidents would not be reported as “non-compliant” if they were still within the State-specified timeframes for completion.

After consideration of these comments, we are finalizing the introductory text at § 441.311(b)(2), with a technical modification for clarity that the State must report to CMS annually in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are also simplifying the title and moving the

reference to § 441.302(a)(6)(i)(A) from the title of § 441.311(b)(2) to the introductory text. As finalized, the introductory text at § 441.311(b)(2) will specify that the State must report to CMS annually on the following information regarding critical incidents as defined in § 441.302(a)(6)(i)(A), in the form and manner, and at a time, specified by CMS. We are finalizing § 441.311(b)(2)(i) through (iii) as proposed.

(3) Person-centered planning (§ 441.311(b)(3))

Under the authority of section 1902(a)(6) of the Act, we proposed at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). Specifically, at § 441.311(b)(3)(i), we proposed to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. At § 441.311(b)(3)(ii), we proposed to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a reassessment of functional need within the past 12 months. These proposed requirements were based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance. As discussed in section II.B.7. of the preamble for the proposed rule, this feedback indicated that we should strengthen person-centered planning reporting requirements and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. These proposed requirements were also based on feedback received through the RFI¹²² discussed earlier about the need to standardize reporting and set minimum standards for HCBS.

As discussed in section II.B.1. of the preamble for the proposed rule, we proposed a revision to the regulatory text so that it is clear that changes to the person-centered service plan

⁸⁴ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

are not required if the re-assessment does not indicate a need for changes. As such, for the purpose of the reporting requirement at § 441.311(b)(3)(ii), beneficiaries would be considered to have had a person-centered service plan updated as a result of the re-assessment if it is documented that the required re-assessment did not indicate a need for changes.

For both of the metrics at § 441.301(c)(3)(ii), we proposed to allow States to report a statistically valid random sample of beneficiaries, rather than for all individuals continuously enrolled in the waiver program for at least 365 days.

We invited comments on whether there are other specific compliance metrics related to person-centered planning that we should require States to report, either in place of or in addition to the metrics we proposed. We also invited comments on the timeframe for States to report on person-centered planning, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the person-centered service plans minimum performance requirements proposed in § 441.301(c)(3)(ii), which form the basis of the reporting requirement at § 441.311(b)(3). These comments and our responses are in section II.B.1. of this final rule.

Comment: A few commenters expressed support for the requirement that States report annually on the specified performance metrics for person-centered planning. Commenters echoed sentiments that are reflected in section II.B.1. of this final rule, that many States are already regularly performing the assessment and reassessment activities in compliance with the minimum performance standards being finalized in § 441.301(c)(3)(ii) and, thus, reporting on these activities is reasonable.

We did not receive feedback in response to our request for comment on additional or alternative metrics that should be included in the reporting requirement at § 441.311(b)(3).

Response: We thank commenters for their support. We note that the metrics in § 441.311(b)(3) are based on the minimum performance requirements being finalized at §441.301(c)(3)(ii); comments on these minimum performance standards are discussed in section II.B.1. of this final rule.

Comment: A few commenters expressed reservations about the proposal to allow States to report data on a statistically valid sample of beneficiaries, suggesting instead that we require complete reporting on all relevant beneficiary data.

Response: We intended that the proposed requirement allow States to report data and information for the person-centered service planning reporting metrics at § 441.311(b)(3) using a statistically valid random sampling of beneficiaries would reduce State burden, while still providing valuable data for strengthening States' person-centered service planning processes. We will consider expanding the reporting to capture the full population of beneficiaries receiving HCBS in future rulemaking if it is determined that such an approach gives a more complete picture of person-centered service planning. We note that States may choose to report on the total population for this measure as opposed to a sample, for instance, if doing so better aligns with their data collection process or needs.

We note that, as proposed, we stated in § 441.311(b)(3)(i) and (ii) that the State may report these metrics for a statistically valid random sample of beneficiaries. We are finalizing the requirements at § 441.311(b)(3)(i) and (ii) with a technical modification to specify that the State may report this metric **using statistically valid random sampling** of beneficiaries. (Revised language identified in bold.) We make this technical correction to better align the language with standard terminology for the sampling methodology we intended in these requirements.

Comment: One commenter specifically noted that the frequency of annual reporting was feasible. One commenter noted that while the reporting frequency is reasonable, it is important to align with other reporting requirements already placed on States and managed care plans to minimize State and managed care plan reporting burdens.

A few commenters requested clarification on when the report required in § 441.311(b)(3) would be due to CMS and whether we would provide a template for the reporting. One commenter requested clarification on how this aggregated data should be reported, noting that current mechanisms for reporting similar data are waiver specific.

Response: We will be releasing subregulatory guidance, including technical specifications for the new reporting requirements in this final rule, and making the required reporting templates available for public comment through the Paperwork Reduction Act notice and comment process. Per § 441.311(f) below, States must comply with the reporting requirement for § 441.311(b)(3) beginning 3 years from the effective date of this final rule]. Specific reporting due dates will be determined through subregulatory guidance; we will work with States to align these due dates with other obligations to minimize administrative burden to the greatest extent possible.

After consideration of the public comments received, we are finalizing the reporting requirement at § 441.311(b)(3)(i) and (ii), with the technical modification noted above to specify that the State may report this metric using statistically valid random sampling of beneficiaries. We are also finalizing a technical correction to the regulation text at § 441.311(b)(3). In the proposed rule (88 FR 27988), we indicated that we were proposing at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). In the publication of the proposed rule, this language was omitted from the regulatory text in error. We are finalizing § 441.311(b)(3) with technical modifications to specify that, to demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually. We are also making a technical modification to indicate that the reporting must be in the form and manner, and at a time, specified by CMS. We believe, based on the language included in the proposed rule (88 FR 27988) and the comments received, that commenters understood the intent of this regulation even with language omitted.

(4) Type, Amount, and Cost of Services (§ 441.311(b)(4))

As discussed previously in section II.B.4. of this preamble, we proposed to amend § 441.302(h) to avoid duplicative or conflicting reporting requirements with the new Reporting Requirements section at proposed § 441.311. In particular, at § 441.302(h), we proposed to remove paragraphs (1) and (2). At § 441.311(b)(4), we proposed to add the language previously at § 441.302(h)(1). In doing so, we proposed to retain the current requirement that States report on the type, amount, and cost of services and to include the reporting requirement in the new consolidated reporting section at § 441.311.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter supported this proposal.

Response: We thank the commenter for their support.

Comment: One commenter requested clarification on whether the reporting requirement at § 441.311(b)(4) will apply to managed care plans.

Response: The requirement at § 441.311(b)(4) replicates the current requirement at § 441.302(h), which applies to section 1915(c) programs, regardless of whether they are part of a FFS or managed care delivery system.

As stated in the proposed rule (88 FR 27988), it was our intent to consolidate the current reporting requirement at § 441.302(h)(1) with the new requirements being finalized at § 441.311. We note that as this requirement was presented in the proposed rule, we inadvertently struck part of the language from § 441.302(h) that we intended to retain in § 441.311(b)(4) that clarified the reporting frequency (annually) and the object (the 1915(c) waiver's impact on the State plan) of the requirement currently at § 441.302(h)(1). We are concerned that without this omitted language, § 441.311(b)(4) does not include information needed to implement this requirement. We believe that, as we expressed our intent in the proposed rule (88 FR 27988) to retain the

reporting requirement at § 441.302(h)(1), readers would have understood that we intended to preserve the essential elements of the reporting.

To ensure that this requirement can be implemented as intended, we are finalizing § 441.311(b)(4) with language from § 441.302(h) to specify that, **annually, the State will provide CMS with information on the waiver's impact on** the type, amount, and cost of services provided under the State plan. (Restored language is noted in bold.)

We also specify here that, as the requirement at § 441.302(h) specifies certain reporting for programs authorized under section 1915(c), this new requirement at § 441.311(b)(4) will similarly apply only to section 1915(c) waiver programs. We discuss the impact of this clarification on references to section 1915(j), (k), and (i) services (at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii)) later in this section.

After consideration of the comments received, and in light of the clarification outlined above, we are finalizing the provision at § 441.311(b)(4) to specify that annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan. Further, we are finalizing § 441.311(b)(4) with a technical modification to specify that the information is to be reported in the form and manner, and at a time, specified by CMS.

b. Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c))

At § 441.311(c), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States report every other year on the HCBS Quality Measure Set, which is described later in section II.B.8. of the preamble. Specifically, we proposed, at § 441.311(c)(1)(i), to require that States report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the HCBS Quality Measure Set described in section II.B.8. of the final rule, on measures identified in the HCBS Quality Measure Set as mandatory measures for States to report or are identified as

measures for which the Secretary will report on behalf of States, and, at § 441.311(c)(1)(ii), to allow States to report on measures in the HCBS Quality Measure Set that are not identified as mandatory, as described later in this section of the rule.

We proposed every other year for State reporting in recognition of the fact that the current, voluntary HCBS Quality Measure Set is heavily comprised of survey-based measures, which are more burdensome, including for beneficiaries who would be the respondents for the surveys, and costlier to implement than other types of quality measures. Further, we believed that requiring reporting every other year, rather than annually, would better allow States to use the data that they report for quality improvement purposes, as it would provide States with sufficient time to implement interventions that would result in meaningful improvement in performance scores from one reporting period to another. We also proposed this frequency in recognition of the overall burden of the proposed requirement .

Because the delivery of high quality services is in the best interest of Medicaid beneficiaries, we proposed at § 441.311(c)(1)(iii), under our authority at section 1902(a)(19) of the Act, to require States to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.¹²³

At § 441.311(c)(1)(iv), we proposed to allow States to establish State performance targets for other measures in the HCBS Quality Measure Set that are not identified as mandatory for States to report or as measures for which the Secretary will report on behalf of States as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those targets.

¹²³ We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the *Olmstead* Decision.

At § 441.311(c)(2), we proposed to report on behalf of the States, on a subset of measures in the HCBS Quality Measure Set that are identified as measures for which we will report on behalf of States. Further, at § 441.311(c)(3), we proposed to allow, but not require, States to report on measures that are not yet required but will be, and on populations for whom reporting is not yet required but will be phased-in in the future.

We solicited comments on whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, and if so, what that threshold should be. We also invited comments on whether the timeframe for States to report on the measures in HCBS Quality Measure Set is sufficient, whether we should require reporting more frequently (every year) or less frequently (every 3 years), and, if an alternate timeframe is recommended, the rationale for that alternate timeframe. We welcomed comments on any additional changes we should consider in this section.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the HCBS Quality Measure Set requirements proposed at § 441.312. These comments and our responses are in section II.B.8. of this final rule.

Comment: Regarding whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, one commenter recommended exemptions for States to develop improvement strategies if they are performing within the top 5th to 10th percentile of performance targets for the quality measures in the HCBS Quality Measure Set, to alleviate administrative burden. Another commenter discouraged CMS from permitting a compliance threshold exemption for States from developing improvement strategies, emphasizing that all States should be held accountable for providing high-quality care and services to beneficiaries receiving HCBS regardless of performance.

Response: We continue to believe that, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report, or are identified as measures for

which we will report on behalf of States, States should establish and describe the quality improvement strategies to achieve the performance targets for those measures.¹²⁴ We reiterate our belief that the HCBS Quality Measure Set will promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, and will allow CMS and States to have comparative quality data on HCBS programs. As such, exempting States from developing improvement strategies for quality measures in the HCBS Quality Measure Set does not align with this intent.

Comment: Several commenters recommended either faster or slower implementation for reporting of the measures in the HCBS Quality Measure Set. A few commenters recommended we change the timeframe requirement for States to report on the quality measures in the HCBS Quality Measure Set to every year. In this same vein, one commenter suggested we align the reporting timelines required for reporting measures in the HCBS Quality Measure Set to other Medicaid, CHIP, Medicare, and Marketplace measure sets, expressing that reporting biennially (every other year) could lock in data lags that could hinder State progress in improving HCBS for beneficiaries. A few commenters recommended alternatives to the HCBS Quality Measure Set biennial reporting time frame. These alternatives included the following: initiating reporting based on State choice; reporting on odd- or even-numbered years; and beginning State reporting upon renewal of their section 1915(c) waiver or based on the State reporting years for their waiver program.

A few commenters expressed concern that the timeframe for reporting measures in the HCBS Quality Measure Set should be longer than every other year, emphasizing the significant amount of systems work, contracting, and survey data needed to capture the necessary data and implement reporting on HCBS measures. Commenters recommended we consider that the implementation of the HCBS Quality Measure Set reporting requirements as proposed at

¹²⁴ We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the *Olmstead* Decision.

§ 441.311(c)(1)(iii) could require State statutory and regulatory amendments, lead time for securing additional technology resources, and operational and workflow changes. Commenters requested CMS consider alternative dates for States beginning reporting on the measures in the HCBS Quality Measure Set, ranging from an additional 3 to 5 years to address these concerns.

Response: We continue to believe that a biennial timeframe requirement for States to report on the measures in HCBS Quality Measure Set is an appropriate frequency that ensures accountability without being overly burdensome and are finalizing the frequency of reporting as proposed. We determined that a shorter annual reporting timeframe would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that States may be required to make. For example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with managed care plans, and modifications of databases or systems might be required to record new variables.

However, to provide States sufficient time to comply with the requirements finalized at § 441.311(c), we are finalizing at § 441.311(f)(2) an applicability date beginning 4 years, rather than 3 years, from the effective date of this final rule for the HCBS Quality Measure Set reporting at § 441.311(c). Our primary purpose in extending the effective date is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

In general, we anticipate that States will not need more than 4 years after the effective date of the final rule, to implement systems and contracting changes, or acquire any additional support needed to report on the quality measures in the HCBS Quality Measure Set.

We plan to work collaboratively with States to provide the technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting.

Comment: A few commenters requested confirmation of whether States with section 1115 demonstrations are expected to comply with the HCBS Quality Measures Set requirements in this final rule.

Response: Yes, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the reporting requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this rule, including the requirements at § 441.311 (and the related quality measure requirements at § 441.312), would apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive or exclude one or more of the requirements as part of the approval of the demonstration project.

Comment: A couple of commenters recommended that we offer States financial assistance to develop and deploy the ability to report the quality measures in the HCBS Quality Measure Set.

Response: We note that Medicaid Federal matching funds are available for State expenditures on the design, development, and installation (including of enhancements), and for operation, of mechanized claims processing and information retrieval systems. We also note that under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan. This may include developing and deploying the ability to report the quality measures in the HCBS Quality Measure Set.

Comment: A few commenters expressed that instructions related to the reporting requirements for the quality measures in the HCBS Quality Measures Set, and how they are related to the section 1915(c) waiver reporting requirements, would be helpful for implementing the reporting of the measure set.

Response: We thank commenters for the feedback. We plan to work collaboratively with States to provide the technical assistance and reporting guidance through the Paperwork

Reduction Act process necessary to support reporting and help facilitate compliance with this requirement.

After consideration of public comments received, we are finalizing the HCBS Quality Measure Set reporting requirements at § 441.311(c) with modifications. At § 441.311(f)(2), we are finalizing that States must comply with the reporting requirements at § 441.311(c) beginning 4 years, rather than 3 years, from the effective date of this final rule for the HCBS Quality Measure Set. Our primary purpose in extending the applicability date is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

c. Access Reporting (§ 441.311(d))

As noted earlier in section II.B.6. of this preamble, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI¹²⁵ discussed earlier, indicated that there is a need to improve public transparency and processes related to States' HCBS waiting lists and for standardized reporting on HCBS access, including timeliness of HCBS and the comparability to services received to eligibility for services. At § 441.311(d) we proposed that the State must report to CMS annually on the following, according to the format and specifications provided by CMS. We are finalizing in this rule § 441.311(d) with a technical modification for clarity that requires that the State must report to CMS annually on the following, **in the form and manner, and at a time**, specified by CMS. (New language identified in bold.)

(i) Waiver Waiting Lists (§ 441.311(d)(1)(i))

At § 441.311(d)(1)(i), relying on our authority under section 1902(a)(6) of the Act, we proposed to require that States provide a description annually, according to the format and

¹²⁵ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

specifications provided by CMS, on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program, if they have a limit on the size of the waiver program and maintain a list of individuals who are waiting to enroll in the waiver program, as described in § 441.303(f)(6). We further proposed to require that this description must include, but be not limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. We also proposed to require States to report, at § 441.311(d)(1)(ii), the number of people on the waiting list, if applicable, and, at § 441.311(d)(1)(iii), the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable. We invited comments on whether there are other specific metrics or reporting requirements related to waiting lists that we should require States to report, either in place of or in addition to the requirements we proposed. We also invited comments on the timeframe for States to report on their waiting lists, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses. We also received comments on the related requirement at § 441.303(f). Those comments are addressed in section II.B.6. of this rule.

Comment: Many commenters supported the proposal at § 441.311(d)(1) to require States to report on waiting lists, including whether the State screens individuals on the list for eligibility, frequency of re-screening, number of individuals waiting to enroll, and average amount of time newly enrolled individuals were on the waiting list. Commenters believed that this reporting would promote consistency, transparency, oversight, and accountability of waiting list practices and help States identify unmet needs among their Medicaid beneficiaries.

Commenters noted that this additional information will better allow interested parties to advocate for policy changes to address underlying causes of waiting lists and expand HCBS programs; one

commenter described this requirement as a good “first step” to understanding access issues for HCBS waivers.

A few commenters stated this requirement, with its potential to support policies that reduce waiting lists, would help beneficiaries avoid having to turn to institutional care for their LTSS needs. Commenters also noted transparent, understandable data about waiting lists may help individuals and families to make more informed decisions about accessing coverage as they plan for their future.

A few commenters noted that nationally comparable data and information-sharing among States will encourage standardization of waiting list processes and help States identify best practices for reducing waiting lists. Commenters noted that inconsistencies in the way States report data about their waiting lists and the current lack of standardized reporting requirements makes it difficult to form a clear picture of how many people are waiting to receive services, as well as how many of these individuals on the waiting list are actually eligible for services. One commenter suggested that making the waiting list public may lead to needed administrative updates to waiting lists, such as removing duplicate applications or applications from beneficiaries who have moved out of State or passed away.

Response: We agree that this critical data is not currently available in a way that allows for monitoring or comparison on a national level. We believe that this reporting requirement is an important first step in making data publicly available that can be used to identify unmet needs among Medicaid beneficiaries, support policymaking, and improve administrative efficiency.

Comment: A few commenters expressed opposition to, or concerns about, the waiting list reporting requirement at § 441.311(d)(1). A few commenters expressed concerns that the reporting requirement did not align with current State waiting list practices and would require significant change in data collection and IT systems. One commenter was concerned that due to differences in States’ HCBS programs, infrastructure, and waiting list practices, attempting to collect and compare data on a national level could be misleading. A few commenters requested

clarification on how CMS would use this data to drive meaningful policy changes and improvement in HCBS access. A few commenters stated that the proposed requirements would not address the underlying causes of waiting lists, which they attributed to limited funding for HCBS waiver slots, low Medicaid reimbursement rates, delays or barriers within States' Medicaid eligibility determination processes, or shortages of HCBS direct care workers. A few commenters, while not necessarily opposing the requirement at § 441.311(d)(1), suggested that we focus on gathering information about why States have caps on the number of beneficiaries who may be served by HCBS waivers and why States have waiting lists when they have not met their waiver caps.

One commenter raised a concern that the reporting requirement would cause States to redirect or prioritize resources for waivers with waiting lists at the expense of waivers that currently do not have waiting lists.

Response: We are not currently collecting States' data on their waiting lists and understand that States may have to update data collection systems to comply with this new requirement. We proposed the reporting requirement at § 441.311(d) to strike a balance between collecting enough information to enable Federal oversight of States' waiting list practices and imposing as minimal an administrative burden on States and providers as possible. We plan to offer States technical assistance as needed to help align their current data collection practices with what will be needed to comply with this reporting requirement. The reporting requirement at § 441.311(d)(1) is a first step in what will be an evolving process to promote transparency, oversight, and data-driven improvements in States' waiting list practices. We acknowledge that differences in States' HCBS programs may initially make comparing States' data challenging, but we believe that collecting this data will help highlight such differences and draw connections between different States' policies and the impact on their beneficiaries' access to HCBS. As noted by other commenters, States may be able to use this data to learn from the experiences of other States.

We acknowledge that there are many underlying causes for States to have long waiting lists, but we believe that the first step toward addressing these challenges, where possible, is to quantify the scope of these waiting lists through data collection. This data will not only help identify situations in which a State appears to be maintaining a waiting list when not all of the waiver's slots are taken but can also facilitate conversations with States about reasons for limitations on waiver enrollment.

We clarify that the purpose of this requirement is to document unmet needs for individuals who are seeking enrollment in HCBS waivers and to identify resources or practices that could be used to improve waiting list processes. As such, our goal is not to require that States shift needed resources away from other areas of their Medicaid programs.

Comment: One commenter requested that we provide reporting tools to help States track the required data. One commenter requested that the data needed for this reporting requirement be derived from the State's own eligibility and service authorization processes, not from providers and beneficiaries, particularly for self-directed services.

Response: We plan to release subregulatory guidance and other tools to assist States with implementation of this reporting requirement. We will also be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process.

While States have flexibility as to how they will gather the data needed to complete this reporting, we encourage States to find ways to rely on administrative data rather than gathering data directly from beneficiaries to meet the reporting requirements.

Comment: A few commenters requested that the information about waiting lists be made available to the public in a consumer-friendly and accessible format in order to facilitate program accountability and potentially improve beneficiary understanding of waiting list information. One commenter suggested that publishing data about the waiting list may help publicize the need for more direct care workers.

Response: As discussed in more detail later in section II.B.9 of this rule, we are finalizing a requirement at § 441.313(a) to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and that provides the results of the reporting requirements at § 441.311 (including this access reporting requirement at § 441.311(d), as well as the incident management, critical incident, person-centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; and payment adequacy data, discussed in this section) and the reporting requirements at § 441.302(k)(6). Please refer to the discussion of the website posting requirements in section II.B.9. of this rule.

Comment: One commenter suggested that we consider offering incentives for States to reduce or end waiting lists through a higher FMAP rate for a limited time period. One commenter requested that States be given a grace period and allowed to update their section 1915(c) waivers prior to any punitive action.

Response: We note that the requirement at § 441.311(d)(1) is a reporting requirement intended to encourage transparency and does not include any specific performance measures with which States must comply. To the extent that States are in compliance with existing requirements for section 1915(c) waiver programs, it is also not intended to require that States make changes to their waiver programs or processes. We intend to use our standard enforcement discretion to require State compliance with the reporting requirement, which (as discussed under § 441.311(f) below) will go into effect three years after the effective date of this final rule. In addition, we note that CMS does not have authority to provide States with a higher FMAP rate for any expenditures than has been authorized by statute.

Comment: A number of commenters noted that waiting list terminology, definitions, and processes vary widely among States and even among individual State programs. Commenters observed that some States operate what they refer to as interest lists, preauthorization lists, or similarly named lists, rather than waiting lists. In some cases, individuals can sign up to express interest in a waiver program but may not have yet been assessed for eligibility at the time they

joined the interest list. Commenters questioned whether these individuals would be considered “waiting to enroll” as described in the proposed rule, as they are waiting to be determined eligible to enroll. Commenters requested clarification as to what data would be collected from States that maintain interest lists or similarly named lists of individuals who have not yet been determined to be eligible for the waiver.

A few commenters expressed concerns that if interest lists are not included in this requirement, States may be encouraged to stop maintaining waiting lists. One commenter noted that if the requirement does apply to interest lists, States that use an interest list approach would have to make significant changes to their processes to meet the waiting list reporting requirement. One commenter observed that in their State, the State maintains a single waiting list for all waivers, which could complicate reporting.

Several commenters requested that we create a definition of a waiting list. One commenter supported what they believed to be our proposed standardized definition of a waiting list (but did not specify what they thought that definition to be). A few commenters requested that we require States to have waiting lists for their waiver programs and that States screen individuals for eligibility prior to placing the individuals on the waiting list.

Response: We intended for the reporting requirement to apply to all States that maintain a list of individuals interested in enrolling in a section 1915(c) waiver program, whether or not the individual has been assessed for eligibility. As we stated in the proposed rule (88 FR 27986), many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services.

We note that the requirement at § 441.311(d)(1) requires States to submit a description of their waiting list that includes information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens

individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. This requirement indicates that § 441.311(d)(1) applies to States even if they do not screen the individuals on their list for eligibility. We believe that for the purposes of this requirement individuals who are waiting to be screened for eligibility for the waiver are considered “waiting to enroll.”

We believe that States that maintain an interest list (or a similarly named list of individuals who have expressed interest in the waiver and are waiting to be assessed for eligibility) can report the same information required in § 441.311(d)(1) as States that maintain lists of individuals who have been screened for eligibility. We expect, for instance, that States typically would have information about the number of individuals who are on an interest list and how long those individuals have been on those lists. If a State maintains two separate lists for a waiver – a list of individuals who have been screened for eligibility for the waiver and a list of individuals who have expressed interest in enrolling in the waiver but have not yet been screened – the State should report on both to meet the reporting requirements at § 441.311(d)(1).

As we did not propose a formal definition of waiting list, nor a requirement for States to maintain a waiting list of individuals who have been screened for eligibility, we will not add these components to the finalized § 441.311(d). States retain flexibility in determining whether or not to maintain a list of individuals who are interested in enrolling in the waiver (whether or not the individual has been screened for eligibility). We will take commenters’ recommendations into consideration for future policymaking if, after monitoring reporting generated by § 441.311(d), we identify the need for further standardization of these processes.

Comment: We received responses to our comment solicitation on additional metrics that could be collected regarding the waiting list. One commenter recommended that we not add more metrics to § 441.311(d)(1). Several commenters did suggest additional metrics. Many of these commenters believed that more detailed data would allow for a better assessment of overall

unmet needs and disparities within the waiting lists. Additional metrics suggested by commenters included:

- Disaggregated data about beneficiaries, by demographic categories, including race, ethnicity, Tribal status, language status, sex or gender identification, sexual orientation, age, and geographic location;
- Disaggregated data on beneficiaries' dual eligible status, disability, diagnosis, functional status, level of care, and risk of institutionalization;
- Whether States maintain separate waiting lists or registries for beneficiaries who are eligible for HCBS but have been determined by the State to not have a need prioritized by the State for enrollment in the waiver;
- The criteria used to determine beneficiaries' placement and movement within a waiting list;
- How much time individuals spend waiting for an eligibility assessment and how much time elapses between an assessment and service authorization;
- The number of eligibility screens performed on each beneficiary on the waiting list in the past year, and why a rescreen was performed;
- The number of beneficiaries removed from the waiting list due to death, admission to an institutional setting, or having been rescreened and deemed ineligible;
- The number of beneficiaries on the waiting list who are receiving care through another State Medicaid program, reasons why beneficiaries prefer to remain on the waiting list rather than enroll in other services, and what beneficiary needs remain unmet by other Medicaid programs while a beneficiary is on a waiting list; and
- Whether a participant who has been approved for HCBS waiver services is able to find a provider, how long it took for them to find that provider, and what services they wanted, but could not access because no provider was available.

Response: We thank commenters for their feedback. We will take these recommendations under consideration for future policymaking, but at this time decline to make modifications to the requirements based on these comments.

We believe it is important to strike a balance between collecting enough information to promote transparency around waiting lists and imposing as minimal an administrative burden on States and providers as possible. We also believe that information on whether States screen individuals on their waiting lists, the number of beneficiaries on the waiting list, and the average amount of time beneficiaries enrolled in HCBS waivers spent on the waiting list provides important preliminary data on the States' waiting list practices. As we gather and review this data, we will consider what additional information may be needed to further improve our oversight of HCBS programs and improve beneficiaries' access to services.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and beneficiary needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support beneficiaries' access to section 1915(c) HCBS waiver programs in their State.

Comment: One commenter recommended requiring that States report duplicated and unduplicated counts of individuals across waiver program waiting lists.

Response: We have not identified a compelling reason to require that States report unduplicated counts of beneficiaries for all waiver programs. We clarify that the reporting required for § 441.331(d)(1) is for each waiting list; if an individual is on multiple waiting lists, we believe that person should be counted among individuals on each of those waiting lists.

Comment: A few commenters recommended additional metrics that fall outside the scope of reporting on waiting list practices or waiver enrollment, including:

- Whether individuals on waiting lists are also being screened for eligibility for other programs that they may be able to benefit from (for example, Supplemental Nutrition Assistance Program);

- How long it takes a State to approve enrollment in any program that provides Medicaid LTSS, from the date that it receives an application until the date of the approval letter; and

- Additional measures to assess the needs of populations that face barriers to navigating the HCBS programs, applying, and getting on a waiting list.

Response: While these metrics lie outside the scope of the proposed reporting requirements, we will add these to other comments regarding broader HCBS access and equity issues that we will consider for future policymaking.

Comment: A few commenters suggested that we collect data on reasons for long waiting times, such as challenges with workforce availability or provider capacity. Some commenters, particularly those representing States or providers, were concerned that without this information, States and providers would be held responsible for long waiting lists or long waiting times for services that are due to reasons beyond States' or providers' control. One commenter recommended adding a requirement that States describe any conditions, such as State funding priorities, that serve to limit access to the HCBS described in the waiver application. A few commenters recommended adding a requirement to the interested parties' advisory group being finalized at § 447.203 that would require States, through their interested parties' advisory groups, to examine reasons for gaps in services that are revealed by the reporting on waiting lists.

Response: We do not believe it would be feasible at this stage to standardize the collection of qualitative data regarding the causes of waiting lists; this data would also be difficult to validate. As noted in prior responses, the purpose of the requirement at § 441.311(d)(1) is to encourage transparency; the requirement does not include any specific performance measures with which States or providers must comply. We believe that collecting

the number of individuals on the waiting list and the length of time individuals spend on waiting list will present quantifiable and comparable baseline data that can facilitate more nuanced conversations with States about potential unmet beneficiary needs and the underlying causes of these unmet needs.

We note that, regarding the interested parties' advisory group being finalized at § 447.203, the requirements at § 447.203 already include an expectation that access reporting that is required by 441.311(d) would be appropriate data for the Interested Parties Advisory Group (IPAG) to consider when making recommendations regarding the sufficiency of rates. We decline to add a specific requirement as suggested by the commenter, as we wish to allow both States and the IPAGs some discretion in determining their approach to examining the impact on payments rates in their State.

Comment: A few commenters supported annual reporting for § 441.311(d)(1). One commenter observed that one of their State agencies had already identified annual reporting on the waiting list as a best practice and was publishing an annual report. One commenter recommended quarterly reporting to encourage States to take more aggressive steps to reduce the size of their waiting lists. A few commenters believed that biennial (every other year) reporting would reduce burden on States and better account for fluctuations in waiting list size that are beyond the State Medicaid agency's control.

One commenter highlighted that waiting list volumes may vary at certain times of year or from year to year, depending on how States structure the release of new waiver slots and the timing of the State legislative sessions where new funding for waiver slots may be approved. The commenter stated that it is important to take these factors into account when considering reporting frequency and when evaluating reported data from year to year.

Response: We are finalizing the annual reporting frequency as proposed at § 441.311(d)(1). We continue to believe that annual reporting on waiting lists strikes the right balance between collecting current data on waiting lists and minimizing burden on States to the

greatest extent possible. We believe reporting more frequently than annually may represent an undue burden on States, although States are encouraged to share information with interested parties within their State on a more frequent basis if they are able to do so. We are concerned that if we extend the reporting to a biennial frequency, the information will become outdated prior to the next public report. We also note that States will likely have to develop or maintain the same data tracking systems regardless of whether the reporting itself is done annually or biennially; we believe the potential reduction in administrative burden by biennial reporting is outweighed by the need for more timely information on waiting lists.

Comment: One commenter requested clarification that the reporting requirement at § 441.311(d)(1) is limited to the section 1915(c) authority and to the section 1915(j) authority, where it is used as the State's authority for self-direction in a section 1915(c) waiver. This commenter recommended limiting this requirement to these authorities.

Response: We agree that, because section 1915(i) and section 1915(k) State plan services cannot have capped enrollment, the reporting requirements at § 441.311(d)(1) would not apply to these authorities. We also agree that the reporting requirements at § 441.311(d)(1) would also apply to section 1915(j) authority only where section 1915(j) is used as the State's authority for self-direction in a section 1915(c) waiver. We note that the reporting requirements at § 441.311(d)(1) would apply to section 1115(a) demonstration projects that include HCBS if the State caps enrollment for the HCBS under the section 1115(a) demonstration project. As discussed later in this section, section II.B.7. of this final rule, we are finalizing the application of the reporting requirements at § 441.311 to section 1915(j), (k), and (i) authorities with modifications to specify that States must only comply with the reporting requirements applicable to the services under these authorities.

After consideration of the commenters received, we are finalizing § 441.311(d)(1) as proposed.

(ii) Reporting on wait times for services and authorized service hours provided (§ 441.311(d)(2))

At § 441.311(d)(2)(i), based on our authority under section 1902(a)(6) of the Act, we proposed to require States report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. We proposed to focus on these specific services for this reporting requirement because of feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties that timely access to these services is especially challenging and because the failure of States to ensure timely access to these services poses substantial risk to the health, safety, and quality of care of individuals residing independently and in other community-based residences. We believed that having States report this information will assist us in our oversight of State HCBS programs by helping us target our technical assistance and monitoring efforts. We requested comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

For this metric, we proposed to allow States to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months, rather than for all individuals newly approved to begin receiving these services within the past 12 months. We invited comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invited comments on whether there are other specific metrics related to the amount of time that it takes for eligible individuals to begin receiving homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed.

At § 441.311(d)(2)(ii), also based on our authority under section 1902(a)(6) of the Act, we proposed to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in

§ 440.180(b)(2) through (4), that are provided within the past 12 months. For this metric, we further proposed to allow States to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these services within the past 12 months. We invited comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invited comments on whether there are other specific metrics related to individuals' use of authorized homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed. We further requested comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposals at § 441.311(d)(2) that States report on the time it takes between service authorization and service delivery and the number of authorized hours compared to the number of hours provided. A few commenters, while characterizing these as imperfect measures, nevertheless noted that the data measurements can help assess systematic issues with provider enrollment and access to care. One commenter observed that similar data is not currently available from their State, and believed this type of data would be useful.

Commenters noted that in their experience, beneficiaries might wait months after being authorized to receive services for the services to actually begin, or do not receive all of the services indicated in their person-centered care plan; these delays and underutilization of services cause a wide array of issues for the beneficiary and their families.

Commenters also noted these proposals complemented the waiver waiting list requirement at § 441.311(d)(1), noting that even when individuals are enrolled in a waiver, this

does not always mean that their services start immediately. A few commenters also stated that in their experience, even in States that do not have waiting lists for their waiver programs, beneficiaries may wait long periods of time for the waiver services to begin.

Response: As we discuss further in responses below, we recognize that the reasons for service delays and underutilization are nuanced. The reporting requirements at § 441.311(d)(2) are a first step in what will be an evolving process to promote transparency, oversight, and data-driven improvements in States' waiting list practices.

Comment: A few commenters cited factors that may contribute to delays or underutilization of services, some of which are beyond the control of State Medicaid agencies, managed care plans, or providers. Commenters cited challenges including administrative inefficiency, shortages of direct care workers or available providers, and geographic constraints. Other commenters cited specific obstacles, such as: difficulty in obtaining complete medical information from the beneficiary, delays in the care planning process, additional training requirements for self-directed service workers, lags in providers submitting claims or other delays in claims processing, or unavailability of the beneficiary due to travel, hospitalization, changes in provider, withdrawal from the program, or loss of Medicaid eligibility. A few commenters suggested that in some cases, beneficiaries decline services or are already receiving a different service that meets their needs prior to the new services being authorized.

One commenter noted that there are service delivery delays in care provided under private payers and wondered how these delays compare to those in Medicaid HCBS and whether they may be attributable to the adequacy of the provider network or to reimbursement rates.

A few commenters believed that the requirements at § 441.311(d)(2) would not address these underlying causes of service delays or underutilization and, thus, would not improve access to services. One commenter requested clarification on how this data would be used to promote meaningful change.

On the other hand, some commenters believed that the requirements at § 441.311(d)(2) can help identify unmet needs and uncover some of the causes of these challenges, which in turn can focus efforts on efficient solutions.

Response: We acknowledge that there are many underlying causes for service delays or service underutilization. We believe that the first step toward addressing these challenges, where possible, is to quantify the scope of these delays or underutilization through data collection. Additionally, some of the challenges commenters cited are within the purview of States, managed care plans, or providers to address. If the data demonstrates what appears to be significant delays or underutilization, we believe this information can help facilitate conversations with States, managed care plans, and providers about the reasons for these reporting results.

We also note that the purpose of the data is to track trends in service delivery times and utilization, not to track the outcomes for each beneficiary. The reporting will be the average amount of time a random sample of beneficiaries waited between service authorization and the start of services, and the total percent of authorized services that were provided. Thus, some of the factors that commenters cited, particularly those involving the behavior of specific beneficiaries, such as failure to provide timely medical data, declining services, or traveling, we believe should not significantly impact the reported numbers unless these obstacles are particularly prevalent (in which case, this may also be an area to identify for policy or program improvement).

Comment: A few commenters opposed the requirements at § 441.311(d)(2). A few commenters suggested that some States or managed care plans are not currently tracking the time between service authorization and the start of services and that it would take significant resources to develop, test, and deploy changes to the State's documentation management system. One commenter noted that it may be difficult to track this data because services are authorized, and claims are paid using different systems or are overseen by different parts of State

government. One commenter noted that, while their State does track service utilization data, it would take additional staff resources to comply with the reporting requirements.

Response: We are not currently collecting States' data on the times between service authorization and when services begin, or the number of authorized hours that are being utilized and understand that States may not be tracking all of this data; the absence of this data is what has prompted us to propose the requirement at § 441.311(d)(2). We recognize that, because this data has not previously been tracked by all States, some States may have to update their data collection systems to comply with this new requirement. As discussed elsewhere in this rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements. We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. We also note that, under section 1903(a)(7) of the Act, Federal matching funds are available for administrative activities necessary for the proper and efficient administration of the Medicaid State plan.

We developed the reporting requirement at § 441.311(d)(2) to strike a balance between collecting enough information to enable Federal oversight of service delivery and utilization and imposing as minimal an administrative burden on States and providers as possible. We believe the long-term benefits of collecting this data outweigh the initial burden of implementation. Accordingly, we decline to make any changes in this final rule based on these comments.

We are finalizing § 441.311(d)(2)(i) with a modification that we believe will further reduce administrative burden on States. As noted in an earlier comment summary, some commenters noted that in some instances beneficiaries may wait long periods of time to receive services. Upon further consideration, we have determined that the requirement at § 441.311(d)(2)

as written may present some data collection challenges in situations in which the beneficiary's date of approval of service and the date when services actually begin are separated by enough time that they fall in two different reporting periods. For instance, if the reporting period aligned with the calendar year, if an individual was approved for services on November 1, 2028, but did not start receiving services until February 1, 2029, it is not clear how that beneficiary's wait time for services would be captured in the reporting period for January 1, 2028, through December 31, 2028. (We note that we are using the calendar year as the reporting period only for the purposes of this example. As discussed later in this section, we will work with States and other interested parties through the Paperwork Reduction Act process to determine the actual reporting period.) It appears that in this circumstance, the State would have to first indicate that the beneficiary had waited 2 months (November 1, 2028, through the end of the reporting period on December 31, 2028); then the State would need to submit updated information for this beneficiary to report the beneficiary's total wait time. This process would need to be repeated on a rolling basis for other beneficiaries whose approval date and service start date fell in different reporting periods. Repeated updates to States' data would be burdensome, make it difficult for States to share meaningful data with CMS and the public, and lead to delays in State reporting of complete data for each reporting period.

To avoid this type of confusion in reporting, we are amending the requirement at § 441.311(d)(2)(i) to specify that the reporting is for individuals **newly receiving services**, rather than for individuals newly approved to begin receiving services. (Revised language is noted in bold.) As applied to the example above, this modification to § 441.311(d)(2)(i) means that the beneficiary whose services began on February 1, 2029 would be included in the January 1, 2029, through December 31, 2029, reporting period; the State would be able to "look back" to identify when the services were approved (in the example, services were approved November 1, 2028) and the State would report the beneficiary's total wait time between November 1, 2028 and February 1, 2029. We believe this modification preserves the intention of what we proposed in §

441.311(d)(2)(i) – to measure the time between when a beneficiary was approved to receive services and when the services actually begin – but clarifies and streamlines the reporting process.

Comment: A few commenters expressed concerns that States would use information about unfilled service hours to infer whether or not authorized services are necessary for the beneficiary. These commenters noted that many reasons exist as to why an individual would be unable to receive authorized care on a particular day but still need the care, such as the service provider was unavailable or there was confusion around when and what services were to be delivered on that day. One commenter requested reassurance that the reporting requirement at § 441.311(d)(2)(ii) to report on the average number of hours authorized that are provided would not be used to reduce or limit beneficiaries' access to services. One commenter suggested that we monitor services to ensure that States are not reducing services in response to this data.

Response: The purpose of this reporting requirement at § 441.311(d)(2)(ii) is not to audit individual beneficiaries' service utilization or to use the information as a reason to reduce their authorized service hours. The purpose and intent of the requirement is to identify barriers to beneficiaries' access to services. Accordingly, we decline to make any changes in this final rule based on these comments. However, we note that the State is required at § 441.301(c)(2) to ensure that the person-centered service plan reflects the services and supports that are important for the individual to meet the needs identified through an assessment of functional need, as well as what is important to the individual with regard to preferences for the delivery of such services and supports, and this requirement remains unchanged. States and managed care plans should not use the data collected to meet the reporting requirement at § 441.311(d)(2)(ii) to reduce authorized hours.

Comment: One commenter requested clarification on when the approval of services occurs, such as at the time of enrollment or when a physician signs the plan of treatment. The

commenter also observed that it will be critical to standardize the data elements that must be captured in this reporting.

Response: Given the variable nature of States' processes, we defer to States to determine when services are considered to have been approved and how this approval date can be tracked consistently for the reported services. We intend to provide States with technical assistance, including technical specifications and sampling guidance, for the new reporting requirements in this final rule, which will aid in consistent data reporting. We will also be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process.

Comment: A couple of commenters recommended requiring States to set a target for timeliness (such as 7 days) and measure the percentage of all cases in which the wait time exceeded that target.

Response: At this time, we are focusing on creating baseline data-reporting standards. We will take these recommendations for setting or requiring benchmarks under consideration should we pursue future rulemaking in this area.

Comment: We received responses to our comment solicitation on whether § 441.311(d)(2) should apply to other section 1915(c) services aside from homemaker, home health aide, and personal care services as set forth at § 440.180(b)(2) through (4).

One commenter recommended narrowing the scope of this requirement to personal care services only and removing homemaker and home health aide services from the requirement. The commenter contended that homemaker services do not cover activities of daily living which are typically associated with direct care to HCBS beneficiaries. The commenter also noted that home health aide services are typically offered under the Medicaid State plan rather than a section 1915(c) waiver. The commenter concluded that limiting the requirement to personal care services would allow CMS and States to concentrate on highly utilized personal care services and would make the requirement more operationally feasible for States.

On the other hand, a few commenters advocated for extending the reporting requirements to all HCBS. One of these commenters suggested that applying the requirement to only a few services would create an unintended consequence of focusing more attention on certain services and the populations receiving those services, at the expense of other beneficiaries. A few of these commenters also pointed out that other services are experiencing direct care worker shortages that could be contributing to service delays or underutilization that need to be identified.

One commenter suggested that we add services offered by specialty providers, such as occupational therapists, physical therapists, or speech-language pathologists, to the requirement.

A couple of commenters recommended extending the requirement to include services typically delivered to people with intellectual or developmental disabilities, such as habilitation services. Similar to the reasons cited by commenters for extending the requirement to all HCBS, commenters in favor of extending the requirements to include habilitation noted that these services are critical and beneficiaries who receive them are experiencing delays in services or other access issues. However, one commenter requested that we not extend these requirements to habilitation services, citing concerns that some States' information systems are not equipped to track this information for habilitation services. The commenter also noted that differences between habilitation services and other types of HCBS require additional study and consideration prior to applying these reporting requirements for habilitation services.

Response: We believe that the services proposed for inclusion in this requirement include activities of daily living that are critical to beneficiaries' health, safety, and ability to live successfully in the community. Additionally, as identified in an analysis performed by CMS, the three services fall within the taxonomy of home-based services, which are both high-volume and high cost.¹²⁶ Thus, we believe that targeting these services will maximize the impact of this requirement by addressing the needs of many beneficiaries and promoting better oversight of

¹²⁶ Centers for Medicare & Medicaid Services. "Trends in Rate Methodologies for High-Cost, High Volume Taxonomies." <https://www.medicare.gov/sites/default/files/2019-12/trends-in-rate-august-2017.pdf>. Last access October 2, 2023.

frequently used services. Given the similarities among homemaker, home health aide, and personal care services, we cannot find a justification for removing homemaker and home health aide services from this requirement.

Because we want to start by focusing on a selection of high-volume, high-cost services, we do not at this time intend to expand the reporting requirement to all HCBS. We do agree with commenters that services in addition to homemaker, home health aide, and personal care services may be particularly vulnerable to delays due to shortages in the direct care workforce. For that reason, we are extending the requirement to habilitation services in this final rule which, like homemaker, home health aide, and personal care services, tend to be hands-on services that are delivered by direct care workers who often earn lower wages. We believe that expanding the reporting to include habilitation services will ensure that beneficiary populations, namely individuals with intellectual or developmental disabilities who commonly receive personal care services as part of their habilitation services, are not excluded from our efforts to support the direct care workforce.

We acknowledge the comment that habilitation services are unique from other services, but also cannot identify reasons why these differences should exclude them from this reporting requirement.

After consideration of these comments and the benefits of aligning reporting requirements across services, we are finalizing the reporting requirements at § 441.311(d)(2)(i) and (ii) with a modification to include homemaker, home health aide, personal care, and habilitation services, as set forth at § 440.180(b)(2) through (4) and (6).

Comment: One commenter requested clarification on whether § 441.311(d)(2) would apply to services in both managed care and FFS delivery systems. One commenter requested that we require reporting on managed care plans' prior authorization practices, including differing lengths of authorizations and untimely authorizations that were not in place or renewed prior to the date of expected services. The commenter noted that missing authorizations may cause

disruptions in payments to providers and threaten the continuity of beneficiaries' access to the services.

Response: The reporting requirements apply to services delivered under both FFS and managed care delivery systems. For additional information, we refer readers to the discussion of §§ 441.311(f) and 438.72(b) below. We note that a State may consider requiring reporting on specific managed care processes through its contracts with managed care plans.

Comment: A few commenters requested clarification as to whether the requirements at § 441.311(d)(2) would apply to self-directed services. A few commenters raised specific questions or concerns about the application of the reporting requirements at § 441.311(d)(2) to self-directed services, particularly self-directed service models with individual budget authority. Commenters noted that the inherent flexibility of these services might make reporting on the utilization of service hours particularly misleading. One commenter noted that, when an individual selects an independent worker to provide services, that worker might have to go through background checks and training that would make it appear that the service delivery is delayed. One commenter worried that States would become concerned with the appearance of delays in the delivery of self-directed services and discourage beneficiaries from seeking self-directed services. Another commenter pointed out that since beneficiaries might use their budget authority to purchase equipment or devices that replace some hands-on services, or may choose to adjust their service schedules, service utilization data on these services might inaccurately suggest that the beneficiary is being underserved. On the other hand, one commenter recommended that self-directed services be included in this reporting. Another commenter stated that from their personal experience as a provider, beneficiaries receiving self-directed services tend to have higher service utilization rates than beneficiaries in agency-directed services. One commenter suggested that data on all models of self-directed services be tailored to the unique needs of the model, such as by requiring reporting on the percent of the budget used rather than

the number of service hours. Another commenter suggested that additional guidance would be needed to apply the reporting requirements to self-directed models.

Response: As discussed in section II.B.7.e. of this final rule, these reporting requirements will apply to self-directed services. We thank commenters for raising these concerns. As noted earlier, we intend to provide States with technical assistance, including technical specifications and sampling guidance, for the new reporting requirements in this final rule, which should aid in reporting on self-directed services. As noted in a prior response, the purpose of the data is to track trends in service delivery times and utilization, not to track the outcomes for each beneficiary. The reporting will be the average amount of time a random sample of beneficiaries waited between service authorization and the start of services, and the total percent of authorized services that are provided. Thus, some of the factors that commenters cited, such as additional training for self-directed service workers or individual beneficiaries' changes in schedules, should not significantly impact the reported numbers. However, we will work with States to monitor this issue.

Comment: A few commenters raised concerns about the proposal to allow States to report data on a statistically valid sample of beneficiaries, suggesting instead that we require complete reporting on all relevant beneficiary data. Commenters were concerned that using a sample could mask disparities or fail to identify individuals with particularly acute unmet needs. One commenter suggested that if we permit reporting on a random sample, we add a requirement that the data must include information on race, ethnicity, and population (such as older adults, people with intellectual and developmental disabilities, and people with physical disabilities) in order to identify disparities in service delivery.

Response: To minimize State reporting burden, we are finalizing the requirement to allow States to report data for § 441.311(d)(2) using statistically valid random sampling. We believe that due to variety in States' current tracking systems, some States might find reporting using statistically valid random sampling to be more manageable and auditable than attempting

to report on all beneficiaries. We will consider expanding reporting to the full population in future rulemaking if it is determined that such an approach gives a more complete picture of service delivery. We note that States may choose to report on the full population, as opposed to sampling their beneficiaries, if for instance, doing so better aligns with their data collection process or needs.

We are finalizing the requirements at § 441.311(d)(2)(i) and (ii) with a technical modification to specify that the State may report this metric using **statistically valid random sampling of beneficiaries**. (Revised language identified in bold.) We make this technical correction to better align the language with standard terminology for the sampling methodology we intended in these requirements.

Comment: We received responses to our comment solicitation on additional metrics that could be collected regarding service delivery and utilization. One commenter recommended that we not add more metrics to § 441.311(d)(2). Several commenters did suggest additional metrics. Many of these commenters noted that more detailed data would allow for a better assessment of overall unmet needs and disparities within service delivery. Additional metrics suggested by commenters included:

- Disaggregated data about beneficiaries, by demographic categories, including race, ethnicity, language status, sex or gender identification, sexual orientation, age, and geographic location;
- Tracking the total number of beneficiaries who received service authorizations versus the number of beneficiaries who received services;
- Tracking why services are not provided or why a beneficiary declines a service;
- Disaggregated data by HCBS authority and population (including dual eligibility), delivery system, provider type, and managed care plan; and
- Tracking beneficiaries' long-term access to services or other metrics to measure continuity of care and how the care contributes to beneficiaries' goals and outcomes.

One commenter, while not recommending that we require the measure for all States, shared a State's experience of including a measure to assess missed visits in its managed LTSS program. The commenter observed that this required a significant amount of time to identify legitimate reasons for services to not have been provided and to build the system mechanisms to capture that data, which was primarily identified through case management record review.

Response: We thank commenters for their thoughtful feedback. We will take these recommendations under consideration for future policymaking, but at this time, we decline to modify the metrics required at § 441.311(d)(2) based on these comments.

As noted in previous responses, we do not believe it would be feasible at this stage to standardize the collection of certain types of qualitative data, such as reasons for delayed or undelivered services, or how the services contribute to beneficiaries' outcomes; this data would also be difficult to validate and, as noted by one commenter, time-consuming to implement.

We believe it is important to strike a balance between collecting information to promote transparency around service times and utilization and imposing as minimal an administrative burden on States and providers as possible. We also believe that the reporting requirements at § 441.311(d)(2) are straightforward metrics on which to begin reporting. As we gather and review this data, we will consider what additional information may be needed to further improve our oversight of HCBS programs and improve beneficiaries' access to services and may consider additional reporting requirements in the future.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and beneficiary needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support beneficiaries' access to HCBS waivers in their State.

Comment: A few commenters recommended additional metrics that fall outside the scope of the reporting in § 441.311(d)(2). One commenter recommended collecting data on case

manager or service coordinator caseloads. A few commenters recommended measuring time between an individual's date of application and their eligibility determination, and the time between an individual's eligibility determination and the plan of care development or authorization for services.

Another commenter noted that a cause of delay in receiving HCBS may be due to delays in the development of care plans that are required for HCBS delivery to begin. The commenter noted that a potential solution to this specific barrier is the use of provisional plans of care, which are discussed in Olmstead Letter #3.¹²⁷ The commenter recommend that we affirm that HCBS provisional plans of care are an available option and require States to report on usage of such plans.

Response: We thank commenters and note these comments are not directly related to the proposed requirements in § 441.311(d), and thus we decline to make modifications to § 441.311(d) based on these suggestions. We plan to consider the comments as we regard broader HCBS access and equity issues for future policymaking. We also note that while requiring use of provisional care plans would be outside the of scope of this requirement, we agree with the commenter that the use of provisional care plans as described in Olmstead Letter #3 may help avoid the delay of services pending the development of the care plan.¹²⁸ In this letter, we explain that we will accept, as meeting requirements, a provisional written plan of care which identifies the essential Medicaid services that will be provided in the person's first 60 days of waiver eligibility, while a fuller plan of care is being developed and implemented. During this time, the

¹²⁷ Refer to Centers for Medicare and Medicaid Services, "Olmstead Letter #3, Attachment 3-a." July 25, 2000. Available at <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd072500b.pdf>; The commenter notes that in Olmstead Letter #3, Attachment 3-a (<https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd072500b.pdf>), CMS explains that it "will accept as meeting the requirements of the law a provisional written plan of care which identifies the essential Medicaid services that will be provided in the person's first 60 days of waiver eligibility, while a fuller plan of care is being developed and implemented." During this time, the relevant agencies work with the beneficiary to develop and finalize a "comprehensive plan of care," which goes into effect as soon as practically possible, and at least within 60 days.

¹²⁸ Centers for Medicare and Medicaid Services, "Olmstead Letter #3, Attachment 3-a." July 25, 2000, which is available at <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/smd072500b.pdf>.

relevant agencies work with the beneficiary to develop and finalize a “comprehensive plan of care,” which goes into effect as soon as practically possible, and at least within 60 days.

Comment: One commenter recommended that we allow States the option to choose one of the proposed criteria in § 441.311(d)(2) on which to report or to propose a different metric on which to report. The commenter believed this would permit flexibility in reporting on and context for data related to timeliness of initiation of service planning and service delivery. The commenter believed that this could serve as the first stage in a phased approach for access reporting.

Response: We thank the commenter for their suggestion. However, we believe it is important to take steps to establish nationally comparable data, which would require States to report on the same metrics. As discussed in previous responses, we are not finalizing any additional metrics for § 441.311(d)(2) and believe that the two metrics included in this requirement are a reasonable first step in data collection.

Comment: A few commenters supported annual reporting for § 441.311(d)(2). One commenter noted that annual reporting will better monitor service interruptions due to shortages of direct care workers. One commenter noted that a beneficiary’s service utilization can fluctuate significantly even from month to month. One commenter believed that biennial (every other year) reporting would reduce burden on States.

Response: We are finalizing the annual reporting frequency as proposed in § 441.311(d)(2). We continue to believe that annual reporting strikes the right balance between collecting current data and minimizing burden on States to the greatest extent possible. We are concerned that if we extend the reporting to a biennial frequency, the information will become outdated prior to the next public report.

After consideration of the comments received, we are finalizing the requirements at § 441.311(d)(2), with modifications. We are finalizing § 441.311(d)(2)(i) with a modification to specify that the reporting is for individuals newly receiving services within the past 12 months,

rather than for individuals newly approved to begin receiving services. We are also finalizing a modification so that both reporting requirements at § 441.311(d)(2)(i) and (ii) require reporting on homemaker services, home health aide services, personal care, or habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), and allow States to report using statistically valid random sampling of beneficiaries.

We note that we are finalizing § 441.311(d)(2) with technical corrections. As a result of modifying § 441.311(d)(2) to include habilitation services, we are modifying the title of this provision to specify *Access to homemaker, home health aide, personal care, and habilitation services*. We are also finalizing a technical modification in both § 441.311(d)(2)(i) and (ii) to indicate that the services are as “set forth” in § 440.180(b)(2) through (4) and (6), rather than as “listed” in.

d. Payment Adequacy (§ 441.311(e))

At § 441.311(e), we proposed new reporting requirements for section 1915(c) waivers, under our authority at section 1902(a)(6) of the Act, requiring that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), spent on compensation for direct care workers. For the same reasoning discussed in section II.B.5. of this preamble, we have focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. These are services that would most commonly be conducted in individuals’ homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We also believed that this reporting requirement could serve as the mechanism by which States demonstrated that they meet the proposed HCBS Payment Adequacy requirements at § 441.302(k).

We considered whether the proposed reporting requirements at § 441.311(e) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services for individuals with chronic mental illness. We had selected homemaker, home health aide, and personal care services (as defined at § 440.180(b)(2) through (4)) for this reporting requirement to align with the payment adequacy minimum performance requirement at § 441.302(k)(3), which is discussed in section II.B.5. of this preamble. However, we requested comment on whether States should be required to report annually on the percent of payments for other services listed at § 440.180(b) spent on compensation for direct care workers and, in particular, on the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services spent on compensation for direct care workers.

We further proposed that States separately report for each service subject to the reporting requirement and, within each service, separately report on payments for services that are self-directed. We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance with the requirement at § 441.302(k) and decided that the proposed requirement would be most effective to demonstrate State compliance. We requested comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments, and whether we should reduce the frequency of reporting to every other year.

To minimize burden on States and providers, we proposed that States report in the aggregate for each service across all of their services across all programs as opposed to separately report for each waiver or HCBS program. However, we requested comment on whether we should require States to report on the percent of payments for certain HCBS spent on compensation for direct care workers at the delivery system, HCBS waiver program, or

population level. We also requested comment on whether we should require States to report on median hourly wage and on compensation by category.

In consideration of additional burden reduction for certain providers, we requested comment on whether we should allow States the option to exclude, from their reporting to us, payments to providers of agency directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service. We also requested comment on whether we should establish a specific limit on this exclusion and, if so, the specific limit we should establish, such as to limit the exclusion to providers in the lowest 5th, 10th, 15th, or 20th percentile of providers in terms of Medicaid revenues for the service, number of Medicaid beneficiaries served, or number of direct care workers serving Medicaid beneficiaries.

We proposed that payments for self-directed services by States should be included in these reporting requirements, although we noted feedback from interested parties indicating that compensation for direct care workers in self-directed models tends to be higher and may comprise a higher percentage of the payments for services than other HCBS. This decision not to exclude them was based on the importance of ensuring a sufficient direct care workforce for self-directed services. We requested comment on whether we should allow States to exclude payments for self-directed services from these reporting requirements.

We note that, for clarity, we are aligning the definitions of compensation, direct care worker, and excluded costs at § 441.311(e)(1) with those we are finalizing in § 441.302(k)(1). As a result, the reporting requirement we proposed at § 441.311(e) is finalized at § 441.311(e)(2)(i), as discussed below. While we consider the reporting requirement at § 441.311(e) to be distinct and severable from the payment adequacy requirements in § 441.302(k), we believe that the reverse is not the case – that § 441.302(k) does rely on the reporting mechanism at § 441.311(e)

to establish compliance with the minimum performance requirement at § 441.302(k)(3). As such, we believe it is advantageous to have aligned definitions.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed general support for our proposed requirement at § 441.311(e) that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), spent on compensation for direct care workers. Commenters believed that this requirement would provide data about how Medicaid payments are being spent, which would improve oversight and enable meaningful comparisons across programs. One commenter requested clarification on the intent of the reporting requirement.

Commenters also believed that this requirement would ensure compliance with the payment adequacy minimum performance requirement at § 441.302(k)(3). Several commenters, however, expressed support for finalizing this reporting requirement, but not for finalizing the minimum performance requirement at § 441.302(k)(3). These commenters noted that the reporting requirement by itself would yield useful data that would support payment transparency in HCBS programs.

Response: This requirement is intended to help track the percent of Medicaid payments for certain HCBS that is spent on compensation for direct care workers. As we discussed extensively in section II.B.5. of this rule, we believe that ensuring that a significant portion of payments for these hands-on services is spent on compensation for direct care workers aligns with our responsibility under section 1902(a)(30)(A) of the Act to require assurance that payments are consistent with efficiency, economy, and quality of care. We do note that this reporting requirement also is a mechanism by which States demonstrate compliance with the payment adequacy requirements at § 441.302(k), which is discussed in detail in section II.B.5. of this rule.

While we are finalizing the payment adequacy requirements at § 441.302(k), we agree that the value provided by this reporting requirement is distinct and severable from the minimum performance requirement and serves as a standalone requirement. To clarify the distinction between this reporting requirement and the payment adequacy requirement at § 411.302(k), we are revising the language at § 411.311(e)(2) to remove the reference to the minimum performance requirement at § 411.302(k)(3). We believe this will better demonstrate that the reporting requirement has a function aside from demonstrating compliance with § 411.302(k). We also believe this to be necessary because, as discussed further below, we are finalizing the reporting requirement at § 411.311(e)(2) to include reporting of data related to habilitation services, which are not subject to the minimum performance requirement at § 411.302(k)(3). Thus, we believe retaining the reference to § 411.302(k)(3) would cause some confusion.

Comment: A few commenters opposed the reporting requirement proposed at § 441.311(e) (which we are finalizing at § 411.311(e)(2)). These commenters noted that the reporting requirement would increase administrative burden and administrative costs for providers; a few commenters believed the increase in administrative tasks would undermine the goal of the minimum performance requirement at § 441.302(k)(3) to reduce providers' spending on administrative activities.

Other commenters expressed concern that this requirement would create a burden for States. One commenter, although recognizing the need for more data about compensation to direct care workers, believed that most States do not currently collect this type of data and would require significant time, administrative effort, and expense to collect, compile, report, and analyze the data in a meaningful way. A few commenters stated that States would need to make significant changes to current billing and reporting practices and IT in order to isolate the use of reimbursements for the three specified services from the larger menu of services a provider typically offers. A couple of commenters expressed concerns about the time and resources it would take to educate providers about the requirements and their reporting responsibilities.

Additionally, a few commenters expressed concerns about whether States have the capacity to validate the accuracy of providers' reports and conduct audits, especially in States with a large number of providers. One commenter expressed concern about the cost associated with hiring and training independent auditors to audit providers' reported compensation of direct care workers. One commenter shared first-hand experience with implementing a wage pass-through requirement as part of the State's spending plan under ARP section 9817; the commenter regarded the process of monitoring and validating the percentage of payments going to direct care workers as administratively burdensome.

Response: We acknowledge that complying with this reporting requirement will necessitate certain expenditures of resources and time on the part of providers and States. As noted by commenters, we believe that the value of the data collected through their efforts makes these expenditures of resources worthwhile. As discussed further below, we are finalizing the redesignated § 441.311(e)(2)(i) to require only aggregated data by service, as proposed, which we believe will reduce burden on both providers and States.

We believe that, generally speaking, States and providers should already have information about the amount of Medicaid payments providers receive for specific services, and that providers likely already track expenditures on wages and benefits for their workers. We also believe that the simpler, aggregated reporting will be easier for States to validate and include in their existing auditing processes.

However, to ensure that States are prepared to comply with this reporting, we are adding a requirement at § 441.311(e)(3) to require that States must report, one year prior to the applicability date for (e)(2)(i) of this section, on their readiness to comply with the reporting requirement in (e)(2)(i) of this section. This will allow us to identify States in need of additional support to come into compliance with § 441.311(e)(2)(i) and provide targeted technical assistance to States as needed.

Comment: A couple of commenters requested that CMS issue subregulatory guidance or share best practices to assist with strategies for collecting data and ensuring compliance with the requirement. One commenter recommended that we work with States to determine the most efficient way to gather comparable, useful data to inform future rate policies, including exploring whether existing State tools could meet the requirement or could do so with modification.

A few commenters raised particular concerns about cost reports, which they believed would be necessary for implementing the reporting requirement. Commenters stated that without standardized cost reports, it will be difficult to ensure consistent and comparable data reporting across programs. Some of these commenters noted that, in States that do not currently require cost reports, this will present a new burden for both providers and States. A couple of commenters worried that providers may lack both the familiarity and the resources to complete cost reports. A few commenters requested that CMS develop a standard cost reporting template to ensure accurate data collection and assessment of compliance across all States.

A couple of commenters, noting the language proposed in § 441.311(e) (which we are finalizing at § 441.311(e)(2)(i)) that the reporting will be at the time and in the form and matter specified by CMS, requested additional information regarding the method of submission and the methodology that will be required for the calculations used in the report.

Response: We intend to release subregulatory guidance to assist States with implementation of this requirement, and we plan to also provide technical assistance and best practices to help States identify ways to use existing infrastructure or tools to gather and report. Further, as noted earlier, we intend to provide States with technical specifications for the new reporting requirements in this final rule, which will aid in consistent data reporting. In addition, we will be making the reporting template available for public comment through the Paperwork Reduction Act notice and comment process. Through that process, the public will have the opportunity to review and provide feedback on the elements of the required State reports,

including the methodology of the calculations, as well as the timing and format of the report to us.

As discussed further below, we are finalizing the requirement at § 441.311(e)(2)(i) (originally proposed at § 441.311(e)) that States need only report aggregated data by service. We believe this will reduce the overall burden on States and providers and reduce the need for complex cost reporting.

Comment: One commenter requested enhanced FMAP for costs associated with the reporting requirement.

Response: Enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.¹²⁹ Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.¹³⁰ We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.¹³¹ We decline to make any changes in this final rule based on this comment.

Comment: One commenter suggested that, instead of requiring reporting on the percentage of Medicaid payments going to compensation for direct care workers, we should require States to report annually on how their rates are determined and if the State's rate review included factors such as current wage rates, inflation, required costs of business, and increasing health insurance rates. Another commenter recommended that CMS consider implementing a regular review and assessment to determine if State Medicaid rates provide competitive wages for the direct care workforce and review how these wages are funded in the various payment models.

¹²⁹ See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

¹³⁰ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹³¹ See § 433.112 (b), 80 FR 75841; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C>.

Response: We focused this particular proposal on the allocation of Medicaid payments, not on rate setting or rate methodology. Such considerations are outside the scope of this proposal. However, we direct readers to the discussion in Documentation of Access to Care and Service Payment Rates (section II.C. of this final rule) which may speak to readers' interests in rate transparency and analysis. We decline to make any changes in this final rule based on this comment.

Comment: A few commenters requested clarification of the enforcement mechanisms for the reporting requirement.

Response: In terms of enforcing compliance of the States' obligation to submit reports as required at § 441.311(e), we intend to use our standard enforcement discretion. In terms of providers' cooperation with States in submitting the data States need to make their reports, we note that States already have broad authority to take enforcement action and create penalties, whether monetary or non-monetary, for providers that have violated their obligations as set forth by the State Medicaid program. We decline to make any changes in this final rule based on this comment.

Comment: A few commenters requested that we clarify managed care plans' responsibility for tracking and reporting expenditures. A few commenters expressed concern that this proposal would pose particular reporting or accounting burdens for providers that participate in multiple Medicaid managed care plans, serve non-Medicaid clients, or receive bundled payments.

Response: We plan to provide technical assistance to States to address the role of managed care plans in adhering to this reporting requirement, as well as to assist with strategies for addressing bundled payments that include the services affected by this requirement. Also, as discussed in greater detail below, we are not proposing granular reporting (such as requiring data be disaggregated by managed care plan or by HCBS waiver program). Additionally, we would like to emphasize that our intention is that the State requires providers share information about

the percent of all of their Medicaid FFS payments and the payment they receive from managed care plans that is being spent on compensation for the direct care workforce; we do not intend that the State should expect providers to provide a separate percent of Medicaid payments from each managed care plan in which they are enrolled, or provide separate calculations based on payment from services provided to non-Medicaid beneficiaries that is separate and distinct from their participation in the Medicaid managed care program. We therefore decline to make any changes in this final rule based on this comment.

Comment: A couple of commenters suggested that we expand reporting to include more HCBS than the three services specified, or even to apply this requirement to all HCBS. One of the commenters noted that, while more work, it would be administratively simpler to report on a broader array of services, rather than trying to isolate data for a few HCBS. One of the commenters recommended that we could phase in these expanded reporting requirements, beginning with homemaker, home health aide, and personal care services.

Response: As discussed below, we are expanding this reporting requirement in this final rule to include habilitation services. We tailored this requirement to address the services that are most likely to be delivered by direct care workers who predominantly earn lower wages. At this time, we do not intend to expand the requirement beyond homemaker, home health aide, personal care, and habilitation services. However, we note that States are free to collect additional information for State use if the States believe this would simplify administration or they would like to track allocations of Medicaid payments to direct care workers providing other types of HCBS.

Comment: In response to our request for comments, a few commenters recommended expanding the reporting requirement to include the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services that is spent on compensation for direct care workers. One commenter believed that it was important to include habilitation because, in the absence of such data, individuals with developmental

disabilities will be disadvantaged since habilitation is a primary vehicle for the delivery of support services to people with intellectual and developmental disabilities in most States. Another commenter believed this information would be critical for determining any future minimum performance level for compensation to direct care workers that was applied to habilitation services.

A few commenters, on the other hand, did not support including habilitation services, but did not specify reasons why these services should be excluded.

Response: We agree with commenters that collecting information about habilitation services would yield useful data about the allocation of Medicaid payments in support of the direct care workforce. Like homemaker, home health aide, and personal care services, habilitation services also tend to be hands-on services that are delivered by direct care workers who often earn lower wages. However, a key difference between habilitation services and the services that were initially selected for this reporting requirement is that they may include facility costs if the service includes residential habilitation or day habilitation. Reporting on habilitation could be useful in better understanding these costs as well, as it will allow for a comparison between the facility-based habilitation services and in-home services. We also agree with commenters that, as habilitation services are more often delivered to people with intellectual and developmental disabilities, excluding habilitation services will disproportionately impact beneficiaries with intellectual and developmental disabilities.

While we agree with commenters that it is important to collect data on habilitation services, we also acknowledge that, as noted above, some services include facility costs that may impact the percent of Medicaid payments being spent on compensation for direct care workers. Similar to our proposed requirement at § 441.311(e), that self-directed services be reported separately, we also are requiring that services that include facility costs in the Medicaid rate be reported separately; this way, we can observe the differences between the allocation of payments

in facility-based services versus services that are provided solely in the beneficiary's home or in community settings that are not facilities.

After consideration of the comments, we are adding habilitation services to this reporting requirement being finalized at § 441.311(e)(2)(i). We are modifying the requirement at § 441.311(e)(2)(i) to specify that the services included in this requirement are those set forth at § 440.180(b)(2) through (4) and (6). We note that § 440.180(b)(6) refers to habilitation services, without distinguishing between residential habilitation services, day habilitation services, and home-based habilitation services. Thus, we are also specifying that services with facility costs included in the Medicaid rate must be reported separately. These categories will be further described in subregulatory guidance. We approximate this distinction in this reporting requirement through the separate depiction of services with facility costs.

Comment: One commenter recommended that we exclude nurses and direct care workers who provide nursing assistance from this reporting requirement. Another commenter suggested that we should require data to be stratified by workforce. This commenter worried that without this disaggregation, workers who typically earn lower wages (such as personal care assistants) will be “overshadowed” in the data by workers who typically earn higher wages (such as nurses). The commenter believed this lack of transparency within the data would limit targeted interventions and advocacy for the lowest-paid positions within HCBS.

Response: Nurses and staff who provide nursing assistance are included in the definition of direct care worker we are finalizing at § 441.311(e)(1)(ii), as discussed previously. While some of the underlying rationale of this reporting requirement is related to concerns about low wages earned by some direct care workers, our broader concern is the health of the HCBS workforce as a whole. The HCBS workforce is experiencing a shortage of workers in all categories, including clinicians and nursing assistants. These workers provide direct, hands-on services to beneficiaries and may in some cases be required to provide or supervise the services. We do not believe excluding them from the reporting serves our larger interests in supporting the

direct care workforce overall. For that reason, we also do not believe that it is necessary to include a Federal reporting requirement that compensation to nurses should be reported separately, as our primary interest is in tracking the allocation of Medicaid payments to the direct care workers who are delivering the services. As noted above, States may choose to disaggregate data (for State use) for different categories of direct care workers in order to examine workforce issues at the State level.

Comment: Several commenters responded to our request for comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments. A few commenters opposed an attestation rather than a reporting requirement. These commenters agreed that the reporting requirement is the most effective means of verifying States' compliance with the payment adequacy minimum performance requirement at § 441.302(k)(3). Commenters also noted that the reporting requirement, rather than an attestation only, will yield granular data that will allow for comparison across States and, within States, across providers and service categories; such data, commenters believe, will enable States to better understand the impact of payment levels on access and adjust their rates accordingly, as well as prove useful for CMS's Federal oversight of beneficiaries' access.

A few commenters, on the other hand, supported requiring an attestation in lieu of a reporting requirement. Commenters, who mostly represented State agencies, preferred the option as being less burdensome and allowing for more flexibility. One commenter suggested that such an attestation could still be a means of limited data collection and proposed that, as part of an attestation, we provide States with a standardized reporting tool to assess whether their rates are sufficient to ensure a livable wage for direct care workers.

A couple of commenters noted that, while an attestation would be helpful to Medicaid programs, some Medicaid agencies noted that they would still need to collect at least some provider-level data to ensure compliance.

Response: We agree with commenters that a reporting requirement will be more effective and useful at monitoring and understanding the allocation of Medicaid payments to compensation for direct care workers, especially as this reporting requirement is intended to do more than simply demonstrate compliance with the payment adequacy requirements at § 441.302(k). We also are persuaded by commenters' observations that, even with an attestation, States would still need to collect data from providers to ascertain the accuracy of their attestation. In light of the fact that an attestation would only slightly reduce burden and would not result in data collection that would allow for national comparisons, we are moving forward with the reporting requirement rather than replacing it with an attestation.

Comment: Several commenters responded to our proposal at § 441.311(e) (which we are finalizing at § 441.311(e)(2)(i)) that reporting would be required annually as well as our request for comment on whether we should reduce the frequency of reporting to every other year. A few commenters supported our proposal that this reporting would be collected annually. One commenter believed that reporting less frequently than every year would result in the reporting of out-of-date data and would delay identification of problems in the HCBS system that could cause access issues for beneficiaries. Another commenter noted that the value of the data for rate-setting and the work of the interested party advisory group (discussed in section II.C.2. of this final rule, specifically in the discussion of § 447.203(b)(6)) outweighs any potential burden of annual reporting.

A few commenters supported reporting every two years, rather than an annual reporting period. One commenter made the specific suggestion that the reporting should be every two years with a 12-month lag to better ensure accurate reporting. Commenters who supported reporting every 2 years stated that this would allow States sufficient time to collect data, conduct necessary follow-up activities, and publish data while also helping them better balance this requirement with other compliance and reporting activities. One commenter opposed an annual

reporting period because it misaligned with their State's cycle of rate methodology review, which occurs every three to five years.

One commenter proposed an alternative reporting frequency of 3 years, but with the expectation that States would be collecting the data quarterly and analyzing the data annually. The commenter noted this frequency would also give the MAC and BAG (discussed in section II.A. of this rule) time to react to the data prior to its being reported to CMS.

Response: We agree that if too much time lapses between each reporting period, the reports, when released, will become quickly out of date. We also appreciate commenters' observations that interested parties, including advisory groups, might rely on this data when making recommendations for Medicaid rates or examining HCBS workforce issues; this places even greater importance on timely data. We also note that, as discussed further below, we are finalizing the requirement that only aggregated data must be reported, which should reduce burden on States and providers and make annual reporting manageable. We note that while annual reporting may be more frequent than States' rate review process, collecting this data annually will allow States to track trends in workforce compensation that they could include in their rate reviews.

We decline to add a requirement specifying how frequently States should review the data they collect. The purpose of this requirement is, in part, to establish the frequency with which States must submit a report to CMS, which we proposed as being on an annual basis. We do not intend to require that States collect and internally review their data quarterly; however, States may choose to do so if feasible and useful. We expect that, at minimum, States will review and analyze the data they receive on an annual basis as part of their submission of the report required by § 441.311(e)(2)(i).

Comment: One commenter specifically noted support for the requirement at § 441.311(e) that States report separately for each service subject to the reporting requirement. A few commenters requested that we finalize the requirement to allow States to report aggregated data

to minimize burden. A few commenters suggested that aggregate reporting would be preferable to a more granular approach (such as reporting on the percent of payments for certain HCBS spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level; reporting on median hourly wage and on compensation by category).

Response: As noted in our background discussion of this provision, we believe that reporting on aggregated data by service strikes the best balance between monitoring the proportion of Medicaid payments that are being spent on compensation for direct care workers and avoiding unnecessary data collection and burden on States and providers.

Comment: We received responses to our request for comment on whether we should require States to report on the percent of payments for certain HCBS that is spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. A number of commenters supported more granular reporting, which they believed would yield more valuable data and support transparency. Several commenters supported reporting at the delivery system level, which commenters believed would help capture differences between managed care and FFS. A few of these commenters also suggested that for managed care delivery systems, reporting should also be disaggregated by plan. One commenter also suggested that within managed care reporting, States should report separately for services delivered to dually eligible beneficiaries.

A few commenters supported breaking down the reporting by HCBS program.

One commenter noted that both provider payments and direct care worker compensation can have considerable variations across all of a State's programs and having this information would be useful for State policymakers as they develop payment rates. This commenter believed that States and providers must already be tracking which services are provided under each program.

A few commenters supported reporting at the population level. Suggestions for what would be included in the population level reporting included race, ethnicity, and geographic

location. One commenter believed that demographic information about beneficiaries and their geographic regions would help address barriers to access that are unique to certain populations and areas (such as access issues in rural regions). One commenter, however, believed that collecting data at the population level was not feasible.

Commenters made suggestions for additional details to add to the reporting requirement, including reporting on:

- Direct care worker turnover;
- Compensation to workers by setting (services delivered at home, residential, or facility-based day settings); and
- The number of direct care workers who are considered W-2 employees versus independent contractors.

Response: We thank commenters for their thoughtful feedback. We will take these recommendations under consideration for future policymaking, but at this time are moving forward with finalizing the language in the requirement at § 441.311(e)(2)(i) specifying that States must report the percent of total Medicaid payments spent on compensation to direct care workers by service. We note that a few of the suggestions are outside of the scope of this proposal, which is intended for States to report data about the percent of payments for certain HCBS that is spent on compensation for direct care workers, not for providers to report on the demographics or employment status of each of their workers, nor on granular beneficiary-level data. We direct readers who are interested to data collection about beneficiaries, including demographic data, to the discussion of the HCBS Quality Measure Set in section II.B.8. of this rule.

As noted in previous responses, we believe it is important to strike a balance between collecting enough information to enable Federal oversight of how Medicaid payments are being allocated and imposing as minimum an administrative burden on States and providers as possible. We believe that the data on the percent of Medicaid payments going to compensation

for direct care workers is sufficient to help us ensure that a significant portion of Medicaid payments for these hands-on services goes to the direct care workforce, which in turn supports our responsibility under section 1902(a)(30)(A) of the Act to require assurance that payments are consistent with efficiency, economy, and quality of care.

However, we agree that some of the granular data elements suggested by commenters could provide States with valuable insight into their own programs and workforce needs. We encourage States to consider what information they have the capacity to collect and would find useful for developing local policies to support direct care workers in their State.

Comment: One commenter also recommended collecting data specifically designed to measure the impact of the payment adequacy minimum performance requirement (which we are finalizing at § 441.302(k)) on the HCBS provider network. The commenter suggested we collect data on:

- The number of providers employing direct care workers that opened or closed before and after the effective date of the minimum performance requirement;
- The number of beneficiaries (particularly those with higher needs) for whom providers started or discontinued service provision before and after the effective date of the minimum performance requirement;
- The number of health and safety waiver requests that were received before and after the effective date of the minimum performance requirement; and
- The causal factors service providers cite when closing their business before and after the rule becomes effective.

Response: As the reporting requirement proposed at § 441.311(e) was intended only to measure the percent of Medicaid rates going to direct care worker compensation, recommendations for data collection regarding provider behavior are outside of the scope of our proposal.

However, we note that there are already data collection requirements for some HCBS regarding the number of beneficiaries served through a section 1915(k) program (as required at § 441.580) or annual reporting on the projected number of beneficiaries who will be served under section 1915(i) (as required at § 441.745(a)(1)).

Additionally, we are finalizing other reporting requirements in this final rule that may speak to some of the commenter's concerns. Specifically, we note that we are finalizing a rate disclosure process (discussed in section II.C., particularly under § 447.203(c)), which will include identification of the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for certain services, including homemaker, home health aide, personal care, and habilitation services defined at § 440.180(b)(2) through (4) and (6). We also note that the reporting requirement finalized in the previous section of this rule (under § 441.311(d)) will require reporting on the following metrics related to beneficiary access to homemaker, home health aide, personal care, and habilitation services: the average amount of time from when services are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months; and the percent of authorized hours for the services that are provided within the past 12 months. We note that these other reporting requirements, as finalized, will go into effect prior to the finalized effective date for the payment adequacy minimum performance requirement. This means that there will be data collected for these metrics both before and after the implementation of the payment adequacy requirement at § 441.302(k). Finally, we note that we do not know what the commenter is referring to by using the term, health and safety waiver requests.

Comment: Commenters responded to our request for comment on whether we should require States to report on median hourly wage and on compensation by category. A number of commenters supported adding this level of detail to the reporting requirement. Commenters noted that this level of reporting would help monitor workforce compensation generally, including identifying whether there were compensation disparities across service types. A few

commenters also suggested this data would help track the impact of the payment adequacy minimum performance requirement (required at § 441.302(k)(3)) on workforce compensation. One commenter also suggested that this data could be helpful to the interested parties advisory group (discussed further in section II.C.2. of this rule, under § 447.203(b)(6)). A few commenters also recommended that we require collection of specific details on other provider expenditures, such as for travel, training, administrative expenses, or other non-compensation program expenses.

One commenter, however, noted that median hourly wage and compensation by category reporting could be duplicative of other measures and required reporting.

Response: We thank commenters for their thoughtful feedback. In the proposed rule, in addition to requesting comment on whether we should require reporting on median hourly wages, in a separate proposal (under § 447.203(b)(3)) we had proposed a payment rate disclosure process for HCBS that included providing information about the hourly Medicaid rates paid for homemaker, home health aide, and personal care services. The proposals under § 447.203(b)(3) were standalone reporting requirements unrelated to the reporting requirement at § 441.311(e). As discussed in section II.C. of this final rule, the payment rate disclosure process at § 447.203(b)(3) is being finalized with modifications to include habilitation services in the reporting requirement. We do not see a need to finalize an additional reporting process that may be duplicative of both data and burden.

Additionally, upon consideration of the comments, we have identified no compelling reason to require a Federal requirement for disaggregating the data by compensation category. We believe that employee benefits, in addition to wages, are also integral to direct care workers. (We refer readers to the discussion in section II.B.5. of this rule, which includes concerns raised by public commenters about the lack of benefits for direct care workers.) Additionally, the third component of compensation – employers' share of payroll taxes – is a fixed cost. While States may want to collect this disaggregated data from providers to observe local compensation trends

or to share with the interested parties advisory group, we are not adding a requirement for this disaggregation as part of the required State reporting at § 441.311(e).

Comment: In response to our request for comment, a few commenters recommended that we allow States to exclude from their reporting to CMS payments to providers of agency-directed services that have low Medicaid revenues or serve a small number of beneficiaries. We did not receive feedback on metrics for determining which providers would be eligible for such an exclusion, nor on possible caps or limits for an exclusion.

One commenter noted that excluding certain providers due to size, revenue, or geography would create further inequities in the HCBS field and be administratively infeasible to implement. A couple of commenters worried that excluding small providers would create perverse incentives for providers to remain small by failing to hire additional workers or declining to serve additional beneficiaries.

Response: We are concerned that excluding certain providers from the reporting requirement at § 441.311(e) would not support the goals of this requirement to promote transparency about how Medicaid payments are being allocated.

For clarity, we also note that the reporting requirement we proposed at § 441.311(e), and are finalizing at § 441.311(e)(2)(i), requires each State to report to CMS annually on the percentage of Medicaid payments for certain services that is spent on compensation for direct care workers. We intend that each State collect and report this data regardless of whether the State establishes, and their providers meet, the hardship exemption we are finalizing at § 441.302(k)(5) or the small provider requirements at § 441.302(k)(3)(ii) and (4). We do note that, under the requirements we are finalizing at § 441.302(k)(6), the State must report additional information regarding any small provider requirements or hardship exemptions the State develops and implements.

However, we are finalizing the reporting requirement at § 441.311(e) with modification, adding § 441.311(e)(4) to exclude data from Indian Health Service and Tribal health programs

subject to the requirements at 25 U.S.C. 1641 from the required reporting. As discussed in section II.B.5.b. of this final rule, the requirements being finalized at § 441.302(k) conflict with statutory requirements at 25 U.S.C. 1641, and we are finalizing, at § 441.302(k)(7), an exemption to the payment adequacy requirement at § 441.302(k) for IHS and Tribal health programs subject to 25 U.S.C. 1641. Given the conflict between § 441.302(k) and the statutory requirements at 25 U.S.C. 1641, we would likely be unable to use HCBS payment adequacy data from IHS and the Tribal health programs subject to 25 U.S.C. 1641 to inform future policymaking related to how IHS or Tribal health programs spend Medicaid payments they receive, including on direct care worker compensation. Further, we do not want data from the exempted IHS and Tribal health programs to skew the other data States would collect and report to CMS under § 441.311(e), which CMS intends to use to evaluate direct care worker compensation nationally and inform policymaking to address the workforce shortage.

Comment: A few commenters suggested other metrics that could be used as the basis for an exception to the reporting requirement. One commenter suggested that an exception could be made for providers in areas (defined as a city, county, or grouping of zip codes) with a documented deficit of service providers accepting new clients. One commenter recommended that any provider who pays a full-time direct care worker at an hourly rate that exceeds 200 percent of the Federal poverty level be exempted from reporting. Another commenter suggested that if a provider can demonstrate they spend more than 85 percent of Medicaid payments on compensation should be exempted from any detailed cost reporting.

Response: As noted above, we are finalizing the reporting requirement without exceptions for providers. However, we appreciate the recommendations for possible exceptions criteria and will take these into consideration for future policymaking.

Comment: One commenter requested that we exclude self-directed services from reporting. However, we received a number of comments encouraging us to include self-directed services in the reporting as proposed and agreeing that these services should be reported

separately. A few of these commenters stated that self-directed services should be reported separately from agency-provided services, due to the differences in these service models.

A few commenters, however, believed that the reporting for self-directed services should be further broken down by whether the service is provided by an independent worker or by a worker who is employed by an agency. One commenter noted that our rationale for separating out self-directed services was that compensation for workers in self-directed models tends to be higher and to comprise a greater percentage of Medicaid payment for services, which the commenter believed to be true of services delivered by independent providers, but not necessarily of self-directed services delivered through agency models.

One commenter noted that some States might have challenges in distinguishing payments for self-directed services delivered via agency models, as these payments may appear in claims processing as traditional HCBS agency payments, rather than as self-directed services.

Response: We agree with commenters that, in terms of the percent of the payment going to compensation for direct care workers, there will be significant differences between the percent for services delivered by independent workers hired by the beneficiary for whom the beneficiary sets the payment rate under a self-directed services delivery model versus those delivered by a worker employed by a provider. In particular, we are concerned that this reporting requirement might not yield meaningful data if applied to the self-directed services delivery models in which the individual beneficiary determines the wage paid directly to the direct care worker out of the beneficiary's service budget (such as models meeting the definition at § 441.545(b) for section 1915(k) services, self-directed services typically authorized under section 1915(j)). We believe the reporting requirement on the percentage of payments going to compensation for direct care workers is only appropriate when applied to a Medicaid rate that includes both compensation to direct care workers and administrative activities. In the former scenario, we expect that all or nearly all of that payment rate routinely is spent on the direct care worker's compensation; in the

latter scenario, we expect the payment rate to a provider includes both the direct care worker's compensation and administrative costs for the provider.

Based on the comments received, and to ensure we are collecting only meaningful data that demonstrates the percent of Medicaid payments that are going to direct care worker compensation, we are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies, if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section. We note that self-directed homemaker, home health aide, personal care, or habilitation services delivered through self-directed services models not described in § 441.311(e)(2)(ii) would still be part of the reporting requirements finalized at § 441.311(e)(2)(i).

After consideration of the comments received, we are finalizing § 441.311(e) with modifications. As discussed in section II.B.5. of this final rule, we are replicating at § 441.311(e)(1)(i), (1)(ii), and (1)(iii) the finalized definitions at § 441.302(k)(1)(i), (k)(1)(ii), and (k)(1)(iii), respectively.

At § 441.311, we are redesignating paragraph (e) as paragraph (e)(2)(i). At finalized § 441.311(e)(2)(i), we are making a technical modification to remove the reference to the definition of direct care workers at § 441.302(k)(1). As we are also adding the definition of direct care workers at § 441.311(e)(1)(ii), the reference to § 441.302(k)(1) is unnecessary. We are finalizing § 441.311(e)(2)(i) with substantive modifications to specify that the State must report to CMS annually on the percentage of total payments (**not including excluded costs**), to include habilitation services (as set forth in § 440.180(b)(6)) in the reporting, and to specify that States must report separately **for services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.** (Revised text in bold font). We

are also finalizing § 441.311(e)(2)(i) with technical modifications to: include references to § 441.311(e)(2)(ii) and (4); clarify that the provision applies to services as **set forth** in § 440.180(b)(2) through (4) and (6) (as opposed to services at § 440.180(b)(2) through (4) that are authorized under section 1915(c) of the Act); and clarify that reporting is at the time and in the form and manner specified by CMS.

We are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

We are finalizing a new § 441.311(e)(3), requiring that the State must report, one year prior to the applicability date for paragraph (e)(2)(i) of this section, on its readiness to comply with the reporting requirement in paragraph (e)(2)(i) of this section.

We are finalizing a new § 441.311(e)(4) to require States to exclude data from the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the required reporting at § 441.311(e), as well as to require that States not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under § 441.311(e)(2).

e. Applicability date (§ 441.311(f))

We proposed at § 441.311(f)(1) to provide States with 3 years to implement the compliance reporting requirements at § 441.311(b), the HCBS Quality Measure Set reporting requirements at § 441.311(c), and the access reporting requirements at § 441.311(d) in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed

to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP, beginning on or after 3 years after the effective date of the final rule to implement these requirements. This time period was based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these proposed reporting requirements. We also considered all of the HCBS proposals outlined in the proposed rule as whole. We invited comments on whether this timeframe was sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

In addition, we proposed at § 441.311(f)(2) to provide States with 4 years to implement the payment adequacy reporting requirements at § 441.311(e) in FFS delivery systems following the effective date of the final rule. For States that implement a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 4 years after the effective date of the final rule to implement these requirements. This time period was intended to align with the effective date for the HCBS payment adequacy requirements at § 441.302(k), which are discussed in section II.B.5. of this preamble. It was also based on feedback from States and other interested parties that it could take 3 to 4 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these reporting requirements. We also considered all of the HCBS proposals outlined in the proposed rule as a whole. We solicited comments on whether this timeframe was sufficient, whether we should require a shorter timeframe (3 years) or longer timeframe (5 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the effective dates in § 441.311(f). One commenter noted that the effective dates appear to be appropriate and necessary to ensure that data is reported accurately and uniformly. One commenter suggested that States should begin to report on person-centered planning within 2 years. One commenter noted particular support for the longer four-year timeframe for the payment adequacy reporting requirements at § 441.311(e), which the commenter noted recognized the additional complexity of this provision. A few commenters stated that they support the 4-year effective date for § 441.311(e) but would advocate for a 6-year effective date if the payment adequacy minimum performance level in § 441.302(k) is also being finalized.

A number of commenters noted that while they are supportive of each of these proposals individually, they were nevertheless concerned that the number of new requirements will be difficult to implement cost-effectively and accurately in the proposed timeframes. Several commenters noted that proposed data elements required in § 441.311 are beyond what the States currently collect and - even if the States are able to expand on existing systems - will require policy and process changes and system updates and will place strain on existing staff resources; some commenters stated these changes may require seeking appropriations from State legislatures for additional staff or system upgrades, as well as acquiring vendor support, which could take additional time. A few commenters noted their States would face challenges in coordinating data collection across multiple systems, which may be administered by different agencies or contracted entities. A few commenters noted the feasibility of compliance with § 441.311 will depend on how quickly CMS can provide subregulatory guidance on the reporting requirements; these commenters requested that we set an effective date of 3 or 4 years after the release of subregulatory guidance.

While commenters requested that we extend the timeframes in § 441.311(f), we received few suggestions for how much additional time would be needed. A few commenters suggested alternative timeframes of 4 to 6 years for the provisions in § 441.311. One commenter suggested that timeframes should be specifically waived for self-directed services and that States should be required to submit transition plans for implementing the requirements for self-directed services.

Response: We are finalizing the substance of § 441.311(f) as proposed, but with minor modifications to correct erroneous uses of the word “effective.” We are retitling the requirement at § 441.311(f) as Applicability dates (rather than Effective dates). We are also modifying the language at § 441.311(f) to specify the dates when States must comply with the requirements in § 441.311(f), rather than stating the dates when the requirements in § 441.311(f) are effective, beginning a specified number of years after the effective date of the final rule.

As noted above in section II.B.7.b. of the rule, we have determined it is necessary to provide States with an additional year for compliance with the quality measure set reporting requirement at § 441.311(c). Our primary purpose in extending the date for States to comply is to ensure States have sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing in section II.B.8. of this rule.

Regarding the dates for States to comply with the other requirements in § 441.311, as discussed throughout this section, we continue to believe that many of these requirements build on activities that States have already been doing as part of the administration of their HCBS programs and will work with States to identify ways to leverage existing data collection tools and update their current systems as efficiently as possible.

We also acknowledge that complying with these reporting requirements will necessitate expenditures of resources and time on the part of States, managed care plans, and (in some cases) providers. We believe that the value of the data collected through their efforts makes this expenditure of resources worthwhile. This data captures information related to beneficiaries’ health and safety (addressed by the incident management system and critical incident reporting

in § 441.311(b)(1) and (2)) and beneficiaries' long-standing concerns about access to HCBS waivers and services (addressed by the person-centered planning and access reporting requirements in § 441.311(b)(3) and (d)). These data are urgently needed, and we do not want to postpone implementation of this reporting further than proposed.

Additionally, the data collected as part of the payment adequacy reporting requirement in § 441.311(e) not only addresses the current workforce shortages that are impacting service delivery, but the data are also going to be relied on by the interested parties advisory group (discussed further in section II.C.2. of this rule, under § 447.203(b)(6)) to develop recommendations to the State on Medicaid rates for certain HCBS. We do not believe the interests of beneficiaries, providers, workers, or States are served by delaying the collection and publication of this information. As a result, we are declining to make changes in this final rule based on these comments. We plan to provide technical assistance to States experiencing challenges implementing specific reporting requirements.

Comment: A few commenters, while not opposing the proposed dates that the reporting requirements become effective, noted that it is important to align these reporting requirements with other reporting requirements in States and for managed care plans to minimize State and managed care plan reporting burdens. Commenters also believed that streamlining reporting requirements across programs could help to ensure that States and CMS do not analyze similar data that report on the same populations and same or similar programs across different timeframes, which would complicate findings.

Response: We will be releasing subregulatory guidance, including technical specifications for the new reporting requirements in this final rule, and making the required reporting templates available for public comment through the Paperwork Reduction Act notice and comment process. Specific reporting due dates will be determined through subregulatory guidance; we plan to work with States to align these due dates with other obligations to minimize administrative burden to the greatest extent possible.

After consideration of public comments, we are finalizing § 441.311(f) with minor modifications to correct erroneous uses of the word “effective.” We are removing from § 441.311(f)(1) the date for States to comply with the quality measure set reporting requirements date and adding it to § 441.311(f)(2) so that States will have 4 years from the effective date of this final rule to comply with those requirements.

We are also finalizing in § 441.311(f)(1) and (2) a modification to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are specifying at § 441.311(f)(1) that States must comply with the reporting requirements at paragraphs (b) and (d) of this section beginning 3 years after the effective date of this final rule; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO’s, PIHP’s, or PAHP’s contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after the effective date of this final rule.

We are specifying at § 441.311(f)(2) that States must comply with the reporting requirements at paragraphs (c) and (e) of this section beginning 4 years after the effective date of this final rule; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO’s, PIHP’s, or PAHP’s contract, the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the date that is 4 years after the effective date of this final rule.

f. Application to Other Authorities (§§ 441.311(f), 441.474(c), 441.580(i), and 441.745(a)(1)(iii))

At § 441.311(f), we proposed to apply all of the reporting requirements described in § 441.311 to services delivered under FFS and managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act

requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs, and as noted in the Medicaid context this would include consistent administration between FFS and managed care programs. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As discussed earlier in section II.B.1. of this preamble, the proposed requirements at § 441.311, in combination with other proposed requirements identified throughout the proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance, also discussed earlier in section II.B.1. of this preamble. We expect that States may implement some of the requirements proposed in the proposed rule in advance of any effective date. We will work with States to phase out the 2014 guidance as they implement the requirements in this final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs, and because these reporting requirements are relevant to other HCBS authorities, we proposed to include these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we proposed to apply the requirements at § 441.311 to section 1915(j), (k), and (i) State plan services at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believed the same

arguments for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.580(i), we proposed to renumber existing § 441.580(i) as § 441.580(j).

We considered whether to also apply these reporting requirements to section 1905(a) “medical assistance” State plan personal care, home health, and case management services. However, we proposed that these requirements not apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for sections 1915(c), (i), (j), and (k) services and because the person-centered planning, service plan, and waiting list requirements that comprise a significant portion of these reporting requirements have little to no relevance for section 1905(a) services, in comparison to section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authority. We requested comment on whether we should establish similar reporting requirements for section 1905(a) “medical assistance” State plan personal care, home health, and case management services.

We noted that we expected that we would establish new processes and forms for States to meet the reporting requirements, provide additional technical information on how States can meet the reporting requirements including related to sampling requirements (where States are permitted to report on a sample of beneficiaries rather than on all individuals who meet the inclusion criteria for the reporting requirement), and amend existing templates and establish new templates under the Paperwork Reduction Act.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported applying the proposed reporting requirements at § 441.311 to services delivered under managed care, noting that it is important to gather data on services across delivery systems. A few commenters requested clarification on whether, or how, the reporting requirements applied to services delivered under managed care.

Response: The reporting requirements in this section apply to services in both FFS and managed care delivery systems. We note that comments about the application of specific provisions to managed care are addressed in the sections above. As needed, we plan to provide technical assistance to States that have additional questions.

Comment: A few commenters expressed support for applying reporting requirements at § 441.311 to services delivered through other section 1915 authorities. A few commenters, while not necessarily recommending that we exclude self-directed services authorized under section 1915(j), noted that because of differences in self-directed services, we should consider extending timeframes for implementation in self-directed services or release additional guidance specific to self-directed services.

Response: We are finalizing our proposal to extend the reporting requirements in this section to services offered under sections 1915(i), (j), and (k). We note that comments about the application of specific provisions to self-directed care are addressed in the sections above. While we do not believe it is necessary to extend timeframes for the implementation of the reporting requirements in section 1915(j) self-directed services, we plan to provide technical assistance to States that have additional questions.

Comment: One commenter requested clarification that the waiver reporting requirement at § 441.311(d)(1) is limited to the section 1915(c) authority and to the section 1915(j) authority, where it is used as the State's authority for self-direction in a section 1915(c) waiver. This commenter recommended limiting this requirement to these authorities.

Response: We agree that, because section 1915(i) and section 1915(k) State plan services cannot have capped enrollment, the reporting requirements at § 441.311(d)(1) would not apply to

these authorities. We also agree that the reporting requirements at § 441.311(d)(1) would also apply to section 1915(j) authority only where section 1915(j) is used as the State's authority for self-direction in a section 1915(c) waiver. We note that the reporting requirements at § 441.311(d)(1) would apply to section 1115(a) demonstration projects that include HCBS if the State caps enrollment for the HCBS under the section 1115(a) demonstration project.

We also note that, similar to the concern raised by commenters about the applicability of § 441.311(d)(1), as discussed in section II.B.7.a.4. of this rule, § 441.311(b)(4) also applies only to section 1915(c) programs.

Comment: A few commenters requested that we extend the reporting requirements at § 441.311 to section 1905(a) services. Commenters noted that, in some States, many people receive services through section 1905(a). A few commenters also raised concerns that there would be a disparate impact on certain populations or less oversight of certain services if reporting requirements were not extended to services under section 1905(a), such as personal care, home health, or rehabilitative services. A few commenters recommended not extending the reporting requirements to section 1905(a) services at this time, citing concerns about additional burden.

Response: At this time, we are not mandating inclusion of section 1905(a) services in the reporting requirements at § 441.311. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider these comments provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. We are not persuaded by the argument that including section 1905(a) services would simply be too much work, as we do agree that transparency, accountability, and oversight are critical for all HCBS. However, we are continuing to review statutory and regulatory differences between services authorized under sections 1905(a) and 1915 of the Act that could impact how these requirements would apply to section 1905(a) services. We also note that we have not extended the minimum performance requirements for

incident management, person-centered planning, or payment adequacy to section 1905(a) services (refer to discussions in sections II.B.1., II.B.3, and II.B.5. of this final rule, respectively, for more detail on those discussions). Furthermore, as section 1905(a) service do not have waiting lists, the requirement at § 441.311(d)(1) would not be applicable to these services.

After consideration of the comments received, we are finalizing application of § 441.311 to section 1915(j), (k), and (i) authorities. We are making modifications at §§ 441.474(c), 441.580(i) and 441.745(a)(1)(vii) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), (k) and (i) of the Act, respectively.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.311 as follows:

- We are finalizing § 441.311(a) with a modification for clarity to remove “simplification” and make a minor formatting change to ensure § 441.311(a) aligns directly with the statutory requirement at section 1902(a)(19) of the Act .
- We are finalizing the incident management system compliance requirement at § 441.311(b) with a technical modification for clarity in § 441.311(b)(1)(i) that the State must report on the results of an incident management system assessment, every 24 months, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS.
- We are finalizing the critical incident compliance requirement at § 441.311(b)(2) with a technical modification for clarity that the State must report to CMS annually in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. For consistency, we are also simplifying the title and removing the reference to § 441.302(a)(6)(i)(A) from the title of §441.311(b)(2).
- We are finalizing the person-centered planning reporting requirement at § 441.311(b)(3) with a technical modification to specify at § 441.311(b)(3), to demonstrate that the

State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS, rather than according to the format and specifications provided by CMS. We are also finalizing the reporting requirement at § 441.311(b)(3)(i) and (ii), with the technical modification noted previously, to specify that the State may report this metric using statistically valid random sampling of beneficiaries.

- We are finalizing the reporting requirement at § 441.311(b)(4) with a modification to restore language that was erroneously omitted, and with additional technical modifications so that § 441.311(b)(4) specifies that annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan, in the form and manner, and at a time, specified by CMS.

- We are finalizing the HCBS Quality Measure Set reporting requirements at § 441.311(c) with modifications. At § 441.311(c), we are finalizing a date of 4 years, rather than 3 years, for States to comply with the HCBS Quality Measure Set reporting requirements at § 441.311(c).

- We are finalizing the access reporting requirement at § 441.311(d) with a technical modification to specify that reporting will be in the form and manner, and at a time, specified by CMS. We are finalizing § 441.311(d)(1) as proposed. We are finalizing § 441.311(d)(2)(i) with a modification to specify that the reporting is for individuals newly receiving services within the past 12 months, rather than for individuals newly approved to begin receiving services. We are finalizing the requirements at § 441.311(d)(2), with modifications so that both reporting requirements at § 441.311(d)(2)(i) and (ii) require reporting on homemaker services, home health aide services, personal care, or habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), and allow States to report using statistically valid random sampling of beneficiaries. We are modifying the title of this provision at § 441.311(d)(2) to specify *Access to homemaker, home health aide, personal care, and habilitation services*. We are also finalizing a technical

modification in both § 441.311(d)(2)(i) and (ii) to indicate that the services are, as set forth in § 440.180(b)(2) through (4) and (6), rather than, as listed in, as noted in the proposed rule.

- We are replicating at § 441.311(e)(1)(i) through (iii) the finalized definitions at § 441.302(k)(1)(i), through (iii), respectively.

- We are redesignating § 441.311(e) as § 441.311(e)(2)(i) and finalizing § 441.311(e)(2)(i) with modifications to specify that, except as provided at (e)(2)(ii) and (4), the State must report to CMS annually on the total percentage of payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

- We are finalizing a new requirement at § 441.311(e)(2)(ii) that specifies if the State provides that homemaker, home health aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

- We are finalizing a new § 441.311(e)(3), requiring that the State must report, 1 year prior to the applicability date for paragraph (e)(2)(i) of this section, on its readiness to comply with the reporting requirement in paragraph (e)(2)(i) of this section.

- We are finalizing a new § 441.311(e)(4) to require States to exclude the Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (e) of this section, and not require submission of data by, or

include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under paragraph (e)(2).

- We are finalizing § 441.311(f) with modification to move the date that States are required to comply with the quality measure reporting at § 441.311(c) from § 441.311(f)(1) to § 441.311(f)(2), and to clarify the language regarding applicability dates in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract.

- We are finalizing §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), (k), and (i) of the Act, respectively.

8. Home and Community-Based Services (HCBS) Quality Measure Set (§§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)).

On July 21, 2022, we issued State Medicaid Director Letter # 22-003132 to release the first official version of the HCBS Quality Measure Set. The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. It is intended to promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. It is also intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. By providing States and other interested parties with a set of nationally standardized measures to assess HCBS quality and outcomes and by facilitating access to information on those measures, we believe that we can

¹³² CMS State Medicaid Director Letter. SMD# 22-003 Home and Community-Based Services Quality Measure Set. July 2022. Accessed at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

reduce the time and resources that States and other interested parties expend on identifying, assessing, and implementing measures for use in HCBS programs.

a. Basis and Scope (§ 441.312(a))

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at sections 1102(a) and 1902(a)(6) of the Act, we proposed a new section, at § 441.312, Home and Community-Based Services Quality Measure Set, to require use of the HCBS Quality Measure Set in section 1915(c) waiver programs and promote public transparency related to the administration of Medicaid-covered HCBS. We proposed to describe the basis and scope for this requirement at § 441.312(a).

In proposing this requirement, we believed that quality is a critical component of efficiency, and as such, having a standardized set of measures used to assess the quality of Medicaid HCBS programs supports the efficient operation of the Medicaid program. Further, we believed that it is necessary for the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act, consistent with section 1902(a)(4) of the Act, as it would establish a process through which we regularly update and maintain the required set of measures at § 441.311(c) in consultation with States and other interested parties (as described later in this section of the rule). The process, as proposed, would ensure that the priorities of interested parties are reflected in the selection of the measures included in the HCBS Quality Measure Set. The process, as proposed, also would ensure that the required set of HCBS quality measures is updated to address gaps in the HCBS Quality Measure Set as new measures are developed and to remove measures that are less relevant or add less value than other available

measures, and the HCBS quality measures meets scientific and other standards for quality measures. Due to the constantly evolving field of HCBS quality measurement, we proposed these requirements based on our belief that the failure to establish such a process would result in ongoing reporting by States of measures that do not reflect the priorities of interested parties, measures that offer limited value compared to other measures, and measures that do not meet strong scientific and other standards. It would also result in a lack of reporting on key measurement priority areas, which could be addressed by updating the HCBS Quality Measure Set as new measures are developed. The failure to establish such a process would lead to inefficiency in States' HCBS quality measurement activities through the continued reporting on an outdated set of measures. In other words, we believed that such a process is necessary for the efficient administration of Medicaid-covered HCBS by ensuring that quality measure reporting requirements are focused on the most valuable, useful, and scientifically supported areas of quality measurement, and that quality measures with limited value are removed timely from quality measure reporting requirements.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposed basis and scope at § 441.312(a). Several commenters supported the requirements at § 441.312 (a) in its entirety.

Response: We thank the commenters for their support for our proposal.

Comment: A few commenters raised concerns that the HCBS Quality Measure Set is overly prescriptive from a Federal perspective and sets a one-size-fits-all approach, expressing that the responsibility for safeguarding quality in HCBS belong to each State.

Response: We disagree with commenters that the proposed requirement for States to use the HCBS Quality Measure Set is overly prescriptive. CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the

requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across services, and instead vary depending on the authorities under which States are delivering services. While we support State flexibility, the lack of standardized measures has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different Medicaid beneficiary populations. We underscore our belief that use of the HCBS Quality Measure Set will promote more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. As discussed further in this section II.B.8. of this rule, we are finalizing the requirements at § 441.312(a) as proposed and plan to provide technical assistance to States as needed to address the concerns raised by commenters.

Comment: Several commenters requested that CMS align the HCBS quality measures universally across Medicaid programs, recommending streamlining measures across the HCBS Quality Measure Set, the Medicaid and CHIP (MAC) Quality Rating System (QRS), and the Adult Core Set. Further, commenters recommended we consider a minimum set of mandatory quality measures and limit them to a small set, similar to the MAC QRS, and allow States the flexibility to utilize voluntary measures in addition to the minimum mandatory measures, as appropriate. Commenters further noted that States already have implemented measures that may not be included in the quality measures identified in the HCBS Quality Measure Set, and this

approach for a small set of mandatory measures could minimize disruption to the quality-related work that is currently being undertaken by States in their Medicaid programs.

One commenter observed that creating a unified reporting structure on mandatory measures would bring a level of discipline and consistency that would foster more reliable data across the Medicaid program, noting that it is imperative to create alignment for data collection across States.

Response: We thank the commenters for this feedback. We will take these comments into consideration when developing and updating the HCBS Quality Measure Set and developing subregulatory guidance on the required use of the HCBS Quality Measure Set. We agree with the commenters on the importance of parsimony, alignment, and harmonization in quality measurement across the Medicaid program, to the extent possible. While we aim to align measures across programs as much as possible, the HCBS Quality Measure Set is designed to promote more common and consistent use of nationally standardized quality measures in HCBS programs and to support States with improving quality and outcomes specifically for beneficiaries receiving HCBS. As a result, we expect the HCBS Quality Measure Set to be in alignment with the MAC QRS and the Child and Adult Core Sets.

We also acknowledge that States are already using quality measures to assess quality in their HCBS programs, and it is not our intent for States to abandon this quality-related work. The measure set is intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. However, States may continue to utilize existing measures not found in the HCBS Quality Measure Set if the States believe they generate valuable information, as long as the measures in the HCBS Quality Measures Set are implemented in accordance with § 441.312, which we are finalizing as discussed further in this section II.B.8. of this rule.

After consideration of the comments received, we are finalizing § 441.312(a) with a minor formatting change to correct punctuation.

b. Definitions (§ 441.312(b))

We proposed a definition at § 441.312(b)(1) for “Attribution rules,” to mean the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures in the HCBS Quality Measure Set as described at § 441.312(d)(6). We also proposed a definition at § 441.312(b)(2) for “Home and Community-Based Services Quality Measure Set” to mean the Home and Community-Based Services Quality Measures for Medicaid established and updated at least every other year by the Secretary through a process that allows for public input and comments, including through the Federal Register.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the proposed definitions at § 441.312(b).

Response: We thank these commenters for their support.

After consideration of the comments received, we are finalizing at § 441.312(b)(1) the definition of attribution rules as proposed. As discussed in more detail in our discussion of § 441.312(c) in the next section below (section B.8.c. of this rule), we are making several changes related to the frequency of updates to the HCBS Quality Measure Set. To accommodate those changes, we are striking the words, at least every other year, from the definition of the Home and Community-Based Services Quality Measure Set we proposed at § 441.312(b)(2).

As finalized at § 441.312(b)(2) the definition of Home and Community-Based Services Quality Measure Set means the Home and Community-Based Services Quality Measures for Medicaid established and updated by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section. We note that the measure updates are specified in § 441.312(c) as finalized, and thus the frequency of updates do not need to be set forth in the definition of the HCBS Quality Measure Set. *Additionally, we are finalizing § 441.312(b) with a minor technical modification to correct*

an inadvertent omission in the regulatory text in the proposed rule and are finalizing the addition of the numbers (1) and (2) in front of each definition.

c. Responsibilities of the Secretary (§ 441.312(c))

At § 441.312(c), we described the proposed general process for the HCBS Quality Measure Set that the Secretary will follow to update and maintain the HCBS Quality Measure Set. Specifically, at § 441.312(c)(1), we proposed that the Secretary will identify, and update at least every other year, through a process that allows for public input and comment, the quality measures to be included in the HCBS Quality Measure Set. At § 441.312(c)(2), we proposed that the Secretary will solicit comment at least every other year with States and other interested parties, which we identified later in this section of the preamble of the proposed rule, to:

- Establish priorities for the development and advancement of the HCBS Quality Measure Set.
- Identify newly developed or other measures that should be added, including to address gaps in the measures included in the HCBS Quality Measure Set.
- Identify measures that should be removed as they no longer strengthen the HCBS Quality Measure Set.
- Ensure that all measures included in the HCBS Quality Measure Set are evidence-based, are meaningful for States, and are feasible for State-level and program-level reporting as appropriate.

The proposed frequency for updating the quality measures included in the HCBS Quality Measure Set was aligned with the proposed frequency at § 441.311(c)(1) for States' reporting of the measures in the HCBS Quality Measure Set. We based other aspects of the proposed process that the Secretary will follow to update and maintain the HCBS Quality Measure Set in part on the processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting final rule (88 FR 60278); (hereinafter the

“Mandatory Medicaid and CHIP Core Set Reporting final rule”). We believed that such alignment in processes will ensure consistency and promote efficiency for both CMS and States across Medicaid quality measurement and reporting activities.

At § 441.312(c)(3), we proposed that the Secretary will, in consultation with States and other interested parties, develop and update the measures in the HCBS Quality Measure Set, at least every other year, through a process that allows for public input and comment. We solicited comments on whether the timeframes for updating the measures in the HCBS Quality Measure Set and conducting the process for developing and updating the HCBS Quality Measure Set is sufficient, whether we should conduct these activities more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe was recommended, the rationale for that alternate timeframe.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal at § 441.312(c)(1) to identify and update the quality measures included in the HCBS Quality Measure Set at least every other year, through a process that allows for public input and comment. One commenter noted that identifying and updating the measures annually, instead of every other year, could maximize the effectiveness of the HCBS Quality Measure Set, especially with a new and rapidly evolving field of HCBS measures, suggesting that an every other year frequency might impact the use of innovative approaches to inform quality improvement in HCBS. Alternatively, several commenters expressed concern and recommended less frequent updates to the HCBS Quality Measure Set, questioning the usefulness of the measures that change every other year and suggesting that taking a longer time between updates to the HCBS Quality Measure Set will minimize financial burden and allow States to more accurately measure improvement over time. In the same vein, one commenter expressed that every other year updates to the measure set might have an effect and impact the usefulness of longitudinal data. These commenters

suggested alternative timeframes ranging from 3 to 5 years, with 3 years being the most frequently suggested frequency for updates to the HCBS Quality Measure Set.

Response: We thank commenters for their feedback. In consideration of comments received, we agree that clarification of the frequency in updates to the HCBS Quality Measure Set is required. We note that the proposed process for updating the quality measures included in the Quality Measure Set differs in frequency from, though is based in part on, the processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the final rule, “Medicaid Program and CHIP; Mandatory Medicaid and Children’s Health Insurance Program (CHIP) Core Set Reporting” (88 FR 60278) (hereinafter the “Mandatory Medicaid and CHIP Core Set Reporting final rule”). We proposed a frequency for updating the quality measures included in the HCBS Quality Measure Set, which is different from the mandatory annual State reporting of the Core Set measures in the Mandatory Medicaid and CHIP Core Set Reporting final rule, because the HCBS Quality Measure Set was only first released for voluntary use by States in July 2022, while Child, Adult, and Health Home Core Sets voluntary reporting has been in place for a number of years. Further, a substantial portion of the measures included in the HCBS Quality Measure Set, particularly compared to the Child, Adult, and Health Home Core Sets, is derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. We recognize that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. Upon further consideration, we assure States that CMS will not update the measure set to add new measures or retire existing measures more frequently than every other year, and are modifying the beginning date as no later than December 31, 2026, instead of 2025. We note that, while the finalized requirement will allow CMS to add new measures or retire existing measures every other year, CMS intends to retain each of the measures in the measure set for at least 5 years to ensure the availability of longitudinal data, unless there are serious issues associated with the measures (such as related to measure reliability

or validity) or States' use of the measures (such as excessive cost of State data collection and reporting or insurmountable technical issues with State reporting on the measures).

After consideration of the comments received about the frequency of updating the quality measures in § 441.312(c)(1), we are finalizing § 441.312(c)(1) with modifications to require that the Secretary shall identify and update **quality measures no more frequently than** every other year, beginning no later than December 31, 2026, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section). (New language identified in bold.)

We are also finalizing a new requirement at § 441.312(c)(2) to require the Secretary to **make** technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate. This addition is intended to ensure that the measures included in the measure set are accurate and up to date, and that we may correct errors, clarify information related to the measures, and align with updated technical specifications of measure stewards, particularly given the revision to § 441.312(c)(2) to indicate that CMS will not update the HCBS Quality Measure Set more frequently than every other year. To accommodate the new requirement at § 441.312(c)(2), we have renumbered the provisions proposed at §§ 441.312(c)(2) and (3) to §§ 441.312(c)(3) and (4), respectively.

We are finalizing redesignated § 441.312(c)(3)(iv) with a minor technical modification for clarity to specify that the Secretary shall ensure that all measures included in the Home and Community-Based Services Quality Measure Set reflect an evidence-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level, program-level, or provider-level reporting as appropriate. We are also finalizing the redesignated requirement at § 441.312(c)(4) with a modification to replace the words, at least, with the words, no more frequently than, to require that the Secretary, in consultation with States, develop and update, no more frequently than every other year, the

Home and Community-Based Services Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

As noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.¹³³ Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.¹³⁴ However, we reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.¹³⁵ We clarify, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in the Interoperability Standards Advisory (ISA)¹³⁶ to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities that can help promote the health and safety of HCBS beneficiaries.

We plan to provide States with technical assistance and subregulatory guidance to support implementation of the HCBS Quality Measure Set.

After consideration of the comments received, we are finalizing § 441.312(c) with modifications. We are finalizing § 441.312(c)(1) with modifications to require that the Secretary

¹³³ See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

¹³⁴ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹³⁵ See § 433.112 (b), 80 FR 75841; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C>.

¹³⁶ Relevant standards adopted by HHS and identified in the ISA include the USCDI (<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>), eLTSS (<https://www.healthit.gov/isa/documenting-care-plans-person-centered-services>), and Functional Assessment Standardized Items (<https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability>).

shall identify, and update no more frequently than every other year, beginning no later than **December 31, 2026**, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section. (New language identified in bold.)

We are finalizing § 441.312(c)(2) without substantive changes, but we are redesignating the requirement as § 441.312(c)(3). We are finalizing a new requirement at § 441.312(c)(2) that the Secretary shall make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate. We are also redesignating what had been proposed as §441.312(c)(3) as (c)(4) and finalizing the redesignated § 441.312(c)(4) with a modification to replace the word at least with no more frequently than.

d. Process for Developing and Updating the HCBS Quality Measure Set (§ 441.311(d))

At proposed § 441.312(d), we described the proposed process for developing and updating the HCBS Quality Measure Set. Specifically, we proposed that the Secretary will address the following through a process to:

- Identify all measures in the HCBS Quality Measure Set, including newly added measures, measures that have been removed, mandatory measures, measures that the Secretary will report on States' behalf, measures that States can elect to have the Secretary report on their behalf, as well as the measures that the Secretary will provide States with additional time to report and the amount of additional time.

- Inform States how to collect and calculate data on the measures.
- Provide a standardized format and reporting schedule for reporting the measures.
- Provide procedures that States must follow in reporting the measure data.
- Identify specific populations for which States must report the measures, including people enrolled in a specific delivery system type such as those enrolled in a managed care plan or receiving services on a fee-for-service basis, people who are dually eligible for Medicare and Medicaid, older adults, people with physical disabilities, people with intellectual or

developmental disabilities, people who have serious mental illness, and people who have other health conditions; and provide attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population.

- Identify the measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary.
- Describe how to establish State performance targets for each of the measures.

As discussed in section II.B.8. of the proposed rule (88 FR 27992 through 27993), we anticipated that, for State reporting on the measures in the HCBS Quality Measure Set, as outlined in the reporting requirements we proposed at § 441.311, the technical information on attribution rules described at proposed § 441.312(d)(6), would call for inclusion in quality reporting based on a beneficiary's continuous enrollment in the Medicaid waiver. This ensures the State has enough time to furnish services during the measurement period. In the technical information, we anticipated we would set attribution rules to address transitions in Medicaid eligibility, enrollment in Medicare, or transitions between different delivery systems or managed care plans, within a reporting year, for example, based on the length of time beneficiaries was enrolled in each. We invited comment on other considerations we should address in the attribution rules or other topics we should address in the technical information.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters provided input on the proposed process that the Secretary will follow to update and maintain the HCBS Quality Measure Set. A few commenters recommended that, to advance meaningful quality improvement and measurement, we should prioritize the importance of a measure and a measure's usability and use for measure selection and suggested an additional evaluative category of advancing equity. A couple of commenters suggested that we should consider implementing a process to determine if quality measures are

based on person-centered planning principles, emphasizing that many of the measures in the HCBS Quality Measure Set are more system and process-oriented, rather than focused on assessing and improving person-centered experiences and preferences. One commenter recommended we conduct a broad-based public review of possible quality measures and domains for individuals with intellectual and developmental disabilities to inform the quality measures process. Another commenter suggested that we include an oral health measure for beneficiaries receiving HCBS in the selection of measures for the HCBS Quality Measure Set. A few commenters recommended we prioritize the development and inclusion of culturally and linguistically appropriate measures within the HCBS Quality Measure Set, prioritizing reporting of the most feasible measures, aligning the CMS Core Sets, to capture the experiences and outcomes of diverse populations and ensure that HCBS programs address the unique needs and preferences of beneficiaries from different cultural backgrounds.

Response: At § 441.312(d), we described the general process that the Secretary will follow to update and maintain the HCBS Quality Measure Set.

We underscore the importance of alignment in quality measurement across the Medicaid program, to the extent possible. We proposed at § 441.312(d)(7), that the process for developing and updating the HCBS Quality Measure Set will address the subset of measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties.

After further consideration, we have identified that including Tribal status as a measure stratification factor is misaligned, as it is not included as a measure stratification factor for the Adult Core Set as defined in the Mandatory Medicaid and CHIP Core Set Reporting final rule. We are also concerned that this additional measure stratification factor will create additional burden for States. After further consideration, to ensure alignment in Medicaid quality measurement and alignment of the HCBS Quality Measure Set with the Adult Core Set, we are

removing Tribal status as a measure stratification factor at § 441.312(d)(7). We note that Tribal status could be included as a measure stratification factor under such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with § 441.312(b)(2) and (g).

At § 441.312(d), we proposed and are finalizing the process for developing and updating the HCBS Quality Measure Set. At § 441.312(d)(5) the process for developing and updating the HCBS Quality Measure Set includes the identification of the beneficiary populations for which States are required to report the HCBS quality measures identified by the Secretary. We are finalizing § 441.312(d)(5)(i) with a technical modification, including the identification of the beneficiaries receiving services through specified delivery systems for which States are required to report the HCBS quality measures identified by the Secretary, replacing managed care plan with **MCO, PIHP, or PAHP as defined in § 438.2.** (New language identified in bold.)

Comment: A few commenters requested we clarify how the HCBS Quality Measure Set would relate to measurement for beneficiaries who are dually eligible for Medicare and Medicaid. One commenter further expressed strong support for disaggregation of data for dually eligible beneficiaries, but also questioned whether partial benefit dually eligible beneficiaries were required to be included in the population for quality measurement, as most do not receive HCBS or any other Medicaid benefits.

Response: We plan to provide States with guidance and technical assistance to help address issues specific to dually eligible beneficiaries. Further, inclusion and exclusion criteria for each measure will be addressed through the technical specifications for the measure. We note that, to the extent that dual-eligible beneficiaries are receiving services authorized under section 1915(c), (i), (j), or (k) Medicaid programs and delivered through managed care plans, and meet the inclusion criteria for the measure, they are required to be included in the reporting on that measure. We will provide technical assistance regarding the application of these requirements to beneficiaries in different categories of dual eligibility.

Comment: One commenter requested that CMS clarify the requirement at § 441.312(d)(7) referencing the subset of measures in the HCBS Quality Measure Set that must be stratified by health equity characteristics, noting that the proposed § 441.312(f) would require States to stratify 100 percent of measures by 7 years after the effective date of the final rule. They emphasized a disconnect between the two provisions, as a subset of measures is not the same as 100 percent of measures and suggest removing the word subset to avoid confusion in implementation.

Response: Reporting of stratified data is a cornerstone of our approach to advancing health equity. We note reporting stratified data helps identify and eliminate health disparities across HCBS populations. As we noted in the proposed rule (88 FR 27993), measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity through data reporting and stratification aligns with EO 13985.¹³⁷

At § 441.312(f), in specifying which measures, and by which factors, States must report stratified measures consistent with § 441.312(d)(7), the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate. We reiterate that we considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as discussed in the Mandatory Medicaid and CHIP Core Set Reporting rule (87 FR 51313), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those

⁸² Exec. Order No. 13985 (2021), Accessed at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

interventions.¹³⁸ This consistency could not be achieved if each State made its own decisions about which data it would stratify and by what factors.^{139,140} We also recognize that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. We also may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify will be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. preserved and model accuracy is improved. In consideration of these factors we are finalizing at § 441.312(d)(7) that the subset of measures among the measures in the HCBS Quality Measure Set that must be stratified by health equity characteristics as proposed.

In response to the commenter's observation regarding when 100 percent of the measures must be stratified, we note that, for reasons discussed in greater detail in section II.B.7. and II.B.8.e. of this final rule, we are modifying the requirement at § 441.311(f) to change the timing by which measures must be stratified. As finalized, § 441.311(f) requires that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

After consideration of the comments received, we are finalizing § 441.312(d)(1) through (6) and (8) as proposed. We are finalizing § 441.312(d)(7) with modification to remove Tribal status as a stratification factor. As finalized, § 441.312(d)(7) provides that the process for developing and updating the HCBS Quality Measure Set will address the subset of measures

¹³⁸ Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. *Health Aff (Millwood)*. 2008;27(2):568-573.

¹³⁹ Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting>.

¹⁴⁰ National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities_The_Four_I_s_for_Health_Equity.aspx.

among the measures in the HCBS Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties.

e. Phasing In of Certain Reporting (§ 441.311(e) and (f))

At § 441.312(e), we proposed, in the process for developing and updating the HCBS Quality Measure Set described at proposed § 441.312(d), that the Secretary consider the complexity of State reporting and allow for the phase-in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and developmental disabilities. At § 441.312(f), we proposed that, in specifying the measures and the factors by which States must report stratified measures, the Secretary will consider whether such stratified sampling can be accomplished based on valid statistical methods, without risking a violation of beneficiary privacy, and, for measures obtained from surveys, whether the original survey instrument collects the variables or factors necessary to stratify the measures.

We considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as we noted was discussed in the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.¹⁴¹ This consistency could not be achieved if each State made its own decisions about which data it would stratify and by what factors.^{142,143}

¹⁴¹ Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. *Health Aff (Millwood)*. 2008;27(2):568-573.

¹⁴² Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; <https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting>.

¹⁴³ National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities_The_Four_I_s_for_Health_Equity.aspx.

In the proposed rule, we recognized that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. We also noted that there are several challenges to stratification of measure reporting. First, the validity of stratification is threatened when the demographic data are incomplete. Complete demographic information is often unavailable to us and to States due to several factors, including the fact that Medicaid applicants and beneficiaries are not required to provide race and ethnicity data. Second, when States with smaller populations and less diversity stratify data, it may be possible to identify individual data, raising privacy concerns. Therefore, if the sample sizes are too small, the data would be suppressed, in accordance with the CMS Cell Size Suppression Policy and the data suppression policies for associated measure stewards and therefore not publicly reported to avoid a potential violation of privacy.¹⁴⁴

We also acknowledged that we may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify would be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. The Transformed Medicaid Statistical Information System (T-MSIS), for example, currently has the capability to stratify some HCBS Quality Measure Set measures by sex and urban/rural status, but not by race, ethnicity, or disability status. This is because applicants provide information on sex and urban/rural address, which is reported to T-MSIS by States, whereas applicants are not required to provide information on their race and ethnicity or disability status, and often do not do so. However, we have developed the capacity to impute race and ethnicity using a version of the Bayesian Improved Surname Geocoding (BISG) method¹⁴⁵ that includes Medicaid-specific enhancements to optimize accuracy, and are able to stratify by race and ethnicity, urban/rural status, and sex.

¹⁴⁴CMS Cell Size Suppression Policy, Issued 2020: <https://www.hhs.gov/guidance/document/cms-cell-suppression-policy> or the cell suppression standards of the associated measure stewards.

¹⁴⁵ Elliott, Marc N., et al. "Using the Census Bureau's surname list to improve estimates of race/ethnicity and associated disparities." *Health Services and Outcomes Research Methodology* 9.2 (2009): 69-83.

With these challenges in mind, we proposed that stratification by States in reporting of HCBS Quality Measure Set data would be implemented through a phased-in approach in which the Secretary would specify which measures and by which factors States must stratify reported measures. At § 441.312(f), we proposed that States would be required to provide stratified data for 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. We noted that the percentages listed here aligned with the proposed phase-in of equity reporting in the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278). However, the timeframe associated with each percentage of measures to phase-in equity reporting that we proposed in this rule is different with a slower phase-in, in large part because when compared to the Child, Adult, and Health Home Core Sets, the HCBS Measure Set in its current form includes a substantial number of measures that are derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. In addition, the slower phase-in was also intended to take into consideration the overall burden of the reporting requirements and that States have less experience with the HCBS Quality Measure Set. Specifically, the Mandatory Medicaid and CHIP Core Set Reporting final rule (88 FR 60278) requires States to provide stratified data for 25 percent of measures within 2 years after the effective date of the final rule, 50 percent of measures within 3 years after the effective date of the final rule, and 100 percent of measures within 5 years after the effective date of the final rule.

In our proposed rule, we determined that our proposed phased-in approach to data stratification would be reasonable and minimally burdensome, and thus consistent with EO 13985 on Advancing Racial Equity and Support for Underserved Communities Through the

Federal Government (January 20, 2021),¹⁴⁶ because we were balancing the importance of being able to identify differences in outcomes between populations under these measures with the potential operational challenges that States may face in implementing these proposed requirements.

We recognized that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. We reminded States that enhanced FFP is available at a 90 percent match rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.¹⁴⁷ Enhanced FFP at a 75 percent match rate is also available for operations of such systems, in accordance with applicable Federal requirements.¹⁴⁸ We also encouraged States to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the ISA.¹⁴⁹

We invited comments on the proposed schedule for phasing in reporting of HCBS Quality Measure Set data. We also solicited comment on whether we should phase-in reporting on all of the measures in the HCBS Quality Measure Set.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal at § 441.312(f) in its entirety.

Response: We thank the commenters for their support of our proposed requirements.

¹⁴⁶ Exec. Order No. 13985 (2021), Accessed at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

¹⁴⁷ See section 1903(a)(3)(A)(i) of the Act and § 433.15(b)(3), 80 FR 75817 through 75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

¹⁴⁸ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹⁴⁹ Relevant standards adopted by HHS and identified in the ISA include the USCDI (<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>), eLTSS (<https://www.healthit.gov/isa/documenting-care-plans-person-centered-services>), and Functional Assessment Standardized Items (<https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability>).

Comment: Several commenters submitted recommendations and requests related to the details of stratified reporting, such as definitions of specific categories of populations, data suppression policies, how to handle missing data, and different measures of delivery systems.

Response: We believe that stratified data would enable us and States to identify the health and quality of life outcomes of underserved populations and potential differences in outcomes based on race, ethnicity, sex, age, rural/urban status, disability, language, and other such factors on measures contained in the HCBS Quality Measure Set. We refer readers to section II.B.8. of the proposed rule (88 FR 27993) for a detailed discussion of stratified data and sampling.

We expect to align with Department of Health and Human Services (HHS) data standards for stratification, based on the disaggregation of the 1997 Office of Management and Budget (OMB) Statistical Policy Directive No 15.¹⁵⁰ We expect to update HCBS Quality Measure Set reporting stratification categories if there are any changes to OMB or HHS Data Standards. We will take this feedback into account as we plan technical assistance and develop guidance for States.

Comment: Several commenters supported all the proposed requirements for stratification but recommended either faster or slower implementation. A couple of commenters suggested that States be required to report stratified data by 3 years after the effective date of this final rule rather than phase in this requirement. Multiple commenters provided alternate phase-in schedules for stratification of the HCBS Quality Measure Set, with the most frequent suggestions to add two to five years to the phase-in timeline for data stratification requirements for the measures in the HCBS Quality Measure Set. Some commenters expressed that they supported a staggered implementation timeline of the data stratification requirements and noted that additional time and flexibility for States could make compliance more attainable because of State legislative, budgeting, procurement, and contracting requirements. Another commenter, who represents

¹⁵⁰ The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard: <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=53>.

State agencies, emphasized that many States have long-standing challenges with collecting complete demographic data on Medicaid beneficiaries, and they expressed concerns with small samples, staffing capacity, survey fatigue, and problems identifying baseline demographics. One commenter recommended that the initial implementation of stratification occur with a rolling start date by State, based on waiver renewal date.

Response: We continue to believe that the time frame for States to implement stratification of data on quality measures in the HCBS Quality Measure Set is an appropriate frequency that ensures accountability without being overly burdensome. We determined that a shorter phase timeframe would not likely be operationally feasible because of the potential systems and contracting changes (to existing contracts or the establishment of new contracts) that States may be required to make, in order to collect these data for reporting. For example, additional reporting requirements may need to be added to State contracts, changes may be needed to data sharing agreements with managed care plans, and modifications of databases or systems might be required to record new variables.

As discussed in section II.B.7. of this final rule, we are finalizing at § 441.311(f)(2) that States must comply with the HCBS Quality Measure Set reporting requirement at § 441.311(c) beginning 4 years after the effective date of this final rule, rather than 3 years. We are making this modification in order to allow for sufficient time for interested parties to provide input into the measures, as required by § 441.312(g), which we are finalizing as described in this section II.B.8. of this rule. To align with this modification, we are finalizing the phase-in requirement at § 441.312(f). As finalized, § 441.312(f) requires that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

We anticipate that States will not need more than 4 years after the effective date of the final rule, to implement systems and contracting changes, or any additional support needed to report on the quality measures in HCBS Quality Measure Set. However, as described at finalized § 441.312(e), we will consider the complexity of State reporting and allow for the phase in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and disabilities. Further, we plan to work collaboratively with States to provide technical assistance and reporting guidance through the Paperwork Reduction Act process necessary to support reporting.

Comment: A couple of commenters recommended that we offer States financial assistance to develop and deploy health equity efforts, including funding support in addressing the capture of self-reported data.

Response: As discussed above, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements. We reiterate that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.¹⁵¹ This may include improving data reporting, which could promote greater health equity.

We clarify, to receive enhanced FMAP funds, the State Medicaid agency is required at § 433.112(b)(12) to ensure the alignment with, and incorporation of, standards and implementation specifications for health information technology adopted by the Office of the National Coordinator for Health IT in 45 CFR part 170, subpart B, among other requirements set forth in § 433.112(b)(12). States should also consider adopting relevant standards identified in

¹⁵¹ See § 433.112 (b), 80 FR 75841; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C>.

the ISA¹⁵² to bolster improvements in the identification and reporting on the prevalence of critical incidents for HCBS beneficiaries and present opportunities for the State to develop improved information systems that can support quality improvement activities. We further clarify that States are responsible for ensuring compliance with the requirements of HIPAA and its implementing regulations, as well as any other applicable Federal or State privacy laws governing confidentiality of a beneficiary's records.

After consideration of the comments we received, we are finalizing § 441.312(e) as proposed.

We are finalizing § 441.312(f) with a modification to require that stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations.

e. Consultation with Interested Parties (§ 441.312(g))

At § 441.312(g), we proposed the list of interested parties with whom the Secretary must consult to specify and update the quality measures established in the HCBS Quality Measure Set. The proposed list of interested parties included: State Medicaid Agencies and agencies that administer Medicaid-covered HCBS; health care and HCBS professionals who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs; health care and HCBS professionals, providers, and direct care workers who provide services to older adults, children and adults with disabilities and complex medical and behavioral health care needs who live in urban and rural areas or who are members of groups at increased risk for poor outcomes; HCBS providers; direct care workers and organizations representing direct care workers; consumers and national organizations representing consumers;

¹⁵² Relevant standards adopted by HHS and identified in the ISA include the USCDI (<https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>), eLTSS (<https://www.healthit.gov/isa/documenting-care-plans-person-centered-services>), and Functional Assessment Standardized Items (<https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability>).

organizations and individuals with expertise in HCBS quality measurement; voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care; measure development experts; and other interested parties the Secretary may determine appropriate.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters commended our proposal at § 441.312(g) to consult and receive input from interested parties. These commenters expressed they are encouraged by the continued collaboration with CMS in identifying and updating the HCBS Quality Measure Set. A few commenters shared suggestions for others to include as interested parties, mentioning managed care plans, community representatives from underserved communities, family members, and caregivers.

Response: We appreciate the submission of these comments and will take them into consideration as the Secretary carries out the responsibilities at § 441.312(g).

Comment: One commenter recommended we establish an ongoing process of consultation with States and interested parties to make updates to the quality measures in the HCBS Quality Measure Set in a longer cycle between updates based on consensus, such as 5 years. This commenter emphasized this approach can assure interested parties that the measure set will continue to be developed over time based on new information and priorities and help avoid making changes too rapidly to be sustained by States.

Response: We appreciate the submission of these comments. As noted previously, we are finalizing § 441.312(c)(1) and (2) with modifications to indicate that we will identify, and update no more frequently than every other year, beginning no later than December 31, 2026, the quality measures to be included in the HCBS Quality Measure Set as defined in paragraph (b) of this section.

We will make technical updates and corrections to the HCBS Quality Measure Set annually as appropriate. Additionally, as discussed in greater detail in section II.B.7. of this final rule, we are giving States more time to engage with interested parties by finalizing an applicability date of 4 years, rather than 3 years, for the requirement that States must comply with the HCBS Quality Measure Set reporting at § 441.311(c). We are making this revision in order to allow for sufficient time for interested parties to provide input into the measures, as required by § 441.312(g).

After consideration of the comments received, we are finalizing § 441.312(g) as proposed.

f. Application to Other Authorities (§§ 441.474(c), 441.585(d), and 441.745(b)(1)(v))

Because these quality measurement requirements are relevant to other HCBS authorities, we proposed to include these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we proposed to apply the proposed requirements at § 441.312 to section 1915(j), (k), and (i) State plan services at §§ 441.474(c), 441.585(d), and 441.745(b)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believed the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We requested comment on the application of these provisions across sections 1915(i), (j), and (k) authorities.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to apply the HCBS Quality Measure Set requirements at § 441.312 to sections 1915(i), (j) and (k) authorities, stating there

should be equally applicable requirements for States across authorities to ensure consistency, coordination, and alignment across quality improvement activities for these HCBS beneficiaries.

Alternatively, a few commenters expressed that applying the HCBS Quality Measure Set requirements across sections 1915(i), (j) and (k) authorities could pose challenges for States since the application of quality measure data collection and reporting for these HCBS authorities is mixed among States. One commenter requested an exemption for the section 1915(i) authority, noting that implementing the HCBS Quality Measure Set requirements for this authority is onerous, since the service array for section 1915(i) programs is more limited than in section 1915(c) programs.

Response: We thank commenters for their support. We note that States can cover the same services under section 1915(i) as they can cover under section 1915(c) of the Act. As such, exempting States from implementing the HCBS Quality Measure Set requirements under section 1915(i) does not align with our intent, which is to ensure consistency and alignment in reporting requirements across HCBS authorities. We are finalizing our proposal to apply the HCBS Quality Measure Set requirements to sections 1915(c), (i), (j) and (k) authorities and plan to provide technical assistance to States as needed to address the concerns raised by commenters.

After consideration of the comments received, we are finalizing the application of § 441.312 to section 1915(j) services by finalizing a reference to § 441.312 at § 441.474(c). (Note that we also discuss finalization of §§ 441.474(c) in section II.B.7. of this final rule.) We are finalizing the application of § 441.312 to sections 1915(k) and 1915(i) services at §§ 441.585(d) and 441.745(b)(1)(v) with modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(k) and 1915(i) of the Act, respectively.

g. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.312 as follows:

- We are finalizing § 441.312(a) with a minor technical change.

- We are finalizing the definition of attribution rules and Home and Community-Based Services Quality Measure Set at § 441.312(b)(1) with a minor formatting change.
- We are finalizing the responsibilities of the Secretary at § 441.312(c)(1) with technical modifications to revise the frequency for updating the measure set to no more frequently than every other year and replace December 31, 2025 with December 31, 2026.
- We are finalizing a new requirement at § 441.312(c)(2) that the Secretary shall make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate.
- We are redesignating § 441.312(c)(2) as paragraphs (c)(3) and finalizing with minor technical modification.
- We are redesignating § 441.312(c)(3) as § 441.312(c)(4) and finalizing § 441.312(c)(4) with a minor technical modification to replace “at least” with “no more frequently than.”
- We are finalizing § 441.312(d)(i) as proposed with a modification for clarity to replace managed care plan with MCO, PIHP or PAHP as defined in § 438.2.
- We are finalizing § 441.312(e) as proposed.
- We are finalizing the requirement at § 441.312(f) with a technical modification in the dates by when a certain percent of measures are to be stratified, delaying each deadline by one year.
- We are finalizing § 441.312(g) as proposed.
- We are finalizing the reference to § 441.312 in § 441.474(c) as proposed.
- We are finalizing the requirements at §§ 441.585(d) and 441.745(b)(1)(v) with modification to clarify that the references to section 1915(c) of the Act are instead references to section 1915(k) and 1915(i) of the Act, respectively.

9. Website Transparency (§§ 441.313, 441.486, 441.595, and 441.750)

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Under our authority at section 1102(a) of the Act, we proposed a new section, at § 441.313, titled Website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS. As noted in the proposed rule, we believe quality is a critical component of efficiency, as payments for services that are low quality do not produce their desired effects and, as such, are more wasteful than payments for services that are high quality. The proposed approach was based on feedback we obtained during various public engagement activities conducted with States and other interested parties over the past several years that it is difficult to find information on HCBS access, quality, and outcomes in many States. As a result, it is not possible for beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid HCBS. We believe that the website transparency requirements support the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act by promoting public transparency and the accountability of the quality and performance of Medicaid HCBS systems, as the availability of such information improves the ability of interested parties to hold States accountable for the quality and performance of their HCBS systems.

a. Website Availability and Accessibility (§ 441.313(a))

At § 441.313(a), we proposed to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and provides the results of the reporting requirements under § 441.311 (specifically, incident management, critical incident, person-centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; access data; and payment adequacy data). We solicited comment on whether the requirements at § 435.905(b) are sufficient to ensure the availability and

accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the availability and accessibility of the information.

We received public comment on these proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the website transparency provisions at § 441.313(a), emphasizing that advancing the collection of information and data by States is important to enable the ability of the public, including beneficiaries, to be able to access and compare performance results across States for the reporting requirements proposed at § 441.311.

Response: We appreciate the support for our proposal and thank commenters for their feedback. We note that consistent with statements we made in the introduction of sections II. and II.B. of this final rule regarding severability, while the intent of § 441.313 is for States to post all information collected under §§ 441.302(k)(6) and 441.311 as required, we believe that the website posting requirements being finalized herein at § 441.313 would provide critical data to the public even in a circumstance where individual provisions at §§ 441.302(k)(6) and 441.311 were not finalized or implemented. We do acknowledge that § 441.313 is interrelated with §§ 441.302(k)(6) and 441.311 to the extent that if one of the reporting requirements was not finalized or implemented, posting of the data collected under that particular requirement would not be available to post on the website as required at § 441.313. However, if one or more of the reporting requirements at §§ 441.302(k)(6) and 441.311 is finalized and implemented, then States must post this data on the website as required in § 441.313, as finalized. We note that in this final rule, we are finalizing the reporting requirement at § 441.302(k)(6) (as discussed in section II.B.5. of this final rule) and the reporting requirements proposed in § 441.311 (with modifications, as discussed in section II.B.7. of this final rule.)

Comment: One commenter requested we consider providing additional FMAP for the website creation and support needed to conduct the public posting of information and data

required under § 441.311 on the State webpage, including to address increased staff time and effort to answer questions regarding the public information required to be reported.

Response: We note we do not have authority to permit States to claim Medicaid expenditures at enhanced FMAP rates that are not specified in statute. As noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.¹⁵³ Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.¹⁵⁴ However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.¹⁵⁵ We plan to provide States with technical assistance related to the availability of enhanced FMAP to support the implementation of the requirements in this final rule.

After consideration of the comments received, we are finalizing the introductory paragraph at § 441.313(a) as proposed with one modification to include the additional reporting requirements to specify that the State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311.

b. Website Data and Information (§ 441.313(a)(1))

We proposed at § 441.313(a)(1) to require that the data and information States are required to report under § 441.311 be provided on one web page, either directly or by linking to the web pages of the MCO, PAHP, PIHP, or primary care case management entity that is authorized to provide services. We solicited comment on whether States should be permitted to link to web pages of these managed care plans and whether we should limit the number of

¹⁵³ See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

¹⁵⁴ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹⁵⁵ See § 433.112 (b), 80 FR 75841; https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C_.

separate web pages that a State could link to, in place of directly reporting the information on its own web page.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported and noted that the States should have one central web page operated and housed solely by the State to ensure data and information is reported consistently across their HCBS programs. One of the commenters suggested a State could, in their centralized State web page, give users the opportunity to filter by provider, managed care plan, or locality and include contact information for managed care plans. A few commenters generally supported permitting States to link to web pages of managed care plans to meet the proposed requirement.

Another commenter identified that beneficiaries may rely on their managed care plan's website for information instead of the State website and recommended limiting web page links to managed care plans' websites, raising concern that requiring States to post the data and information from the managed care plans could be duplicative and lead to user confusion if website updates between the State and managed care plans were not synched. A few commenters emphasized that having multiple managed care plan web page links to access the data and information that States are required to report under § 441.311 could place a burden on beneficiaries, consumers, and the public, to find and navigate the unique displays of managed care plan websites.

Response: We thank commenters for their suggestions. We have attempted to provide States with as much flexibility as possible in reporting of data and information required at § 441.311. State and managed care plan reporting of required data and information must be available and accessible for HCBS beneficiaries and other interested parties, without placing undue burden on them. Upon further consideration, we agree that it adds a undue level of

complexity and the potential for duplicate sources of the data and information by requiring the State to link to individual web pages of managed care plans.

After consideration of these public comments, we are finalizing the requirements at § 441.313(a)(1) with a modification to remove the word, web page, and replace with the word, website, and made minor formatting changes. We plan to provide technical assistance to States as needed to address the concerns raised by commenters.

Comment: One commenter agreed that the State should link to managed care plan web pages to report on the results of the reporting requirements at § 441.311, rather than have the managed care plans forward these results to the State to report on their State website. This commenter also recommended requiring the same language and format requirements in § 438.10(d) apply to § 441.33 and noted that many States serve Medicaid HCBS participants who receive services under managed LTSS and FFS, and that misalignment could occur between the regulations for managed care and FFS.

Response: Managed care plan websites required at § 438.10(c)(3) are already subject to the requirements at § 438.10(d), and we have not identified a compelling reason to make a similar reference in § 441.311. We decline to add mention of § 438.10(d) and are finalizing the requirements at § 441.311 as proposed.

After consideration of public comments, we are finalizing the requirements at § 441.313(a)(1) with a modification to require the State to include all content on one website, either directly or by linking to websites of individual MCO's, PIHP's, or PAHP's, as defined in § 438.2. We also are finalizing the requirements at § 441.313(a)(1) with a modification to remove the word, web page, and replace with the word, website, and make minor formatting changes.

c. Accessibility of Information (§ 441.313(a)(2))

At § 441.313(a)(2), we proposed to require that the website include clear and easy to understand labels on documents and links. We requested comments on whether these requirements are sufficient to ensure the accessibility of the information for people receiving

HCBS and other HCBS interested parties and for specific requirements to ensure the accessibility of the information.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Two commenters recommended we recognize the communication needs of deaf, hard of hearing, deaf-blind, and blind individuals, including those who have low vision, emphasizing that these beneficiaries should have access to culturally and linguistically competent services, as well as services and auxiliary aids pursuant to Title II of the Americans with Disabilities Act (ADA) of 1990 and section 504 of the Rehabilitation Act of 1973 (section 504). They also recommended that we reference the Twenty-First Century Communications and Video Accessibility Act of 2010 (Pub.L.111-260), which includes the use of clear language, icons, captioned videos, American Sign Language, and suitable color contrast. The commenters emphasized that any website materials and reports should be written with accommodations, including large print and braille, to ensure beneficiaries have equal, effective, and meaningful website communication. One commenter recommend that we also consider that due to the “digital divide” many HCBS beneficiaries do not have easy access to the internet and recommended we require States and managed care plans to share the information posted on their websites in an alternative format at the beneficiary’s request.

Response: We confirm that our proposal requires States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter, which requires the provision of auxiliary aids and services at no cost to individuals with disabilities in accordance with the ADA and section 504. We have attempted to provide the State with as much flexibility as possible in the design of their website. We agree that State and managed care plan websites must be available and accessible for people receiving HCBS and other HCBS interested parties. Further, we note that States’ websites are subject to State or local laws regarding accessibility,

and States must comply with other applicable laws independent of the requirements at § 441.313(a).

We encourage States to identify inequities for HCBS beneficiaries who have insufficient internet access and develop mechanisms to communicate website information that is available and accessible.

After consideration of comments received, we are finalizing § 441.313(a)(2) as proposed.

d. Website Operation Verification (§ 441.313(a)(3))

At § 441.313(a)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. We requested comment on whether this timeframe is sufficient or if we should require a shorter timeframe (monthly) or a longer timeframe (semi-annually or annually).

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters responded to our comment solicitation, expressing alternative timeframes related to the requirements at § 441.313(a)(3). Two commenters suggested websites should be updated on a more frequent monthly basis to ensure accuracy and functionality. A few other commenters suggested that websites should be updated semi-annually. Alternatively, another commenter requested that the verification of web content be completed annually to minimize administrative burden on States with significant web content to review and verify.

Response: We agree that accurate function of the website and the timeliness of the information is important. We note in section II.B.9. of the proposed rule (88 FR 27995 through 27996), and reiterate here, that we believe promoting public transparency and accountability of the quality and performance of Medicaid HCBS systems, and the availability of such information will improve the ability of beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high

quality for people who need Medicaid. We believe that verification quarterly, is reasonable taking into account the level of complexity required for such State reporting. We decline to make any changes to § 441.313(a)(3) in this final rule.

After consideration of the comments received, we are finalizing § 441.313(a)(3) as proposed.

e. Oral and Written Translation Requirements (§ 441.313(a)(4))

At § 441.313(a)(4), we proposed to require that States include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll free and TTY/TDY telephone number.

We received public comment on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed requirements at § 441.313(a)(4). One commenter further stated that, to ensure best quality, instructions to States on expectations for conducting translation in non-English languages to support the availability of oral interpretation in all languages and to assure uniformity across State policies to implement this component of the provision would be helpful. A few commenters opposed the proposed requirements at § 441.313(a)(4), expressing concern about the State financial and administrative burden that could occur due to the necessity to hire vendors to meet the expectations to conduct translation in non-English languages as required.

Response: We believe that the proposed requirements at § 441.313(a)(4) are important for ensuring that the required information on the website is accessible to people receiving HCBS and other interested parties. We reiterate, as noted in the proposed rule (88 FR 27979 and 27995), in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information

retrieval systems, in accordance with applicable Federal requirements.¹⁵⁶ Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.¹⁵⁷ However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.¹⁵⁸

After consideration of comments received, we are finalizing the requirements at § 441.313(a)(4) as proposed.

f. CMS Website Reporting (§ 441.313(b))

We proposed at § 441.313(b) that CMS report on its website the information reported by States to us under § 441.311. For example, we envisioned that we will update CMS's website to provide HCBS comparative information reported by States that can be compared to HCBS information shared by other States. We also envisioned using data from State reporting in future iterations of the CMS Medicaid and CHIP Scorecard.¹⁵⁹

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal that CMS would report on its own website the results of the data and information required to be reported under § 441.311, noting this enables easier comparison of results across States and serve as a single information source for users. One commenter suggested we consider a source, such as an HCBS hub, as defined by the commenter, on the CMS website, where users can quickly be directed to State HCBS programs and contracted managed care plan website pages.

One commenter suggested we initiate a best practice using the CMS website as an example for States to follow and share input with States on developing their websites to meet the requirements at § 441.313(a). Another commenter recommended we convene a technical expert

¹⁵⁶ See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

¹⁵⁷ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹⁵⁸ See § 433.112 (b), 80 FR 75841; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C>.

¹⁵⁹ CMS's Medicaid and CHIP Scorecard. Accessed at <https://www.medicaid.gov/state-overviews/scorecard/index.html>.

panel of relevant interested parties to create a set of guidelines and best practices that States could leverage to meet the proposed website transparency requirements at § 441.313(a) to offset States' time and resource investments in building the website, and to assist with minimizing the State's risk of updating websites that do not meet requirements.

Response: We appreciate the submission of these comments and will take this feedback into consideration as CMS updates its website to report on the results of the data and information required to be reported under § 441.311.

After consideration of the comments received, we decline to make any changes to § 441.313(b) in this final rule and are finalizing as proposed.

g. Applicability dates (§ 441.313(c))

We proposed at § 441.313(c) to provide States with 3 years to implement these requirements in FFS delivery systems. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or section 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we proposed to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. We based this proposed time period primarily on the effective date for State reporting at § 441.311.

We solicited comments on whether this timeframe is sufficient, whether we should require a longer timeframe (4 years) to implement these provisions, and if a longer timeframe is recommended, the rationale for that longer timeframe.

We received comments on this proposal. Below is a summary of the comments and our responses.

Comment: Most commenters supported the timeframe of 3 years following the effective date of the final rule to implement the website transparency requirements at § 441.313, emphasizing that these requirements facilitate the process of comparing results across States and create a single source where beneficiaries, providers, advocates, and policymakers can find a

“wealth of information about HCBS access.” One commenter expressed support for the proposed section regarding transparency related to the administration of Medicaid-covered HCBS but did not believe it should take 3 years to implement. A few commenters also expressed concerns about the challenges they believe will be associated with the website transparency requirements at § 441.313, due to administrative burden States may face with significant web content to review and verify to implement the provision.

Response: We believe that 3 years is a realistic and achievable timeframe for States to comply with the website transparency requirements, and we have not identified a compelling reason make changes to this date. We are finalizing the requirement at § 441.313(c) as proposed with modifications as described later in this section. We reiterate, as noted in the proposed rule, in Medicaid, enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.¹⁶⁰ Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.¹⁶¹ However, receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.¹⁶²

After consideration of public comments, we are finalizing the substance of § 441.313(c) as proposed, but with minor modifications to correct erroneous uses of the word “effective” and to make technical modifications at § 441.313(c) to the language pertaining to managed care delivery systems to improve accuracy and alignment with common phrasing in managed care contracting policy. We are retitling the requirement at § 441.313(c) as Applicability date (rather than Effective date). We are also modifying the language at § 441.313(c) to specify that States

¹⁶⁰ See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; <https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf>; <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf>.

¹⁶¹ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹⁶² See § 433.112 (b), 80 FR 75841; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C>.

must comply *with the* requirements in § 441.313(c) *beginning* 3 years from the effective date of this final rule.

h. Application to Managed Care and Fee-for Service (§§ 441.486, 441.595, and 441.750)

As discussed in section II.B.1. of the proposed rule, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care plan to its enrollees. The requirement for consistent administration should require consistency between these two modes of service delivery. We accordingly proposed to specify that a State must ensure compliance with the requirements in § 441.313, with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because we proposed to apply the reporting requirements at § 441.311 to other HCBS State plan options, we also proposed to include these website transparency requirements within the applicable regulatory sections. Specifically, we proposed to apply the requirements of § 441.313 to section 1915(j), (k), and (i) State plan services at §§ 441.486, 441.595, and 441.750, respectively. Consistent with our proposal for section 1915(c) waivers, we proposed these requirements based on our authority under section 1102(a) of the Act to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. We believe the same reasons for these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities.

We solicited comment on the application of these provisions across section 1915(i), (j), and (k) authorities.

We did not receive public comments on this provision.

After consideration of public comments received on this rule, we are finalizing the application of the website transparency requirements at § 441.313 to section 1915(j), (k), and (i)

State plan services. We are finalizing our proposed requirements at §§ 441.486, 441.595, and 441.750 with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

i. Summary of Finalized Requirements

After consideration of the public comments, we are finalizing the requirements at § 441.313 as follows:

- We are finalizing the requirement at § 441.313(c), with a technical modification to the language to improve accuracy and alignment with common phrasing in managed care contracting policy. We also are finalizing § 441.313(c) to specify that States must comply with the requirements as described in § 441.313(c) of this section beginning 3 years after the effective date of this final rule; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after the effective date of this final rule.

- We are finalizing at §§ 441.313(a) and (b) with minor technical modifications to include the additional requirements at § 441.302(k)(6).

- We are finalizing the requirements at § 441.313(c) with minor formatting changes.

- We are finalizing §§ 441.486, 441.595, and 441.750 with minor modifications to clarify that the references to section 1915(c) of the Act are instead references to section 1915(j), 1915(k), and 1915(i) of the Act, respectively.

10. Applicability of Proposed Requirements to Managed Care Delivery Systems

As discussed earlier in sections II.B.1., II.B.4., II.B.5., II.B.7., and II.J. of this rule, we proposed to apply the requirements we proposed at §§ 441.301(c)(3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 to both FFS and managed care delivery systems. Although the proposed provisions at §§ 441.301(c)(3), 441.302(a)(6) and (k), 441.311, and 441.313 would apply to

LTSS programs that use a managed care delivery system to deliver services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities, we believe incorporating a reference in 42 CFR part 438 would be helpful to States and managed care plans. Therefore, we proposed to add a cross reference to the requirements in proposed § 438.72 to be explicit that States that include HCBS in their MCO's, PIHP's, or PAHP's contracts would have to comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6) and (k), 441.311, and 441.313. We believed this would make the obligations of States that implement LTSS programs through a managed care delivery system clear, consistent, and easy to locate. While we believed the list proposed in § 438.72 would help States easily identify the provisions related to LTSS, we identified that a provision specified in any other section of 42 CFR part 438 or any other Federal regulation but omitted from § 438.72, is still in full force and effect. We also noted that § 438.208(c)(3)(ii) currently references § 441.301(c)(1) and (2). We did not propose any changes to the regulatory language at § 441.301(c)(1) or (2) or to § 438.208(c)(3)(ii) in the proposed rule. We included § 441.301(c)(1) and (2) in the proposed regulatory language at § 438.72 so that it would be clear that the requirements at § 441.301(c)(1) and (2) continue to apply.

We received various comments and questions about how specific provisions would be implemented in managed care contexts; these comments and our responses are addressed in the sections pertaining to those provisions. We did not receive other comments specifically on this proposal at § 438.72.

Upon further review, we have determined it necessary to make a clarifying correction to § 438.72, which we are finalizing with modifications. We proposed that § 438.72(b) would read that the State must comply with the review of the person-centered service plan requirements at § 441.301(c)(1) through (3), the incident management system requirements at § 441.302(a)(6), the payment adequacy requirements at § 441.302(k), the reporting requirements at § 441.311, and the website transparency requirements at § 441.313 for services authorized under section

1915(c) waivers and section 1915(i), (j), and (k) State plan authorities. We noted that in some cases, our description of the references in the regulations did not align with the titles of those regulations (such as at § 441.302(a)(6), in which only § 441.302(a)(6)(i) is specifically titled requirements, although our intent was for States to comply with § 441.302(a)(6)(i) through (iii). To avoid confusion due to any misaligned language, we are removing the narrative descriptions of the requirements and retaining just the references to the regulatory text.

After consideration of public comments, we are finalizing § 438.72(b) with this modification, which will read that the State must comply with requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

C. Documentation of access to care and service payment rates (§ 447.203)

Section 1902(a)(30)(A) of the Act requires that State plans “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” Through the provisions we are finalizing in § 447.203, we are establishing an updated process through which States will be required to document, and we will ensure, compliance with the requirements of section 1902(a)(30)(A) of the Act.

In the 2015 final rule with comment period, we codified a process that requires States to complete and make public AMRPs that analyze and inform determinations of the sufficiency of access to care (which may vary by geographic location in the State) and are used to inform State policies affecting access to Medicaid services, including provider payment rates. The AMRP must specify data elements that support the State’s analysis of whether beneficiaries have sufficient access to care, based on data, trends, and factors that measure beneficiary needs, availability of care through enrolled providers, and utilization of services. States are required to update their AMRPs at regular intervals and whenever the State proposes to reduce FFS provider payment rates or restructure them in circumstances when the changes could result in diminished access. Specifically, the AMRP process at § 447.203 before this final rule (which we refer to in this final rule preamble as the previous AMRP process) required States to consider the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The analysis further required consideration of beneficiary and provider input,

and an analysis of the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates within geographic areas of the State, for each of the services reviewed, by the provider types and sites of service. While the previous regulations included broad requirements for what an acceptable methodology used to conduct this analysis must include, States retained discretion in establishing their processes, including but not limited to the specification of data sources and analytical methodologies to be used. For example, States were broadly required to include actual or estimated levels of provider payments available from other payers; however, States retained discretion on which payers they reported on, including where the payment data was sourced from. The result has been a large analytical burden on States without a standardization that allows us and other interested parties to compare data between States to understand whether the Federal access standards are successfully achieving access consistent with section 1902(a)(30)(A) of the Act for beneficiaries nationwide.

Through the previous AMRP process, we aimed to create a transparent and data-driven process through which to ensure State compliance with section 1902(a)(30)(A) of the Act. Following publication of the 2011 proposed rule and as discussed in both the 2015 final rule with comment period and the 2016 final rule, as we worked with States to implement the previous AMRP requirements, many States expressed concerns about the rule.^{163,164,165} States were concerned about the administrative burden of completing the previous AMRPs and questioned whether the previous AMRP process is the most effective way to establish that access to care in a State's Medicaid program meets statutory requirements. States with high managed care enrollment were also concerned about the previous AMRP process because the few remaining FFS populations in their State often reside in long-term care facilities or require only specialized care that is "carved out" of managed care (that is, not covered under the State's contract with managed care plans), but long-term care and specialized care services were not required to be

¹⁶³ 76 FR 26341.

¹⁶⁴ 80 FR 67576 at 67583 and 67584.

¹⁶⁵ 81 FR 21479 at 21479.

analyzed under the previous AMRP process. We have also heard concerns from other interested parties, including medical associations and non-profit organizations, that the 2015 final rule with comment period afforded States too much discretion in developing access measures which could lead to ineffective monitoring and enforcement, as well as challenges comparing access across States. One commenter on the 2015 final rule was concerned that States had too much discretion in “...setting standards and access measures...” and “...whether they have met their chosen standards” as this process relies on self-regulation rather than “an independent, objective third party as the primary arbiter of a State’s compliance...”¹⁶⁶ Another commenter stated that “CMS should designate a limited and standardized set of data measures that would be collected rather than leaving the decision of which data measures to use to State discretion” as this would “enable the development of key, valid, and uniform measures; more effective monitoring and enforcement; and will ensure comparability of objective measures across the States.”¹⁶⁷ At the time of publication of the 2011 proposed rule and 2015 final rule with comment period, we noted our belief that a uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act, including setting standardized access to care data measures, could prove difficult given then-current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles.^{168,169}

Separately, the Supreme Court, in *Armstrong v. Exceptional Child Center, Inc.*, 575 U.S. 320 (2015), ruled that Medicaid providers and beneficiaries do not have a direct private right of action against States to challenge Medicaid payment rates in Federal courts. This decision means provider and beneficiary legal challenges against States are unavailable in Federal court to supplement our oversight as a means of ensuring compliance with section 1902(a)(30)(A) of the Act. The *Armstrong* decision also underscored HHS’ and CMS’ unique responsibility for

¹⁶⁶ American Medical Association, Comment Letter on 2015 Final Rule with Comment Period (January 4, 2016), <https://www.regulations.gov/comment/CMS-2011-0062-0328>.

¹⁶⁷ American Association of Retired Persons, Comment Letter on 2011 Propose Rule (July 5, 2011), <https://www.regulations.gov/comment/CMS-2011-0062-0121>.

¹⁶⁸ 76 FR 26341 at 26349.

¹⁶⁹ 80 FR 67576 at 67577, 67579, 67590.

resolving issues concerning the interpretation and implementation of section 1902(a)(30)(A) of the Act. The Supreme Court's *Armstrong* decision placed added importance on CMS' administrative review of SPAs proposing to reduce or restructure FFS payment rates. Accordingly, the 2015 final rule with comment period was an effort to establish a more robust oversight and enforcement strategy with respect to section 1902(a)(30)(A) of the Act.

In consideration of State agencies' and other interested parties' feedback on the previous AMRP process, as well as CMS' obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we are updating the requirements in § 447.203. We are rescinding and replacing the AMRP requirements previously in § 447.203(b)(1) through (8) with a streamlined and standardized process, described in § 447.203(b) and (c). This change is informed by a center-wide review of our policy and processes regarding access to care for all facets of the Medicaid program. The 2015 final rule with comment period acknowledged our need to better understand FFS rate actions and their potential impact on State programs, and the requirements we finalized require a considerable amount of data from States. To ensure States were meeting the statutory requirement under section 1902(a)(30)(A) of the Act, the previous AMRP process was originally intended to establish a transparent data-driven process for States to measure the current status of access to services within the State and utilize this process for monitoring access when proposing rate reductions and restructurings.¹⁷⁰ As the rule took effect and as we reviewed States' previous AMRPs, we found that some rate reductions and restructurings had much smaller impacts than others. The 2017 SMDL reflected the experience that certain payment rate changes would not likely result in diminished access to care and do not require the substantial review of access data that generally is required under the 2015 final rule with comment period. Since publication of the 2019 CMCS Informational Bulletin stating the agency's intention to establish a new access strategy, we have developed the new process we are finalizing in this final rule that considers the lessons learned under the previous AMRP process,

¹⁷⁰ 80 FR 67576 at 67577.

and emphasizes transparency and data analysis, with specific requirements varying depending on the State's current payment levels relative to Medicare, the magnitude of the proposed rate reduction or restructuring, and any access to care concerns raised to State Medicaid agency by interested parties. With these provisions, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

We received public comments on our overall approach to a new access strategy as well as broad comments about multiple provisions in the rule. We received some comments that were outside of the scope of the proposed rule entirely (for example, related to access in managed care and coverage of services), and therefore, are not addressed in this final rule. We also note that some commenters expressed general support for all of the provisions in section II.C. of this rule, as well as for this rule in its entirety. In response to commenters who supported some, but not all, of the policies and regulations we proposed in the proposed rule (particularly in section II.C related to FFS access), we are clarifying and emphasizing our intent that each final policy and regulation is distinct and severable to the extent it does not rely on another final policy or regulation that we proposed.

While the provisions in section II.C. of this final rule are intended to present a comprehensive approach to ensuring that FFS payment rates are adequate to ensure statutorily sufficient access for beneficiaries, and these provisions complement the goals expressed and policies and regulations being finalized in sections II.A. (MAC and BAC) and II.B. (HCBS) of this final rule, we intend that each of them is a distinct, severable provision, as finalized. Unless otherwise noted in this rule, each policy and regulation being finalized under this section II.C is distinct and severable from other final policies and regulations being finalized in this section or in sections II.A. or II.B of this final rule, as well as from rules and regulations currently in effect. Consistent with our previous discussion earlier in section II. of this final rule regarding severability, we are clarifying and emphasizing our intent that if any provision of this final rule is

held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further State action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. For example, we intend that the policies and regulations we are finalizing related to the payment rate transparency publication requirement (section II.C.2.a. of this final rule) are distinct and severable from the policies and regulations we are finalizing related to the comparative payment rate analysis requirement and the payment rate disclosure publication requirement (sections II.C.2.b. of this final rule, which we further intend are severable from each other). These provisions are in turn also severable from the interested parties advisory group provision in section II.C.2.c. of this final rule, the State analysis procedures for rate reduction and restructuring SPAs in section II.C.3. of this final rule, and from the Medicaid provider participation and public process to inform access to care policies in section II.C.4. of this final rule, and each of these in turn is intended to be severable from each other.

The following is a summary of the general comments we received on our proposal to rescind the previous AMRP requirements in § 447.203(b)(1) through (8) and replace them with a streamlined and standardized process in § 447.203(b) and (c), and our responses.

Comment: We received general support from most commenters for our proposal to rescind the AMRP process finalized in the 2015 final rule with comment period in its entirety and replace it with new requirements for payment rate transparency and State analysis procedures for rate reductions and restructuring as described in the proposed rule to ensure compliance with section 1902(a)(30)(A) of the Act. We also received commenter feedback encouraging CMS to ensure the process replacing the AMRPs is robust and public, and that it ensures access to critical services is measured adequately.

Response: We thank the commenters for their support and are finalizing the rescission of the previous AMRP process in its entirety and its replacement with the new requirements as

proposed, apart from some minor revisions to the proposed regulatory language, which we address in detail later in this final rule. As of the effective date of this final rule, States are no longer required to submit AMRPs to CMS as previously required in § 447.203(b)(1) through (8). We believe our new policies are robust and that they ensure public transparency and that access to critical services is measured adequately.

Comment: While most commenters generally supported the proposal to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, a couple of commenters recommended that CMS maintain some or all of the AMRP process for certain providers (that is, FQHCs, clinics, dental care providers, and community mental health providers), in addition to the newly proposed payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. Additionally, these commenters raised concerns that the newly proposed requirements focused exclusively on fee schedule payment rate transparency and comparison to Medicare payment rates; therefore, FQHCs, clinics, dental care providers, and community mental health providers would be excluded from the proposed payment rate transparency and comparative payment rate analysis provisions because these providers generally are not paid fee schedule payment rates (within the meaning of this final rule) and/or lack corresponding Medicare payment rates. One commenter recommended keeping the AMRP requirements in place as a separate process for analyzing access to primary care services provided by FQHCs, clinics, or dental providers if these providers are excluded from the payment rate transparency and comparative payment rate disclosure as a way to assess access to care to these services and providers as they were previously included in the AMRP requirements. Another commenter stated that, in comparison to the AMRPs, the provisions in the proposed rule are an oversimplified approach to evaluating Medicaid FFS payment rates and do not sufficiently focus on payment levels for a comprehensive continuum of behavioral health services.

Response: We acknowledge these commenters' support for the previous AMRP process and suggestion to continue to subject payment rates for FQHCs, clinics (as defined in § 440.90), dental care providers, and community mental health providers to the previous AMRP process. However, we are not incorporating this suggestion, to ensure a consistent approach to evaluating access to care within FFS and across delivery systems that more appropriately balances administrative burden on States and us with the usefulness of the process for ensuring that payment rates comply with section 1902(a)(30)(A) of the Act.

To address commenters' concerns about services being excluded from the payment rate transparency provision in § 447.203(b)(1), we will briefly address which payment rates are and are not subject to the payment rate transparency provisions, but this issue is discussed in greater detail in a later comment response. For purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are payment amounts made to a provider and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. To the extent a State pays fee schedule payment rates for clinic services (as defined in § 440.90), dental services, and community mental health services that meet the previously stated description, those payment rates are subject to the payment rate transparency provisions in § 447.203(b)(1). As for the comparative payment rate analysis requirements in § 447.203(b)(2)-(3), as discussed in greater detail later in this final rule, only codes included on the CMS-published list of evaluation and management (E/M) Current Procedural Terminology or Healthcare Common Procedure Coding System (HCPCS) CPT/HCPCS codes are subject to the analysis.

Additionally, as further discussed in a later comment response, States use provider-specific cost and visit data for a particular benefit category to set the prospective payment system (PPS) rates that are paid to FQHCs or rural health clinics (RHCs) in a process governed by section 1902(bb) of the Act. Because States utilize these data rather than fee schedule payment rates within the meaning of this final rule, those rates paid to FQHCs and RHCs are not subject

to the new payment rate transparency provisions in § 447.203(b)(1) or the comparative payment rate analysis requirements in § 447.203(b)(2) through (3). Lastly, like all State plan services for which the State proposes a rate reduction or restructuring in circumstances where the changes could result in reduced access, FQHC, RHC, clinic (as defined in § 440.90), dental, and community mental health services are subject to access analyses in § 447.203(c) for proposed rate reductions and restructuring.

While we recognize that there may be multiple approaches to evaluating access to care for Medicaid beneficiaries, we respectfully disagree with the commenter that the payment rate transparency and State analysis procedures for rate reductions and restructuring are an oversimplified approach for evaluating Medicaid FFS payment rates. As part of a comprehensive review of our policy and processes regarding access to care for all facets of the Medicaid program, we proposed a more streamlined approach, as compared to previous AMRP process, that we intended better to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act.

Additionally, we disagree with the commenter that, in comparison to the previous AMRP process, the provisions in the proposed rule do not sufficiently focus on payment levels for a comprehensive continuum of behavioral health services. The provisions of this final rule serve as one part of our comprehensive efforts to ensure that payment levels across the continuum of behavioral health services are economic and efficient, as well as consistent with quality and access consistent with the statute. As we discussed in the proposed rule, we limited the scope of behavioral health services subject to comparative payment rate analysis to include only outpatient services.¹⁷¹ For this final rule, we have revised the outpatient behavioral health services category of service in § 447.203(b)(2)(iii), which we are finalizing as “Outpatient mental health and substance use disorder services.” This revision will ensure this final rule is consistent with the services in the Managed Care final rule (as published elsewhere in this

¹⁷¹ 88 FR 27960 at 28006.

Federal Register) and reflects a more granular level of service description. As this category of service remains outpatient, this allows us to focus on ambulatory care provided by practitioners in an office-based setting without duplicating existing Federal requirements for demonstrating compliance with applicable upper payment limits (UPLs) and the supplemental payment reporting requirements under section 1903(bb) of the Act. Therefore, between the comparative payment rate analysis requirements that we are finalizing in this rule (including outpatient mental health and substance use disorder services) and existing UPL and supplemental payment reporting requirements (including requirements specific to inpatient services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals), we believe that States and CMS will have available sufficient information about inpatient and outpatient mental health and substance use disorder services payment rates to appropriately monitor payment levels across the continuum of mental health and substance use disorder services.

Comment: Several commenters raised concerns about administrative burden on States to comply with the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements. Commenters were generally concerned about the compounding effect on already overburdened State resources that would be required to meet these provisions, the other HCBS and MAC and BAG provisions of the proposed rule, and the provisions of the Managed Care proposed rule. Specifically for the payment rate transparency provisions under § 447.203(b), commenters were generally concerned about the significant amount of State resources (including number of staff, staff time, and financial expense) that would be required to collect, prepare, analyze, and publish the data and information required.

Additionally, a few commenters expressed concerns about the burden associated with the proposed rule and stated that they did not believe the requirement to publish Medicaid payment rates through the payment rate transparency publication would benefit the Medicaid program by providing States and CMS with an effective and meaningful way of ensuring access to care is

sufficient. One commenter stated that they expect their State Medicaid program to limit future program enhancements and improvements because they would need to redirect resources to complying with the provisions of the proposed rule, if finalized.

Response: We appreciate the commenters' concerns, and we would like to note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. We are also providing States with a full 2-year compliance period between the effective date of this final rule and the initial applicability date of July 1, 2026, rather than 6 or 9 months as finalized with the previous AMRP process.¹⁷² Given that the previously referenced requirements of this final rule should be less burdensome for States than the rescinded, previous AMRP requirements, and the length of time States have to prepare to implement these new requirements, we expect that States will be able to meet the payment rate transparency, interested parties' advisory group, and State analysis procedures for payment rate reductions or payment restructuring requirements, if a rate reduction or restructuring is proposed through a SPA, without needing to limit future program enhancements or increase the level of State resources dedicated to ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act.

We would also like to reassure States that the provisions of § 447.203(b)(1) in this final rule include flexibilities that could further ease the burden on States. For example, the payment rate transparency publication requirements described in paragraph (b)(1) and paragraph (b)(1)(ii)

¹⁷² In the 2015 final rule with comment period (80 FR 67576), the previous AMRPs were originally due on July 1 providing States with approximately 6 months between the final rule effective date of January 4, 2016, and due date of July 1, 2016. Based on comments received on the 2015 final rule with comment period, the 2016 final rule (81 FR 21479) extended the due date to October 1, 2016, providing States with an additional 3 months to submit their first AMRPs for a total of approximately 9 months from the effective date of the 2015 final rule when States were first notified they would be required to submit AMRPs.

have limited formatting requirements, and therefore we expect many States that already publish at least some of their Medicaid FFS fee schedule payment rates directly on fee schedules posted on the State agency's website would only need to make minor revisions or updates (if any) to comply with the new requirements with respect to these already-published payment rates. States are not required to create new fee schedules if their published payment rate information is already organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for each covered service, consistent with § 447.203(b)(1).

Additionally, because commenters informed us that some States use a contractor to maintain their fee schedules on the contractor's website, we have revised the language in § 447.203(b)(1) to permit the State to "publish all Medicaid fee-for-service payment rates on a website that is accessible to the general public" by removing the proposed requirement that the payment rates be published on a website that is "developed and maintained by the single State agency." This flexibility is being provided for States to continue utilizing a contractor to develop fee schedules as well as utilizing a contractor's (or other third party's) website to publish the payment rate transparency publication so long as the State publishes a readily accessible link on its State-maintained website to the required content and ensures on an ongoing basis that the linked content meets all applicable requirements of this final rule. We continue to require that "[t]he website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website" in § 447.203(b)(1)(ii). We acknowledge that States utilization of contractors to meet certain programmatic responsibilities is a common occurrence, and with this modification, we are ensuring flexibility for States to rely on these relationships to meet the payment rate transparency publication requirement.

With respect to the comparative payment rate analysis in § 447.203(b)(2) and (3), as discussed in the proposed rule, States have the flexibility to map their geographical areas to those used for Medicare payment for purposes of meeting the requirement that States break down their

payment rates by geographical location, as applicable.¹⁷³ We will provide States with a list of the CPT/HCPCS codes to be used for comparison in subregulatory guidance, including an example list, that will be issued prior to the effective date of this final rule.¹⁷⁴ While the first published list will be an example list of codes that would have been subject to the comparative payment rate analysis if it were in effect for CY 2023, we will publish the initial list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis no later than June 30, 2025, to provide States 1 full calendar year between the issuance of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis, as described in the proposed rule.¹⁷⁵

For the payment rate disclosure in § 447.203(b)(2) and (3), which requires States to publish the average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, as discussed in detail in a later response to comments in this section, there is no Medicare comparison component. Because the disclosure will reflect only the State's payment rate data, we chose not to specify codes; this will provide States more flexibility in meeting the requirements in line with each State's unique circumstances. For example, the payment rate disclosure requirements can accommodate the flexibility States have in setting their payment rates and methodologies for personal care, home health aide, homemaker, and habilitation services, as well as the provider types licensed to deliver these services to beneficiaries.

We disagree with commenters that the requirement to publish Medicaid payment rates through the payment rate transparency publication would not benefit the Medicaid program by providing States and CMS with an effective and meaningful way of ensuring access to care is sufficient. As discussed in the proposed rule, payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. By publishing their Medicaid

¹⁷³ 88 FR 27960 at 28013.

¹⁷⁴ 88 FR 27960 at 28008.

¹⁷⁵ 88 FR 27960 at 28008 through 28009.

payment rates publicly, States will be providing the necessary information to evaluate if State payment rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area and interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.¹⁷⁶ Also as discussed in section V.D. of the proposed rule, we considered, but did not propose, to require Medicaid payment information be directly submitted to CMS, rather than publicly published, because this requirement to publicly display payment rate information is methodologically similar to the previous regulation at § 447.203, which required previous AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance, and are carrying it forward into the provisions finalized in this rule.¹⁷⁷ Additionally, the Supreme Court's *Armstrong* decision underscored the importance of CMS' determinations, as the responsible Federal agency, regarding the sufficiency of Medicaid payment rates.

Comment: A couple of commenters requested clarification regarding CMS exempting States that deliver all of their Medicaid services through managed care from all of the payment rate transparency provisions under § 447.203(b).

Response: All States are required to comply with the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure provisions finalized in this rule under § 447.203(b), regardless of the quantity of services covered or delivered or beneficiaries enrolled in managed care. Due to coverage transition periods, such as where an

¹⁷⁶ 88 FR 27960 at 27967.

¹⁷⁷ 88 FR 27960 at 28075.

individual is Medicaid eligible but not yet enrolled in a managed care plan or benefits are covered retroactively,¹⁷⁸ even States that generally enroll all beneficiaries into managed care plans pay for some services on a FFS basis that are carved out of the managed care plan contracts, and therefore, are expected to have Medicaid FFS fee schedule payment rates in effect. Such Medicaid FFS fee schedule payment rates are subject to the provisions finalized in this rule under § 447.203(b).

Comment: Several commenters requested CMS clearly define the services considered to be categories of services subject to all provisions under § 447.203(b). One commenter requested CMS publish information regarding the timing of when States can expect the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis.

Response: For the payment rate transparency requirements in § 447.203(b)(1), as further discussed in a later response to comments in this section, services for which providers are paid Medicaid FFS fee schedule payment rates within the meaning of this final rule, which generally are payment amounts made to a provider and known in advance of a provider delivering a service to a beneficiary, are subject to the requirements of § 447.203(b)(1)(i) through (vi).

For the comparative payment rate analysis described in § 447.203(b)(3)(i), the list of the E/M CPT/HCPCS codes that specifies the services subject to the analysis will be published in subregulatory guidance. Prior to the effective date of this final rule, we will issue subregulatory guidance, including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the services that would be subject to the comparative payment rate analysis through the identification of specific E/M CPT/HCPCS codes that are in effect for CY 2023. In other words,

¹⁷⁸ Once an individual is enrolled in Medicaid, coverage is effective either on the date of application or the first day of the month of application. Benefits also may be covered retroactively for up to three months prior to the month of application if the individual would have been eligible during that period had he or she applied. Coverage generally stops at the end of the month in which a person no longer meets the requirements for eligibility. <https://www.medicaid.gov/medicaid/eligibility/index.html>.

the example list of E/M CPT/HCPCS codes includes codes that meet the following criteria: the code is effective for CY 2023; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the hypothetical comparative payment rate analysis (CY 2023) and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare Physician Fee Schedule (PFS) with a Medicare established relative value unit (RVU) and payment amount for CY 2023. As discussed in the proposed rule, we expect to provide States with approximately 1 full calendar year of access to the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as established in the annual Medicare PFS rule for a calendar year to provide States with sufficient time to develop and publish their comparative payment rate analyses as described in § 447.203(b)(4).¹⁷⁹ Therefore, we expect that the first CMS-published list of the E/M CPT/HCPCS codes that actually will be subject to the comparative payment rate analysis requirements will be published by July 1, 2025 for CY 2025, to facilitate States' publication of their comparative payment rate analyses by the applicability date of July 1, 2026.

The categories of services subject to the payment rate disclosure requirements described in § 447.203(b)(3)(ii), as discussed later in this preamble, are personal care, home health aide, homemaker, and habilitation services provided under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority. We are not identifying codes for these categories of services because States may use a wide variety of codes to bill and pay for these services, and because the payment rate disclosure does not have a comparison element that would necessitate

¹⁷⁹ 88 FR 27960 at 28008-28009

uniformity with another payer. While we encourage States to organize their payment rate disclosure on a code basis, when possible, for clarity and formatting consistency with the comparative payment rate analysis, States have flexibility in meeting the payment rate disclosure requirements to ensure each State's unique circumstances can be accounted for in the disclosure.

Comment: Several commenters urged CMS to delay the proposed applicability date of the § 447.203(b) provisions, including the compliance actions described in § 447.203(b)(5), to allow States sufficient time for compliance. Commenters stated that the amount of recently proposed Federal changes, including this rulemaking and the Managed Care proposed rule, raised concerns about State resources necessary to comply with all new Federal regulations. Some commenters expressed concern that withholding administrative FFP would further hinder States' ability to meet the requirements and CMS should only act after exhausting all other efforts to ensure States are compliant (including adopting a tiered approach to enforcement and directly engaging with non-compliant States to create a corrective action plan).

Commenters suggested the following alternative applicability dates: approximately 3 years from the effective date of a final rule (that is, January 1, 2027), 4 years (that is, January 1, 2028), or 5 years (that is, January 1, 2029). Alternatively, a few commenters urged CMS to accelerate the proposed applicability date of the § 447.203(b) provisions by one year from January 1, 2026, to January 1, 2025, to ensure payment rate information is published timely to help address questions about access, particularly for HCBS. In addition to the proposed compliance procedures described in § 447.203(b)(5), a couple of commenters suggested CMS publish an annual calendar for States to follow and CMS should also report on the timeliness of each State's compliance with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.

Response: We are finalizing the payment rate transparency requirements in § 447.203(b) with an applicability date of July 1, 2026, which is 6 months later than we proposed. This date is an alternative applicability date that was described in the proposed rule to allow for States to

have a period of at least 2 years between the effective date of the final rule and the applicability date for the § 447.203(b) provisions. The July 1, 2026, applicability date applies to the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. For payment rate transparency, the initial publication of the Medicaid FFS payment rates shall occur no later than July 1, 2026, and include approved Medicaid FFS payment rates in effect as of July 1, 2026. For the comparative payment rate analysis and payment rate disclosure, the initial comparative payment rate analysis and payment rate disclosure must include Medicaid payment rates in effect as of July 1, 2025, and be published no later than July 1, 2026. As finalized in this rule, the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year included in the comparative payment rate analysis must be effective for the same time period for the same set of E/M CPT/HCPCS codes used for the base Medicaid FFS fee schedule payment rate. The Medicare PFS is published through annual notice and comment rulemaking, and takes effect January 1 of the upcoming calendar year. As discussed in the proposed rule, we acknowledged that Medicare may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes and we would like to reemphasize that we expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the requirements in paragraphs (b)(2) through (4).¹⁸⁰ States are required to use the Medicare non-facility payment rates as established in the Medicare PFS final rule for calendar year 2025 for purposes of the initial comparative payment rate analysis to be published by July 1, 2026. In accordance with paragraph (b)(4), the comparative payment rate analysis is required to be updated no less than every 2 years and by no later than July 1 of the second year following the most recent update, therefore, the second comparative payment rate analysis would be for calendar year 2027, the third analysis would be for calendar year 2029, so on and so forth. Each comparative payment rate analysis would use the respective year's CMS

¹⁸⁰ 88 FR 27960 at 28009.

published list of E/M CPT/HCPCS codes which will be updated by CMS approximately one full calendar year before the due date of the next comparative payment rate analysis and the list will include changes made to the AMA CPT Editorial Panel and the Medicare PFS based on the most recent Medicare PFS final rule, as described in the proposed rule.¹⁸¹

We are not finalizing the alternative applicability dates, including dates sooner and later than the July 1, 2026, due date finalized in this rule, as suggested by commenters. We are not accelerating the date as we are mindful of the numerous new regulatory requirements established in this final rule, the Managed Care final rule (as published elsewhere in this **Federal Register**), and the Streamlining Eligibility & Enrollment final rule. We want to ensure States have adequate time to implement all newly finalized provisions, with at least 2 years between the effective date and applicability date as described in the proposed rule.¹⁸² We are also not delaying the applicability date as we believe the applicability date for the provisions finalized in section II.C. of this final rule are reasonable given that States should have their Medicaid FFS fee schedule payment rates data readily available, Medicare payment rate data are publicly available, and we are making available supportive guidance and templates with this final rule. In the beginning of section II. of this final rule, we include a table with the provisions and relevant timing information and applicability dates of all provisions in the rule. We believe this table delivers the information the commenter was seeking. We expect the information published in this final rule is sufficient for States to comply in a timely manner and we currently do not intend to publish a calendar in any other format. We are finalizing the compliance provisions at § 447.203(b)(5) as proposed. While we currently do not intend to publish a report of the timeliness of each State's compliance with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, as suggested by a couple of commenters, given that our work to better ensure access in the Medicaid program is ongoing, we intend to

¹⁸¹ 88 FR 27960 at 28008.

¹⁸² 88 FR 27960 at 28008.

gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A number of commenters suggested CMS conduct the proposed payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure on behalf of States to ensure a consistent, national approach to analyzing and publishing payment rate information. These commenters stated CMS could do this by requiring States to submit their fee schedules to CMS or CMS could collect fee schedule rate information during the SPA approval process. Specifically for the payment rate disclosure, two commenters suggested using existing data collection tools, specifically the State of the Workforce Survey, to source the information required for the disclosure to ease burden on States.¹⁸³ Additionally, a couple of commenters suggested CMS create a centralized data repository of all States' payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications for public use, including data analysis, if the proposed requirements are applied to States.

Response: As described in section V.D.3 of this final rule, prior to the issuance of the 2023 proposed rule, we specifically considered ways for CMS to produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates.¹⁸⁴ We decided not to propose this approach because it would rely on T–MSIS data, which would increase the lag in available data due to the need for CMS to prepare it and then validate the data with States to ensure the publication is accurate, in addition to introducing uncertainty into the results due to ongoing variation in State T–MSIS data quality and completeness. Given the increased lag time

¹⁸³ The State of the Workforce Survey collects comprehensive data on provider agencies and the Direct Support Professional (DSP) workforce providing direct supports to adults (age 18 and over) with intellectual and developmental disabilities (IDD). The goal of the survey and the resulting data is to help States examine workforce challenges, identify areas for further investigation, benchmark their workforce data, measure improvements made through policy or programmatic changes, and compare their State data to those of other States and the NCI-IDD average. <https://idd.nationalcoreindicators.org/staff-providers/>

¹⁸⁴ 88 FR 27960 at 28075

associated with T-MSIS data and uncertainty in results that would diminish the utility of the comparative payment rate analysis, we decided producing and publishing the analysis would likely result in inaccuracies, resulting in burden on States to correspond with CMS to provide missing information and correct other information. After considering, and ultimately not proposing, CMS complete a comparative payment rate analysis on behalf of States, we did not further consider conducting the payment rate transparency publication or payment rate disclosure on behalf of States due to the previously stated reasons (that is, lagging data from T-MSIS and the need that would remain to validate data with States).

We are not creating a centralized data repository of all States' payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications for public use as suggested by commenters because we are striving to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. Requiring States to submit the information they already published on their State or contractor's website would be duplicative and create additional burden on States. We acknowledge that we could also pull data from State or contractor websites to create a central Federal repository; however, we intend our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements; providing States with support during the compliance period; and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Additionally, we believe that the States, as stewards of Medicaid payment rate information in each of their Medicaid programs, are the party in the best position to publish and analyze their own payment rate information. States' ownership of payment rate information will ensure accurate payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider

the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

While we appreciate the suggestion to utilize existing data collection tools, specifically the State of the Workforce Survey, we will not be relying on the State of the Workforce Survey because the data do not include all States, the District of Columbia, and the Territories (2021 Survey only sourced data from 28 States and the District of Columbia); account for payment rate variation by population (pediatric and adult), provider type, and geographical location (2021 Survey only includes mean starting wage, the median starting wage, as well as the minimum and maximum starting hourly wages); or include individual providers (2021 Survey only sourced data from provider agencies). Accordingly, it would not be a sufficient data source to meet the requirements for the payment rate disclosure as finalized in this final rule.

Comment: We received some comments about CMS requiring States to change their payment rates. A couple of commenters requested CMS require States to change their payment rates when deficiencies are identified through the payment rate transparency publication, comparative payment rate analysis, or payment rate disclosure; when provider shortages are documented; and when reimbursement or payment rates fall below a certain threshold, such as 50 percent of the corresponding Medicare payment rate; however, most commenters who suggested CMS set a threshold did not suggest a specific number for the threshold. One commenter specifically asked if CMS would require States to increase institutional service payment rates. The commenter was concerned that an increase in a direct care worker's Medicaid hourly rate, without a corresponding increase in a Medicaid payment rate for institutional services, would result in fewer hours of care able to be delivered. We received one comment requesting CMS to expressly permit States to pay more than Medicare for services furnished through the FFS system. Additionally, one commenter expressed caution that increasing payment rate transparency does not necessarily ensure access to care or coverage of services in Medicaid.

Response: To clarify, the provisions in this final rule do not require States to change their payment rates. Although we intend for States to consider the information produced for the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure in an ongoing process of evaluating the State's payment rate sufficiency and when considering changing payment rates or methodologies (and we intend to make similar use of the information in performing our oversight activities and in making payment SPA approval decisions), we did not propose and are not finalizing that any payment rate changes necessarily would be triggered by the proposed requirements.

Specifically, we did not propose, nor are we finalizing, a requirement that States must increase their institutional or non-institutional service payment rates through this final rule. Based on the information provided by the commenter (and without additional information about providers, such as, number of providers in a State or number of provider accepting new patients or accepting Medicaid), we understand the concerns raised to generally be an issue with a State's limitations on service coverage (that is, a coverage limit of \$1,000/month limit on institutional services is insufficient for the amount of care required). While we do not have the authority to require States to change their Medicaid payment rates, we remind States that the Medicaid program is a Federal-State partnership and States have the flexibility and responsibility to set payment rates that are consistent with efficiency, economy, quality of care, and access as required by section 1902(a)(30)(A) of the Act and a coverage limit could be inconsistent with this standard. We encourage the commenter to utilize the public process procedures described in § 447.204 to raise these concerns with their State. We also did not propose and are not finalizing a regulatory change that explicitly permits States to pay more than Medicare for services furnished through the FFS system. We acknowledge that existing UPL requirements limit Medicaid payments to a reasonable estimate of what Medicare would have paid.¹⁸⁵ However,

¹⁸⁵§ 447.272 for inpatient hospitals, § 447.321 for outpatient hospitals and clinic services, § 447.325 for other inpatient and outpatient facilities (nursing facilities, intermediate care facilities for the developmentally disabled (ICF/DD), psychiatric residential treatment facilities (PRTF), and institutions for mental disease (IMDs)).

outside of the services subject to UPL requirements limiting aggregate State Medicaid payment amounts, as the Medicaid program is a Federal-State partnership, States have the flexibility and responsibility to set payment rates that are consistent with efficiency, economy, and quality of care as required by section 1902(a)(30)(A) of the Act. Currently, States can set FFS payment rates that are more than Medicare for numerous services, provided any applicable aggregate UPL is satisfied, and creating an explicit permission in regulation would not change the existing flexibilities States have in setting their payment rates.

We understand the commenter's concerns that increasing payment rate transparency does not necessarily ensure access to care or coverage of services in Medicaid. We acknowledged in the proposed rule that there may be other causes of access to care issues outside of provider payment rates, such as beneficiaries experiencing difficulty scheduling behavioral health care appointments due to a provider shortage where the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population.¹⁸⁶ However, we believe it is important to address one of the potential causes of access to care issues: payment rates that are not sufficient to enlist an adequate supply of providers as required by section 1902(a)(30)(A) of the Act. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider additional areas of access to care outside of payment rates to help inform any future rulemaking to promote improved access to care, as appropriate.

Comment: A number of commenters requested CMS provide States with guidance, templates, tools, examples, or descriptions of acceptable forms for publishing the payment rates, comparative payment rate analysis, and payment rate disclosure to ensure States understand how to comply with these provisions. A few commenters requested guidance on specific aspects of provisions of the proposed rule: accessible web pages and accounting for additional ways payment rates can vary (such as site of service and patient acuity). Those commenters also noted

¹⁸⁶ 88 FR 27960 at 28016.

that some States use value-based payment (VBP) methodologies and requested guidance on how the various provisions of the proposed rule has accounted for these payment methodologies. Additionally, a couple of commenters suggested CMS provide guidance to the public to ensure the newly published data are understandable.

Response: Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023; illustrative examples of compliant payment rate transparency, comparative payment rate analysis, and payment rate disclosure publications (including to meet accessibility standards); and a template to support completion of the additional State rate analysis under § 447.203(c)(2). We encourage States to review the subregulatory guidance to be issued prior to the effective date of this final rule and reach out to CMS for technical guidance regarding compliance with the comparative payment rate analysis and any other requirement of this final rule.

We are only requiring the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure include payment rate breakdowns by population (pediatric and adult), provider type, and geographical location, as applicable. Payment rate variations by site of service are not required, but States have flexibility to include this optional payment rate break down in the payment rate transparency publication. While not required in this final rule, should a State opt to breakdown their payment rates by site of service, the State should use the minimum payment amount for purposes of the requirements of § 447.203(b), because a provider is assured to receive at least this amount for furnishing the service at any site of service. At State option, the State could also include additional payment rate breakdowns a provider might receive at other sites of service in the State (for example: office, inpatient hospital, school, mobile unit, urgent care facility, nursing facility). We did not propose or finalize in this rule a requirement for States to include a payment rate breakdown for site of

services because we want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are available to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues. We believe that payment rate breakdowns by population (pediatric and adult), provider type, and geographical location will provide a sufficient amount of transparency to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.

Additionally, payment rate variations based on patient acuity are also not explicitly required in the payment rate transparency publication. Payment adjustments for patient acuity generally are limited to institutional settings (for example, inpatient hospitals and nursing facilities). Should a State opt to breakdown their payment rates by patient acuity, to the State should use the minimum payment amount for purposes of the requirements of § 447.203(b), because a provider is assured to receive at least this amount for furnishing the service to any patient. At State option, the State could also include additional payment rate breakdowns the provider might receive for other levels of patient acuity. We also acknowledge that prospective payment system rates, such as Medicare's Patient Driven Payment Model (PDPM) for nursing facilities and inpatient prospective payment system (IPPS) for inpatient hospitals, typically account for patient acuity. As further discussed in a later response to comments in this section, PPS rates for inpatient hospital, outpatient hospital, and nursing facility services that are paid to most hospitals and nursing facilities and are payments based on a predetermined, fixed amount are subject to the payment rate transparency provision in this final rule. This is because these PPS rates are typically known in advance of a provider delivering a service to a beneficiary and fall into the scope of a Medicaid FFS fee schedule payment rate within the meaning of this final

rule, as discussed in a later response to comments in this section.

We understand the commenters' concerns about ensuring the various payment rate transparency publications of this final rule are understandable to the public. We expect State publications of Medicaid payment rate transparency information, comparative payment rate analysis, and payment rate disclosures that comply with the requirements of this final rule to be transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. Therefore, we do not anticipate a need for guidance for the public at this time, but we will continue to assess once the requirements are in effect.

Comment: A couple of commenters suggested CMS conduct provider shortage assessments and engage providers, beneficiary advocacy organizations, direct service workers, caregivers, and other relevant interested parties in the data collection and analysis processes in the proposed rule and create a Federal-level public comment process within the CMS review of SPAs and HCBS waiver applications or renewals.

Response: We appreciate the commenters' suggestions; however, we did not propose to conduct provider shortage assessments, or to engage with interested parties in the data collection and analysis processes outside of the work of the interested parties' advisory group in § 447.203(b)(6). After obtaining implementation experience of these new policies, we will keep these suggestions in mind as we consider whether additional requirements may be appropriate to propose through future rulemaking.

Comment: One commenter suggested CMS consider future rulemaking to require States survey HCBS participants and their support systems to identify additional access issues and perceived causes, with a particular focus on assessing access related to unpaid and paid support. The commenter provided an example of a parent of an adult child providing a significant number of hours, both paid and unpaid, which the commenter suggested could be an indicator that the family cannot find a qualified provider for the services.

Response: We appreciate the commenter's suggestion. Given that our work to better

ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter questioned the relationship between higher payment rates in FFS and higher rates of accepting new Medicaid patients, as well as the potential for affecting rates across payers and delivery systems, noting that even if the State raise the rates for the Medicaid FFS that does not mean that Medicaid or Medicare managed care plans, including managed care plans for individuals dually eligible for both Medicare and Medicaid, also will raise their provider payment rates. The commenter noted that raising the rates for Medicaid FFS does not mean that the State will ensure that the managed care plans operating in the State also pay higher rates, noting that practitioners are less likely to accept Medicaid if the managed care plans do not raise payment rates to align when FFS rates have been increased.

Response: We appreciate the views of the commenter. The provisions of § 447.203(c) only apply to Medicaid FFS, and do not apply to Medicaid managed care plans. Requirements for Medicaid managed care are discussed in the Medicaid Managed Care final rule (as published elsewhere in this **Federal Register**). Payment rates that managed care plans pay to providers are not required to be set at the Medicaid FFS rate levels as managed care is a risk-based arrangement whereby States pay managed care plans prospective capitation rates, and plans contract with network providers and negotiate provider payment rates. Managed care plans have their own access to care requirements, including the network adequacy requirements in 42 CFR 438.68. Managed care plan capitation rates are subject to actuarial soundness requirements at § 438.4.

1. Fully Fee-For-Service States

We solicited comments on whether additional access standards for States with a fully FFS delivery system may be appropriate. Because the timeliness standards of the proposed Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality

proposed rule (Managed Care proposed rule) at § 438.68 would not apply to any care delivery in such States, we stated that we were considering whether a narrow application of timeliness standards to fully FFS States that closely mirrored the proposed appointment wait time standards, secret shopper survey requirements, and publication requirements (as applied to outpatient mental health and substance use disorder, adult and pediatric; primary care, adult and pediatric; obstetrics and gynecology; and an additional type of service determined by the State) in that rule might be appropriate. Given that timeliness standards would apply directly to States, we also solicited comments on a potentially appropriate method for CMS to collect data demonstrating that States meet the established standards at least 90 percent of the time.

In developing the proposed rule, with respect to FFS, our intent and focus was on replacing the previous AMRP process. While we saw value in discussing and seeking public input on timeliness standards for fully FFS States that would mirror those proposed in the Managed Care proposed rule, creating additional alignment between the delivery systems, we were mindful of the volume of proposed changes that would require State resources for implementation. Therefore, we chose to maintain our goal with the FFS provisions of this access rule to replace the previous AMRP process, and we believed that timeliness standards were better suited to a larger, ongoing access strategy, to be considered and proposed in future rulemaking. Nevertheless, we saw value in gauging the appetite for CMS to adopt timeliness standards in fully FFS States, and as such included a short section about the possibility of those standards in the fully FFS context in the proposed rule. Although we are not finalizing any FFS timeliness standards in this final rule, we intend to propose them in future rulemaking, informed by the comments received on this discussion in the proposed rule. Additionally, by keeping this current rulemaking focused on replacing the previous AMRP process and not implementing FFS timeliness standards at this time, we afford ourselves an opportunity to observe and learn from those standards being established in managed care (and in the marketplace). Those experiences will provide greater insights into how to best propose these standards in FFS and provide time to

engage with interested parties on how we might best include newly proposed FFS timeliness standards in existing requirements, including those we are finalizing in this rule, mitigating unnecessary burden on States.

We received public comments in response to this request for comment. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted general support for timeliness standards for fully FFS States. Generally, these commenters agreed that there is value in aligning access monitoring strategies across delivery systems so that all Medicaid beneficiaries would benefit from a new policy, and that these standards could improve access by confirming whether beneficiaries are actually able to access care in a timely manner. Some commenters had suggestions if CMS were to adopt timeliness standards in FFS, such as phasing in the requirements over time or by service, collecting information on geographic variations in wait times, and either applying the standards to all FFS programs or allowing exception for States with minimal covered services delivered through FFS. Others cited concerns that they would want a future proposal to address, such as establishing protections for providers who do not have direct control over their scheduling. Commenters varied on whether they believed providers should have to perform any additional work to meet new standards, with one requesting that providers, not just States, be held accountable for outcomes based on these standards, while another commenter wanted to ensure these requirements would not add any burden on providers. One commenter suggested including provider surveys in addition to participant surveys.

Response: We appreciate the support expressed by a number of commenters for the concept of applying timeliness standards in fully FFS delivery systems as a further means to ensure beneficiary access to covered services. We are also grateful for the suggestions that will allow us to formulate future proposed rulemaking that considers various needs and concerns. We note that the request for comment was with respect to fully FFS States (that deliver no services through managed care), but we will consider for future rulemaking whether to expand

on that limit, for example, applying standards to States that cover only a small number of services through managed care delivery, to apply them to FFS generally, or to maintain the focus on fully FFS States. We intend to use the experience of the managed care plans and the States implementing timeliness requirements to assess things like a phased-in approach, or whether such standards should be proposed for FFS delivery systems in non-fully FFS States.

Comment: We received a number of comments expressing general opposition to establishing timeliness standards for services delivered on a FFS basis, particularly in the context of implementing them simultaneously with the other access provisions in the proposed rule. These commenters expressed concern about the burden, both in time and cost, of establishing the necessary administrative infrastructure to meet timeliness requirements as well as the requirements proposed in the proposed rule. One commenter suggested CMS explore how these areas could be better monitored using existing data collections and processes. Another pointed out the differences in available resources between managed care and FFS, such as increased matching rates associated with managed care External Quality Review that does not exist with respect to FFS Medicaid, making FFS timeliness standards more cost prohibitive to implement. Another commenter pointed out that in FFS delivery systems, States would not know whether wait time issues identified through monitoring were specific to Medicaid or whether similar wait time issues were encountered by other patients with other payers.

Response: We understand the concerns about burden on States, and for that reason we limited the proposed rule and are only finalizing provisions that, generally, serve to replace the previous AMRP process. We see value in the oversight and positive program outcomes that could be achieved through proposing and implementing FFS timeliness standards in the future, and also understand there will be differences between managed care and FFS that create unique issues to address in any future proposal. For example, there are differences in how providers interact with plans in a managed care system versus how they interact with the State Medicaid agency in a FFS system. There are also differences in the idea of a “network” between these

delivery models that may impact how we would assess network adequacy. We will explore how we can best support States with the administrative burden, and how we can establish standards that identify problems unique to providing services to Medicaid beneficiaries.

Comment: Many commenters expressed support for specific aspects of our request, such as for establishing wait time standards in a FFS delivery system or utilizing secret shopper surveys for oversight. These commenters generally pointed to the access improvements such standards can provide, as they would highlight where there are deficiencies in finding available providers. One commenter shared personal experience of longer wait times as a Medicaid beneficiary than those experienced by non-Medicaid enrollees. One commenter shared suggestions regarding which benefit categories needed more focus, both for oversight and in length of wait times, and this commenter along with a couple others encouraged CMS to align with the Health Insurance Marketplace®.¹⁸⁷ Another commenter cautioned that provider shortages must be addressed as part of the overall access strategy.

Response: We appreciate hearing from commenters on the specifics of the timeliness standards request for comments, as we hope to use this feedback to inform and enhance a future set of proposals. We also fully intend to include lessons from the experience of the marketplace and Medicaid managed care in proposing these future standards for the FFS delivery system and will continue to engage with interested parties between now and when we undertake future rulemaking on this topic. We agree that provider shortages present a challenge to access and the efficacy of wait time standards, and we will examine how best to acknowledge that reality while holding States and providers to appropriate standards.

Comment: Several commenters opposed the specific standards listed in our request for comment. One encouraged CMS to achieve its access goals through a focus on payment adequacy rather than wait times. Similarly, another requested CMS allow States to provide verification and assurances of sufficient access through other, existing data collection

¹⁸⁷ Health Insurance Marketplace® is a registered service mark of the US Department of Health & Human Services.

mechanisms. Another stated wait time standards that do not account for differences in provider availability, as in whether there are sufficient providers in a geographic area to meet the standards based on the beneficiary population in that area, would not achieve the desired effect of increasing access. One commenter expressed that a secret survey process would be duplicative of existing directory review processes already undertaken by States and would also force States to switch vendors from an existing outside entity performing the role, and stated CMS should instead allow States to continue with current practices that achieve a similar purpose. Another questioned the data integrity of a secret survey approach to oversight, stating there are inherent challenges in collecting consistent information.

Response: We intend to make every effort to utilize existing processes and to mitigate duplication wherever possible when we propose FFS timeliness standards in the future. However, we are exploring proposing these standards because, in our view, appointment wait time maximums and secret shopper surveys may provide for unique and valuable oversight of access that we may wish to propose in the future. As stated previously, in this rule we prioritized a replacement for an existing rate-based process, but our evaluation and enhancement of means to ensure beneficiary access will be ongoing. We will utilize lessons learned from the implementation of timeliness standards under managed care to inform our future FFS proposals.

Comment: Some commenters were unclear as to whether CMS was proposing to implement the timeliness standards for fully FFS States as proposed in the Managed Care proposed rule. One commenter was concerned how and when CMS would communicate to States that these requirements had taken effect. Another pointed out specifically that CMS had included preamble language without including proposed regulatory text or burden estimates, which they noted would be significant. The commenter was concerned that the public had not been afforded a meaningful opportunity for notice and comment.

Response: We apologize for the confusion experienced by some as to whether this section of the rule was intended as a proposed policy. This discussion in the proposed rule was a

request for comment, not a proposed policy. We intend to propose these timeliness standards under FFS in future rulemaking, affording States and other interested parties the ability to examine a complete proposal and provide comments that we would consider in a subsequent finalization decision. We are not finalizing any timeliness standards for FFS delivery systems in this final rule.

2. Documentation of access to care and service payment rates (§ 447.203(b))

We proposed to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, including a new process to promote payment rate transparency. This new proposed process would require States to publish their FFS Medicaid payment rates in a clearly accessible, public location on the State's website, as described later in this section. Then, for certain services, States would be required to conduct a comparative payment rate analysis between the States' Medicaid payment rates and Medicare rates or provide a payment rate disclosure for certain HCBS that would permit CMS to develop and publish HCBS payment benchmark data.

a. Payment Rate Transparency § 447.203(b)(1)

In paragraph (b)(1), we proposed to require the State agency to publish all Medicaid FFS payment rates on a website developed and maintained by the single State agency that is accessible to the general public. We proposed that published Medicaid FFS payment rates would include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. We also proposed to require that the website be easily reached from a hyperlink on the State Medicaid agency's website.

Within this payment rate publication, we proposed that FFS Medicaid payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. We

also proposed that, if the rates vary, the State must separately identify the Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

We noted that longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. Under Title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and implementing regulations, qualified individuals with disabilities may not be excluded from participation in, or denied the benefits of any programs or activities of the covered entity, or otherwise be subjected to discrimination by any covered entity, on the basis of disability, and programs must be accessible to people with disabilities.¹⁸⁸ Individuals with disabilities are entitled to communication that is as effective as communication for people without disabilities, including through the provision of auxiliary aids and services.¹⁸⁹ Section 1557 of the Affordable Care Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide meaningful access to their health programs or activities for individuals with limited English proficiency, which may include the provision of interpreting services and translations when reasonable.¹⁹⁰

We proposed that for States that pay varying Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, those States would need to separately identify their Medicaid FFS payment rates in the payment rate transparency publication by each grouping or multiple groupings, when applicable to a State's program. In the event rates vary according to these factors, as later discussed in this final rule, our intent is that a member of the public be readily able to determine the payment amount that will be made, accounting for all relevant circumstances. For example, a State that varies their Medicaid FFS

¹⁸⁸29 U.S.C. 794; 42 U.S.C. 18116(a); 42 U.S.C. 12132; 28 CFR 35.130(a); 45 CFR 84.4 (a); 45 CFR 92.2(b).

¹⁸⁹28 CFR 35.160; 45 CFR 92.102; *see also* 45 CFR 84.52(d).

¹⁹⁰ 45 CFR 92.101; *see also* <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html>.

payment rates by population may pay for a service identified by code 99202 when provided to a child at a rate of \$110.00 and when provided to an adult at a rate of \$80.00. Because the Medicaid FFS payment rates vary based on population, both of these Medicaid FFS payment rates would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication. As another example, a State that varies their Medicaid FFS payment rates by provider type may pay for 99202 when delivered by a physician at a rate of \$50.00, and when delivered by a nurse practitioner or physician assistant at a rate of \$45.00.

In the proposed rule, we acknowledged that we are aware that some State plans include language that non-physician practitioners (NPPs), such as a nurse practitioner or physician assistant, are paid a percentage of the State's fee schedule rate. Because the Medicaid FFS payment rates vary by provider type, both of the Medicaid FFS payment rates in both situations (fee schedule rates of \$50.00 and \$45.00) would need to be separately identified as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication, regardless of whether the State has individually specified each amount certain in its approved payment schedule or has State plan language specifying the nurse practitioner or physician assistant rate as a percentage of the physician rate. Additionally, for example, a State that varies their Medicaid FFS payment rates by geographical location may pay for 99202 delivered in a rural area at a rate of \$70, in an urban or non-rural area as a rate of \$60, and in a major metropolitan area as a rate of \$50. We are also aware that States may vary their Medicaid FFS payment rates by geographical location by zip code, by metropolitan or micropolitan areas, or other geographical location breakdowns determined by the State. Because the Medicaid FFS payment rates vary based on geographical location, all Medicaid FFS payment rates based on geographical location would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication.

For a State that varies its Medicaid FFS payment rates by any combination of these groupings, then the payment rate transparency publication would be required to reflect these multiple groupings. For example, the State would be required to separately identify the rate for a physician billing 99202 provided to a child in a rural area, the rate for a nurse practitioner billing 99202 provided to a child in a rural area, the rate for a physician billing 99202 provided to an adult in a rural area, the rate for a nurse practitioner billing 99202 provided to an adult in a rural area, the rate for a physician billing 99202 provided to a child in an urban area, the rate for a nurse practitioner billing 99202 provided to a child in an urban area, and so on. We proposed that this information would be required to be presented clearly so that a member of the public can readily determine the payment rate for a service that would be paid for each grouping or combination of groupings (population (pediatric and adult), provider type, and geographical location), as applicable. We acknowledged that States may also pay a single Statewide rate regardless of population (pediatric and adult), provider type, and geographical location, and as such would only need to list the single Statewide rate in their payment rate transparency publication.

We acknowledged that there may be additional burden associated with our proposal that the payment rate transparency publication include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' Medicaid FFS payment rates vary based on these groupings. Despite the additional burden, we noted our belief that the additional level of granularity in the payment rate transparency publication is important for ensuring compliance with section 1902(a)(30)(A) of the Act, given State Medicaid programs rely on multiple provider types to deliver similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each area of each State.

We further proposed that Medicaid FFS payment rates published under the proposed payment rate transparency requirement would only include fee schedule payment rates made to

providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. To ensure maximum transparency in the case of a bundled fee schedule payment rate or rate determined by a similar payment methodology where a single payment rate is used to pay for multiple services, we proposed that the State must identify each constituent service included in the bundled fee schedule payment rate or rate determined by a similar payment methodology. We also proposed that the State must identify how much of the bundled fee schedule payment rate or rate determined by a similar payment methodology is allocated to each constituent service under the State's payment methodology. For example, if a State's fee schedule lists a bundled fee schedule rate that pays for day treatment under the rehabilitation benefit and the following services are included in the day treatment bundle: community based psychiatric rehabilitation and support services, individual therapy, and group therapy, then the State would need to identify community based psychiatric rehabilitation and support services, individual therapy, and group therapy separately and each portion of the bundled fee schedule payment rate for day treatment that is allocated to community based psychiatric rehabilitation and support services, individual therapy, and group therapy. We proposed to require States identify the portion of the bundled fee that is allocable to each constituent service included in the bundled fee schedule payment rate, which would add an additional level of granularity to the payment rate transparency publication to enable a member of the public to readily be able to determine the payment amount that would be made for a service, accounting for all relevant circumstances, including the payment rates for each constituent service within a bundle and as a standalone service. We also proposed to require that the website be easily reached from a hyperlink to ensure transparency of payment rate information is available to beneficiaries, providers, CMS, and other interested parties.

In the proposed rule, we proposed the initial publication of Medicaid FFS payment rates would occur no later than January 1, 2026, and include approved Medicaid FFS payment rates in effect as of that date, January 1, 2026. We proposed this timeframe to provide States with at

least 2 years from the possible effective date of the final rule, if this proposal were finalized, to comply with the payment rate transparency requirement. We explained that the proposed timeframe would initially set a consistent baseline for all States to first publish their payment rate transparency information and then set a clear schedule for States to update their payment rates based on the cadence of the individual States' payment rate changes.

We noted that the same initial publication due date for all States to publish their payment rates would promote comparability between States' payment rate transparency publications. In proposing an initial due date applicable to all States, we reasoned that, once States would begin making updates to their payment rate transparency publications, there would be a clear distinction between States that have recently updated their payment rates and States that have long maintained the same payment rates. For example, say two States initially publish their payment rates for E/M CPT code 99202 (office or outpatient visit for a new patient) at \$50. One State annually increases its payment rate by 5 percent over the next 2 years, and would update its payment rate transparency publication accordingly in 2027 with a payment rate of \$52.50, then in 2028 with a payment rate of \$55.13, while the other State's payment rate for the same service remains at \$50 in 2027 and 2028. The transparency of a State's recent payment rates including the date the payment rates were last updated on the State Medicaid agency's website, as discussed later, as well as the ability to compare payment rates between States on accessible and easily reachable websites, highlights how the proposed payment rate transparency would help to ensure that Medicaid payment rate information is available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues to better ensure compliance with section 1902(a)(30)(A) of the Act.

We also proposed that the initial publication include approved Medicaid FFS payment rates in effect as of January 1, 2026. We proposed this language to narrow the scope of the publication to CMS-approved payment rates and methodologies, thereby excluding any rate changes for which a SPA or similar amendment request is pending CMS review or approval.

SPAs are submitted throughout the year, can include retroactive effective dates, and are subject to a CMS review period that varies in duration.^{191,192}

As discussed later in this final rule regarding paragraph (b)(2) and (b)(3), we encouraged States to use the proposed payment rate transparency publication as a source of Medicaid payment rate data for compliance with the paragraph (b)(3)(i)(B) proposed comparative payment rate analysis and paragraph (b)(3)(ii)(B) proposed payment rate disclosure requirements. However, we noted that the comparative payment rate analysis and payment rate disclosure requirements would look to rates in effect one year before the publication of the required analysis or disclosure. We include a more in-depth discussion of the timeframes for publication of the comparative payment rate analysis and payment rate disclosure in paragraph (b)(4) later in this final rule, where we note that the 1-year shift in timeframe is necessitated by the timing of when Medicare publishes their payment rates in November and the rates taking effect on January 1, leaving insufficient time for CMS to publish the code list for States to use for the comparative payment rate analysis and for States develop and publish their comparative payment rate analysis by January 1. We noted that the ongoing payment transparency publication requirements would allow the public to view readily available, current Medicaid payment rates at all times, even if slightly older Medicaid payment rate information must be used for comparative payment rate analyses due to the cadence of Medicare payment rate changes as well as the payment rate disclosure. We are cognizant that the payment rate disclosure does not depend on the availability of Medicare payment rates; however, we proposed to provide States with the same amount of time to comply with both the proposed comparative payment rate analysis and payment rate disclosure requirements.

¹⁹¹ In accordance with 42 CFR 430.20, an approved SPA can be effective no earlier than the first day of the calendar quarter in which an approvable amendment is submitted. For example, a SPA submitted on September 30th can be retroactively effective to July 1st.

¹⁹² In accordance with 42 CFR 430.16, a SPA will be considered approved unless CMS, within 90 days after submission, requests additional information or disapproves the SPA. When additional information is requested by CMS and the State has responded to the request, CMS will then have another 90 days to either approve, disapprove, and request the State withdraw the SPA or the State's response to the request for additional information. This review period includes two 90-day review periods plus additional time when CMS has requested additional information which can result in a wide variety of approval timeframes.

We stated that, if this proposal were finalized at a time that would not allow for States to have a period of at least 2 years between the effective date of the final rule and the proposed January 1, 2026, due date for the initial publication of Medicaid FFS payment rates, then we proposed an alternative date of July 1, 2026, for the initial publication of Medicaid FFS payment rates and for the initial publication to include approved Medicaid FFS payment rates as of that date, July 1, 2026. This shift would allow more than 2 years from the effective date of this final rule for States to comply with the payment rate transparency requirements.

We proposed to require the that the single State agency include the date the payment rates were last updated on the State Medicaid agency's website. We also proposed to require that the single State agency ensure that Medicaid FFS payment rates are kept current where any necessary updates to the State fee schedules made no later than 1 month following the date of CMS approval of the SPA, section 1915(c) HCBS waiver, or similar amendment revising the provider payment rate or methodology. Finally, in paragraph (b)(1), we proposed that, in the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State would be required to update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate. This provision is intended to capture Medicaid FFS payment rate changes that occur because of previously approved SPAs containing payment rate methodologies. For example, if a State sets its Medicaid payment rates for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) at a percentage of the most recent Medicare fee schedule rate, then the State's payment rate would change when Medicare adopts a new fee schedule rate through the quarterly publications of the Medicare DMEPOS fee schedule, unless otherwise specified in the approved State plan methodology that the State implements a specific quarterly publication, for example, the most recent April Medicare DMEPOS fee schedule. Therefore, the State's Medicaid FFS payment rate automatically updates when Medicare publishes a new fee schedule, without the submission of a SPA because the State's methodology pays a percentage of the most recent State

plan-specified Medicare fee schedule rate. In this example, the State would need to update its Medicaid FFS payment rates in the payment rate transparency publication no later than 1 month after the effective date of the most recent update to the Medicare fee schedule payment rate made applicable under the approved State plan payment methodology.

While there is no current Federal requirement for States to consistently publish their rates in a publicly accessible manner, we noted our awareness that most States already publish at least some of their payment rates through FFS rate schedules on State agency websites. Currently, rate information may not be easily obtained from each State's website in its current publication form, making it difficult to understand the amounts that States pay providers for items and services furnished to Medicaid beneficiaries and to compare Medicaid payment rates to other health care payer rates or across States. However, through this proposal, we sought to ensure all States do so in a format that is publicly accessible and where all Medicaid FFS payment rates can be easily located and understood. The new transparency requirements under this final rule help to ensure that interested parties have access to updated payment rate schedules and can conduct analyses that would provide insights into how State Medicaid payment rates compare to, for example, Medicare payment rates and other States' Medicaid payment rates. The policy intends to help ensure that payments are transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. We solicited comments on the proposed requirement for States to publish their Medicaid FFS payment rates for all services paid on a fee schedule, the proposed structure for Medicaid FFS payment rate transparency publication on the State's website, and the timing of the publication of and updates to the State's Medicaid FFS payment rates for the proposed payment rate transparency requirements in § 447.203(b)(1).

We received public comments on these provisions. The following is a summary of the comments we received and our responses.

Comment: Commenters overwhelmingly supported the proposed payment rate transparency provision at § 447.203(b)(1) in its entirety. A couple of commenters specifically

expressed support for ensuring the State's website where the payment rate transparency is published is fully accessible and provides meaningful access for individuals with limited English proficiency. Additionally, a couple of commenters stated that their State already publishes their fee schedules as proposed by the payment rate transparency requirements.

However, a couple of commenters expressed opposition to the proposed payment rate transparency provision in its entirety. Commenters in opposition stated the proposed payment rate transparency requirements would be administratively burdensome for States and that the payment rate transparency publication would not result in a meaningful access analysis. One commenter questioned CMS' authority to require States to publish their payment rates because section 1902(a)(30) of the Act does not explicitly grant CMS this authority.

Response: We thank the commenters for their support of the proposed payment rate transparency provision at § 447.203(b)(1). We are finalizing the payment rate transparency provisions by adding and deleting regulatory language for clarification, making minor revisions to the organizational structure, updating the required timeframe for compliance and for updating payment rates after SPA or other payment authority approval, and incorporating a technical change to account for States submitting SPAs with prospective effective dates. We list and describe the specific revisions we made to the regulatory language for the payment rate transparency provision at § 447.203(b)(1) at the end of this section of responses to comments. The policies in this final rule allow flexibility that we believe will allow some States to use existing fee schedule publications for compliance, and we expect additional States will only need minor revisions. We encourage States that already publish their fee schedules to review the final regulatory language and reach out to CMS with any questions regarding compliance.

We disagree with the commenters regarding administrative burden of the payment rate transparency publication. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group

requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States will have for compliance with this final rule.

Specifically for the payment rate transparency publication, and as discussed in a later response to comments, States have flexibility to (1) organize and format their publication, so that they can use existing fee schedule publications for compliance (assuming all requirements in § 447.203(b)(1) are met); (2) utilize contractors or other third party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule); and (3) for the initial publication, if necessary historical information about bundled payment rates is unavailable to the State, then the State does not need to include the bundled payment rate breakdown as required in § 447.203(b)(1)(iv) of this final rule (however, we remind States that upon approval of a SPA that revised the bundled payment rate, the State will be required to update the publication to comply with § 447.203(b)(1)(iv)). Additionally, we are providing examples of payment rates that are not subject to the payment rate transparency publication and an illustrative example of a compliant payment rate transparency (including to meet accessibility standards) through subregulatory guidance issued prior to the effective date of this final rule. We expect these flexibilities and clarifications to minimize the State administrative burden commenters expressed concern about, which potentially stemmed from an imprecise understanding of the Medicaid FFS fee schedule payment rates that are required to be published in the payment rate transparency publication. Finally, we would expect that States already have the data for the payment rate transparency publication readily available through existing fee schedules, SPAs, or other internal documentation, so the work to compile that data into a format that complies with this final rule

should require minimal effort.

To clarify, the payment rate transparency publication is not an analysis requirement, but a transparency requirement for States to publish their Medicaid FFS fee schedule payment rates, as discussed in detail in a later response to comments in this section. However, an analysis component is being finalized in § 447.203(b)(2) and (3) called the comparative payment rate analysis, which we believe will result in a meaningful access analysis because it requires States to compare certain of their Medicaid FFS payment rates to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. This access analysis will help States and CMS to assess compliance with section 1902(a)(30)(A) of the Act where Medicare payment rates serve as a benchmark for comparing Medicaid payment rates to another of the nation's large public health coverage programs. As described in the proposed rule and in greater detail later in this final rule, Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States, Medicare payment rates are publicly available, and broad provider acceptance of Medicare makes Medicare non-facility payment rates as established on the Medicare PFS for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.¹⁹³

We disagree that we do not have the authority to require States to publish their payment rates. As discussed in the proposed rule, payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act, which requires that State plans assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.¹⁹⁴ Transparency, particularly the requirement that States must publicly publish their

¹⁹³ 88 FR 27960 at 28011

¹⁹⁴ 88 FR 27960 at 27967

payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. As noted in the proposed rule, most States already published at least some of their payments through FFS rate schedule on State agency websites.¹⁹⁵ Our efforts finalized in this rule will help ensure all States publish their payment rates consistently and accessibly so interested parties have fundamental information about payment rates and can utilize existing public processes to raise concerns about access. Additionally, the Supreme Court's *Armstrong* decision placed added importance on CMS' determinations, as the responsible Federal agency, regarding the sufficiency of Medicaid payment rates. The payment rate transparency requirements included in this final rule reflect that statutory responsibility to ensure compliance with section 1902(a)(30)(A) of the Act. We also note that the previous AMRP process that was in effect prior to this final rule established a transparent data-driven process to measure access to care in States, including oversight of provider payment rates, actual or estimated levels of provider payment available from other payers, and the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates. This final rule merely streamlines the approach under the same statutory authority and shared responsibility that applied for the previous AMRP process. We remind States of longstanding, general requirement for the State to maintain statistical, fiscal, and other records necessary for reporting and accountability under § 431.17(b)(2).

Comment: Some commenters expressed concerns about the burden associated with the payment rate transparency publication. They specifically cited concern about meeting strict State-level website accessibility requirements, extensive changes that could be needed to existing claims payment systems (that is, for a State that does not currently include beneficiary copayment information on their existing fee schedules, the State may need to make change

¹⁹⁵ 88 FR 27960 at 28000.

requests of their contractor to modify their claims payment system to produce the Medicaid payment information required in the payment rate transparency publication to include the total payment amount a provider would receive inclusive of beneficiary cost sharing), conducting research on when payment rates were last updated, and monthly monitoring of Medicare rates to ensure State fee schedule rates set at a percentage of Medicare are updated timely.

Response: As described in the proposed rule, longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the websites containing Medicaid FFS payment rate information. These requirements apply to all State agency, contractor, or other third-party websites and any burden associated with meeting those Federal obligations is not created by policies finalized in this rule. With respect to any State-level accessibility requirements that might exceed Federal requirements, we refer the commenter to the State Medicaid agency or other agency responsible for compliance with State accessibility requirements for guidance or technical assistance concerning State-imposed accessibility requirements.

Regarding commenters' concerns that States would need to change existing claims payment systems (that is, the State may need to make change requests of their contractor to modify their claims payment system to produce the Medicaid payment information required for the payment rate transparency publication that includes beneficiary cost sharing in fee schedule amounts), we want to clarify State claiming and payment systems, and the output of these systems, generally are not subject to the payment rate transparency publication requirements as the provision only applies to Medicaid FFS fee schedule payment rates. We do not anticipate it would be unduly burdensome for a State to maintain its Medicaid FFS fee schedules in an appropriate format outside of its claiming and payment systems. States are not required to publish claims data or data about actual payments made to providers under the payment rate transparency publication provision.

Commenters were concerned about whether beneficiary cost sharing information should be included in the payment rate transparency publication. To clarify, the payment rates published under § 447.203(b)(1)(i) must be inclusive of the payment amount from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. By requiring States to publish the payment amount the Medicaid agency would pay and any beneficiary cost sharing as a single payment amount, we focus on the total Medicaid payment amount a provider would expect to receive for furnishing a given service to a Medicaid beneficiary and which is therefore most relevant to a provider's decision to accept the Medicaid payment rate, thereby furthering our section 1902(a)(30)(A) access goals to ensure payment rates are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Furthermore, this representation of payment rates is consistent with the comparative payment rate analysis,¹⁹⁶ which minimizes burden on States by requiring the Medicaid FFS fee schedule payment rate be displayed in the same way for both publications. Additionally, we recognize that beneficiary cost sharing amounts can vary depending on the State Medicaid program and the status of the Medicaid enrollee. Therefore, we expect States with cost-sharing requirements could experience additional burden in complying with the payment rate transparency publication, if States were required to remove variable cost sharing amount from the Medicaid FFS fee schedule payment rate for each service subject to the publication.

Regarding commenters' concerns about conducting research on when payment rates were last updated, we want to clarify that the requirement to include the date the rates were last updated refers to a date for the website publication. In other words, the date should provide assurance that the rates on the website are current as of the specified date. We do not expect, nor did we propose, States to examine historical records to find the dates every rate was last updated.

¹⁹⁶ 88 FR 27960 at 28013

However, if a State wishes to include that information for all or a subset of published rates, it can.

Regarding commenters' concerns about monthly monitoring of Medicare rates to ensure the payment rate transparency publication is up to date, firstly, to clarify, only States that set their Medicaid payment rates at a percentage of a Medicare payment rate would be affected by this consideration. For those States that set their Medicaid payments rates as a percentage of a Medicare payment rate, we expect the State to already be monitoring changes in Medicare rates in accordance with their approved payment methodology and §§ 430.10 and 430.20 and part 447, subpart B, which require States to pay the approved State plan payment rates in their State plan effective on or after the approved effective date of the State plan provision. Therefore, if a State's approved State plan pays a rate based on the most current Medicare payment rate for a particular service, then payment of any rate outside of the approved State plan methodology would result in a State plan compliance issue. We expect that States with such payment methodologies routinely are monitoring Medicare payment rates to ensure that their Medicaid payment rates are updated according to the approved methodology. Medicare fee schedule updates are well documented and accessible to States on cms.gov, even in the event of a change to a Medicare payment rate outside the usual cadence of Medicare updates for that rate (an off-cycle update) and keeping up with Medicare fee schedule updates is critical for ensuring a State's payment rate transparency publication is accurate and updated timely.¹⁹⁷

Comment: A few commenters requested clarification on the format of the payment rate transparency publication, particularly if Medicaid FFS payment rates should be organized by CPT code.

Response: In this final rule, in regard to the payment rate transparency provision, we are not requiring States to publish their payment rates by CPT/HCPCS code, which is required in the comparative payment rate analysis discussed later in this section. However, we encourage States

¹⁹⁷ <https://www.cms.gov/medicare/payment/fee-schedules>.

to consider organizing their publication by CPT/HCPCS code, due to the common use of CPT/HCPCS for billing for medical services across the country, including in State Medicaid programs. The goal of the payment rate transparency publication is to ensure all States publish their Medicaid FFS fee schedule payment rates in a format that is publicly accessible and where all these rates can be easily located and understood. States can determine what organizational and formatting structure is most suitable for organizing rates in a manner that will be easily understood by providers and beneficiaries.

Comment: A couple of commenters requested clarification on the requirement that States separately identify Medicaid FFS fee schedule payment rates by population, specifically inquiring if “population” referred to beneficiary demographics or waiver/program population.

Response: As indicated in the regulation text, population refers to beneficiary demographics, specifically adult and pediatric populations. Under this final rule, States will be required to publish their Medicaid FFS fee schedule payment rates separately identified by rates paid for the adult population and the pediatric population, if the rates differ in the State. As stated in the proposed rule, we acknowledge that a State may pay a single Statewide rate regardless of population, provider type, or geographical location, and such a State would only need to list the single Statewide rate in its payment rate transparency publication. We also acknowledge that States define pediatric differently (such as, 18 years old or younger, 19 years old or younger, and 21 years old or younger) and we encourage States to disclose the age range the State’s Medicaid program uses in the payment rate transparency publication for transparency purposes.

Comment: Some commenters requested clarification regarding which payments are subject to the payment rate transparency requirements outlined in paragraph (b)(1). Multiple commenters questioned if the following payment methodologies would be subject to the payment rate transparency requirements under paragraph (b)(1): manually priced items (for example, physician administered drugs), provider-specific rates (for example, PPS rates typically paid to

FQHCs or all-inclusive per-visit rates typically paid to clinics (we assume commenters meant clinics as defined in § 440.90)), per diem rates, cost and cost-based payment methodologies (including interim payments) typically paid to facility-based providers, and negotiated rates. Additionally, many commenters questioned if disproportionate share hospital (DSH) payments, FFS supplemental payments, or managed care State directed payments (SDPs) would be included in the payment rate transparency publication. A couple of commenters stated that only requiring States to publish base payment rates would not provide a member of the public with the ability to readily determine the amount Medicaid would pay for a service because excluding DSH payments and supplemental payments is an inaccurate, incomplete, and misleading representation of a Medicaid provider's actual, overall payments from the Medicaid program.

Response: In § 447.203(b)(1) of the proposed rule, we proposed that “[t]h State agency is required to publish all Medicaid fee-for-service payment rates Published Medicaid [FFS] payment rates include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a [FFS] delivery system.” We acknowledge that this language was not clear that we intended to require the publication requirement to include only Medicaid FFS fee schedule payment rates. Accordingly, in this final rule, we have made some revisions to the proposed regulatory language in § 447.203(b)(1) to change the organizational structure of (b)(1) by adding romanettes and clarify that only Medicaid FFS fee schedule payment rates are required to be published in the payment rate transparency publication. Throughout (b)(1), references to “fee schedule payment” were replaced with “Medicaid fee-for-service fee schedule payment rates” for clarity and consistency. Therefore, in (b)(1) we state that, the State agency is required to publish all Medicaid FFS fee schedule payment rates. Further, in § 447.203(b)(1)(i), we specify that, “for purposes of paragraph (b)(1), the payment rates that the State agency is required to publish are Medicaid fee-for-service fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system.”

We would like to clarify which Medicaid FFS fee schedule payment rates are subject to the payment rate transparency provisions in § 447.203(b). Medicaid FFS fee schedule payment rates are payment amounts made to a provider, known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. A fee schedule is a list, table, or similar presentation of covered services and associated payment amounts that are generally determined at the State's discretion. We also consider a State to use a fee schedule when the State has not yet organized its payment amounts into such a straightforward list, table, or similar presentation, but under the State's approved payment methodology, the State determines payment rates based on the application of a mathematical formula to another fee schedule or other reference rate stated as an amount certain. In other words, a fee schedule that utilizes a formula, but has not yet been organized into a list, table, or similar presentation of covered services and associated payment amounts, is included in the scope of fee schedules subject to the payment rate transparency provisions. For example, a Medicaid payment methodology that provides for payment at 80 percent of the corresponding Medicare PFS rate would constitute a Medicaid fee schedule payment methodology because it applies a formula to a fee schedule to produce a fee schedule payment rate that is known in advance of a provider delivering the service. This formula reflects that the State's fee schedule payment methodology starts with the Medicare PFS fee schedule, then reduces the fee schedule amount to 80 percent of the Medicare PFS amount to arrive at the Medicaid fee schedule payment rate. States that utilize the previously described formula-based methodology that may not currently publish these payment rates on a fee schedule will be required to publish the actual payment amounts as determined by their formula in the payment rate transparency publication under this final rule. This final rule focuses on ensuring transparency of Medicaid FFS fee schedule payment rates so that they are "...organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service," as stated in the proposed regulatory language in § 447.203(b)(1), which we are finalizing in § 447.203(b)(1)(iii) of this final rule with a slight modification to replace "the

service” with “a given service.” Merely publishing the mathematical formula that a member of the public would need to use to calculate each payment rate the State has set for a particular service would not meet this requirement of this final rule. To summarize, fee schedule payment methodologies that utilize a formula applied to another fee schedule are included in the scope of fee schedules, and the payment rate transparency publication must reflect the actual fee schedule payment rate amounts.

Certain bundled payment rates (as discussed later in this comment response) and PPS rates for inpatient hospital, outpatient hospital, and nursing facility services are considered fee schedules payment rates subject to the payment rate transparency publication because these payment amounts are also known in advance of a provider delivering a service to a beneficiary and are stated (or can readily be stated) as a list, table, or similar presentation.

We recognize that PPS rates are utilized in different contexts in Medicaid to pay for various services (including for services of FQHCs, RHCs, inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities) and can be calculated differently, depending on the service. PPS rates in Medicaid used to pay for services provided by inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities would be included. In the context of payment rates to hospitals and nursing facilities, the term “encounter rate” or “per diem rate” can also be used to describe the PPS rate received by these providers. This term generally describes a daily payment rate that is paid to a hospital or nursing facility during a patient’s admission to a hospital or nursing facility. In this situation, the PPS payment methodology typically makes payment based on a predetermined, fixed amount. States often use or model their payment methodologies after Medicare’s prospective payment systems to pay for outpatient hospital, inpatient hospital, and nursing facility services. In these situations, under Medicare’s prospective payment systems, Medicare typically pays providers for a particular service an amount derived based on the services

expected to be received during a visit or course of treatment (for more complex conditions). For example, under the Medicare IPPS, payment is made based on the Diagnosis Related Group (DRG) to which the patient discharge is assigned. States also often use other grouping systems, such as Medicare's PDPM for nursing facilities, Ambulatory Payment Classifications under Medicare's hospital outpatient PPS for hospital outpatient services items, or Medicare's End Stage Renal Disease PPS for facilities or hospital-based providers that furnish dialysis services and supplies. These PPS rates for inpatient hospital, outpatient hospital, and nursing facility services are paid to most hospitals and nursing facilities and are typically known in advance of a health care provider delivering a service to a beneficiary. Therefore, these types of PPS rates would be subject to the payment rate transparency publication in this final rule.

In contrast, FQHCs and RHCs are paid PPS rates that are developed under a methodology that is statutorily mandated under section 1902(bb) of the Act, which generally requires that FQHCs and RHCs receive a per visit, or encounter, rate that is provider-specific and must be based on a health center's unique cost and visit data.¹⁹⁸ This requirement creates a payment rate floor where FQHC and RHCs cannot be paid less than the PPS rate developed under this statutorily mandated methodology. Because this statutory payment floor is set by Congress, FQHC and RHC payment rates are uniquely situated in a manner that does not exist for other Medicaid payment rates under State discretion.¹⁹⁹ Although States must comply with section 1902(a)(30)(A) of the Act, this statutory provision does not set a specific payment rate floor. Therefore, because of the unique provider-specific payment floor mandated by Congress for FQHCs and RHCs, we believe access concerns related to payment rates for FQHCs and RHCs are attenuated and as such, we are not including FQHC and RHC PPS rates in the payment

¹⁹⁸ In the context of payment rates to FQHCs and RHCs, the terms "encounter rate," "per visit rate," and "provider-specific rate" can also be used to describe the PPS payment rate.

¹⁹⁹ We acknowledge that Medicaid payment rates for hospice services also have a statutorily mandated payment floor: the Medicaid hospice payment rates are calculated based on the annual hospice rates established under Medicare. These rates are authorized by section 1814(i)(1)(C)(ii) of the Act, which also provides for an annual increase in payment rates for hospice care services. However, we do not believe these rates would be burdensome on States to include because they are paid to all Medicaid participating hospice providers and are therefore not carving them out of this requirement.

rate transparency publication requirement. Furthermore, because the FQHC and RHC PPS rates are provider-specific based on an individual provider's costs and scope of service and required to be paid by States as a floor set by Congress, we generally do not believe that publication of the individual providers' payment rates as part of the payment rate transparency provision finalized in this rule would not result in actionable information for CMS to consider in ensuring compliance with section 1902(a)(30)(A) of the Act as intended through this final rule at this time.

In addition, if we were to require States to also publish FQHC and RHC PPS rates, we would expect a significant increase in burden on States in meeting this requirement. FQHC and RHC PPS rates are unique to each FQHC and RHC in a State (rather than a single fee schedule rate that Medicaid would pay for a given service to any provider in a State) and, therefore, publicizing the FQHC and RHC rates would represent a sharp increase in States' efforts for rates that are less concerning to CMS due to the statutory payment floor in section 1902(bb) of the Act. We do not believe the increase in burden is justifiable given our aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act with this final rule. Finally, and as discussed in detail in an earlier response to comments in this section, like all State plan services for which the State proposes a rate reduction or restructuring in circumstances where the changes could result in reduced access, FQHC and RHC services are subject to the access analyses in § 447.203(c) for proposed rate reductions and restructuring.

Certain FFS VBP payment methodologies are also fee schedule payment methodologies, even if the exact dollar amount that a particular provider will receive for a given service is not known in advance because of the need to adjust for metric-based performance. In such a case, a State might have an approved FFS VBP payment methodology in the State plan that includes a 2 percent withhold of the fee schedule payment amount and the potential for an additional 3 percent bonus to the provider based on the provider's performance for the year on certain quality

measures. Assuming the State's payment methodology starts with a base payment of 80 percent of the Medicare PFS payment amount, the provider's minimum payment for the service would be $.98 * (PFS * .80)$, and the maximum payment (achieved through a retrospective true-up payment based on final quality performance for the year) would be $1.03 * (PFS * .80)$. The provider's minimum and maximum possible payment amounts are known in advance (2 percent less than the Medicaid fee schedule amount, and 3 percent more, respectively) and are based on the application of a formula to a fee schedule. We also consider this type of FFS VBP arrangement to constitute a fee schedule payment methodology, because although the State does not know in advance the final payment amount a given provider will receive for a particular service (since the provider's quality performance is not known in advance), the minimum payment amount is calculable in advance based on the application of a mathematical formula to a fee schedule amount. We expect the State to use the minimum payment amount for purposes of the requirements of § 447.203(b), because this is the amount that a provider is assured to receive for furnishing the service. At State option, the State could also include information on the maximum payment amount the provider might receive under the FFS VBP payment methodology.

We would also like to clarify what payments are not subject to the payment rate transparency publication provision. Payment rates that are not subject to the transparency provisions include those where the minimum fee schedule payment is not known in advance of a provider delivering a service to a beneficiary because certain variables required for the payment calculation are unknown until after the provider has delivered the service. For example, cost-based and reconciled cost payment methodologies (including those that involve interim payments) are not subject to the payment rate transparency provisions because actual cost is unknown until the end of the provider's reporting period. As another example, FFS supplemental payment methodologies are not subject to the payment rate transparency publication provision because these methodologies often utilize variables, such as claims volume

or number of qualifying providers, for dividing up a pre-determined payment pool, and actual supplemental payment amounts are unknown until the end of the provider's (or providers') reporting period.

While a relatively simple FFS VBP payment methodology (such as the one discussed earlier in this response, with a bonus and withhold percentage added to or subtracted from a fee schedule rate based on provider performance) is considered to result in a fee schedule payment rate subject to the payment rate publication requirement, we acknowledge that some States already utilize more complex FFS VBP payment methodologies (including episodes of care²⁰⁰ and integrated care models²⁰¹) that utilize quality and cost measures to determine the provider's unique payment amount. Providers who participate in one of these complex VBP payment arrangements generally report quality and cost data to the State at the end of the provider's reporting period and then the State uses that data to determine the provider's payment amount after the provider has furnished services. Excluding complex VBP payment methodologies from the payment rate transparency publication balances burden on States to publish the required information with the ability of interested parties to understand key Medicaid payment levels so that they may raise concerns to State Medicaid agencies. If we were to require States to publish payment rates determined by complex FFS VBP payment methodologies, it would be burdensome on States, as these payment rates are unique to the provider and are determined

²⁰⁰ We consider episodes of care to be a complex VBP because the payment methodology determines the total payment by comparing the provider's cost of care for an episode to the State determined thresholds for how much the State expects a provider to spend on an episode. The provider's cost of care is an unknown variable that can be higher, the same, or lower than the State's threshold and will vary from provider to provider and episode to episode. Therefore, the unknown amount of a provider's cost of care for an episode relative to the State's threshold affects the actual payment the provider will receive for delivering a service, creating a situation where the State is unable to reasonably know a provider's payment in advance.

²⁰¹ We consider integrated care models to be a complex VBP because the payment methodologies used in these models, for example, shared savings methodologies, determine the total payment by comparing the provider's cost of care to the State determined total cost of care benchmark for how much the State expects a provider to spend. The provider's cost of care is an unknown variable that can be higher, the same, or lower than the State's threshold and will vary from provider to provider. Additionally, States can apply risk and gain-sharing arrangements that decreases or increases provider's payment rate based on their performance in meeting specific quality goals. Therefore, the unknown amount of a provider's cost of care relative to the State's total cost of care benchmark and additional decreases or increases to payment rates based on performance meeting quality goals affects the actual payment the provider will receive for delivering a service, creating a situation where the State is unable to reasonably know a provider's payment in advance.

using variables (the provider's quality performance and cost of furnishing services) that are unknown until after a provider's reporting period has ended. As these measures are generally unknown until after the provider's reporting period has ended, the State does not know a provider's payment in advance. Therefore, complex VBP payment methodologies as previously described are not fee schedule payment methodologies within the meaning of this final rule that are subject to the payment rate transparency provision.

We also recognize that an advanced payment methodology, as described in SMDL 20-004, could utilize fee schedule payments within the meaning of this final rule.²⁰² For example, a State could calculate an advanced payment of \$10,000 for a provider that is expected to furnish 1,000 services and each service is paid at a fee schedule payment rate of \$10. The advanced payment amount was originally determined by a fee schedule payment rate, which is known in advance of a provider delivering a service to a beneficiary, and therefore these rates would appear to be covered by this requirement. However, there are also features of certain advanced payment methodologies that could place them outside the scope of this requirement. For example, an advanced payment methodology that permits States to include risk adjustments and quality performance adjustments to the advanced payment amount, and/or requires the State to perform a reconciliation to the actual number of claims, could mean that the Medicaid payment amount that the provider could expect to receive could not be known in advance. At the time of publication of this final rule, there are no approved SPAs that utilize an advanced payment methodology as discussed in SMDL 20-004, so we are unable to state definitively whether any advanced payment methodology that may be used in FFS Medicaid pursuant to a future SPA would be subject to the payment rate transparency publication requirement. Without implementation experience of advanced payment methodologies, we will review future advanced payment methodologies on a case-by-case basis to determine if the methodology uses a fee schedule payment methodology within the meaning of this final rule. We encourage States that

²⁰² <https://www.medicaid.gov/sites/default/files/2020-09/smd20004.pdf>.

propose advanced payment methodology after finalization of this rule to reach out to CMS for technical assistance on determining whether advanced payment amounts are subject to the payment rate transparency publication requirements.

We interpret the commenter's reference to "manually priced items" to mean a provider payment rate that the State determines after a service or item has been delivered to a beneficiary and the provider has billed for it. For example, certain durable medical equipment items that are infrequently furnished to beneficiaries may be paid at the manufacturer's suggested retail price minus a percentage. This is described in the approved State plan, and when such an item is furnished to a beneficiary, the State must manually adjust the amount paid for the claim to equal the manufacturer's suggested retail price minus the percentage listed in the State plan, rather than pay a particular Medicaid FFS fee schedule payment rate. Because these services and items are infrequently furnished and States manually price each service and item as they are delivered to the beneficiary, we understand that it would be impractical and burdensome on States to maintain current lists of the manufacturer's suggested retail price for all potential items or services a beneficiary might require and a provider may bill for, and that States often source these items and services from multiple manufacturers. Therefore, for the purposes of the payment rate transparency publication, we consider manually priced payment methodologies that utilize the manufacturer's suggested retail price to result in a payment amount that is not known in advance of a provider delivering a service or item to a beneficiary, and thus not to be a fee schedule payment methodology subject to the payment rate transparency publication requirements.

We interpret the commenter's reference to "negotiated rates" to mean a provider payment rate where the individual provider's final payment rate is agreed upon through negotiation with the State Medicaid agency. For example, negotiated rates may be offered by a State when a particular service has very low utilization, a custom item is required (for example, certain wheelchairs), or the State does not have information needed to establish a payment rate under an

approved State plan payment methodology (for example, information from other payers, such as Medicare or the State's employee health insurance on how much they pay for the service or item) to establish a fixed payment rate. In these instances, generally, the State has not developed a rate prior to service delivery; payment for the service or item on a case-by-case-basis in the circumstances does not constitute a fee schedule payment methodology. Additionally, DSH payments and supplemental payments are not subject to the payment rate transparency publication requirement because they do not fall into the description of Medicaid FFS fee schedule payment rates for purposes of the payment rate transparency provision in § 447.203(b)(1). Finally, SDPs in Medicaid managed care delivery systems are outside the scope of § 447.203(b)(1)(i), which is specific to the FFS delivery system.

We invite States to reach out to CMS for technical assistance if they have a FFS payment rate or methodology that may not clearly align with the previous descriptions and examples of Medicaid FFS fee schedule payment rates that are subject to the payment rate transparency publication provision, and other payment methodologies that are not.

We disagree with commenters that that only requiring States to publish base payment rates would not provide a member of the public with the ability to readily determine the amount Medicaid would pay for a service. To clarify, we did not intend for the payment rate transparency publication to reflect the entire universe of payments a provider may receive. Setting the scope of the publication to Medicaid FFS fee schedule payment rates, as previously discussed in this response to commenters, balances burden on States to publish the required information with the ability of interested parties to understand key Medicaid payment levels so that they may raise concerns to State Medicaid agencies. If we were to require States to also include DSH payments and supplemental payments along with the Medicaid FFS fee schedule payment rates, it would significantly increase burden on States and might not result in the public clearly understanding the amount that any given provider could expect to receive for furnishing the service to a Medicaid beneficiary, as DSH payments and supplemental payments are

generally paid on a provider-level basis rather than a service-level basis, and not all providers of a given service will qualify for these payments.

Comment: One commenter requested clarification regarding whether payment rates paid to the direct support workforce are subject to the payment rate transparency publication requirements. Another commenter questioned if self-directed service payment rates should be published separately from agency model personal care services.

Response: We interpret the commenter's reference to "the direct support workforce" to generally mean the direct support workers or direct support professionals that provide hands-on and in-person Medicaid services to beneficiaries. To the extent a State's payment rates to direct support workforce utilize Medicaid FFS fee schedule payment rates within the meaning of this final rule, as discussed in detail in an earlier response to comments in this section, those payment rates would be subject to payment rate transparency requirements under § 447.203(b)(1).

Regarding self-directed service payment rates being separately published from agency model personal care services, we assume the commenter was referring to self-directed models with service budget and agency-provider models authorized under 42 CFR 441.545. We would like to clarify that, to the extent a State pays an agency-provider a Medicaid FFS fee schedule payment rate as discussed in detail in an earlier response to comments in this section, then those payment rates are subject to the payment rate transparency requirements in § 447.203(b)(1). Self-directed models with service budget²⁰³ are not subject to the payment rate transparency publication requirement in § 447.203(b)(1). As previously stated, payment rates that are not subject to the payment rate transparency publication requirement include those that are not known in advance of a provider delivering a service to a beneficiary. Under the self-directed model with service budget, the State only sets the beneficiary's overall service budget, and the

²⁰³ Self-directed services are paid for using an individualized budget. States are required to describe the method for calculating the dollar values of individual budgets based on reliable costs and service utilization, define a process for making adjustments to the budget when changes in participants' person-centered service plans occur, and define a procedure to evaluate participants' expenditures. <https://www.medicaid.gov/medicaid/long-term-services-supports/self-directed-services/index.html>.

beneficiary negotiates the payment rate with the direct support worker; therefore, the State is not setting the payment rate and does not know in advance what rate the direct service worker will be paid for furnishing services to the beneficiary. This does not constitute a fee schedule payment methodology for purposes of the payment rate transparency publication requirement, and as such these types of payment rates are excluded from the publication requirement. We further clarify that we do not expect States to list each beneficiary's individual self-directed service budget in the payment rate transparency publication.

Comment: One commenter expressed concern that requiring States to publish all Medicaid FFS payment rates online could have unintended consequences, such as beneficiary confusion about how much their copayment amount would be if it was included on the State's fee schedule which typically lists the amount allowed for the service, as well as State burden from increased documentation on the State's website. The commenter recommended CMS permit States to provide easily accessible links where the fee schedules are located to copayment information already available to providers and clients in a clear and concise manner.

Response: We understand commenters' concerns about the effects of the payment rate transparency publication in practice. Regarding commenters' concerns about beneficiary confusion, we want to clarify that the payment rates published under § 447.203(b)(1)(i) must be inclusive of the payment amount from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments, as discussed earlier in a response to comments this section. We encourage States, as part of transparency efforts, to include in the payment rate transparency publication a link to the page on the website where existing beneficiary cost sharing information is located so beneficiaries and other interested parties will be able to easily access this existing source of information about beneficiary cost sharing obligations. Additionally, regarding commenters' concerns about burden from increased documentation on the State's website, as documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative

payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. With the finalization of the provisions in this rule, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same). As previously stated, States also have the flexibility to utilize contractors or other third-party websites to publish the payment rate transparency publication on (however, we remind States that they are still required to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule).

Comment: One commenter requested clarification on the 1-month update requirement for the payment rate transparency requirement. The commenter stated that there are instances where SPAs are submitted with prospective effective dates or where States may face a delayed operationalization in their claims system that includes approved rate changes. The commenter noted that, in both instances under the proposed regulatory language for the payment rate transparency requirement, a State would be expected to publish rates that are not yet in effect or not currently being paid to providers. The commenter suggested revising the regulatory language to require States update rate changes in the payment rate transparency publication within 1 month of CMS approval of a SPA, the effective date of payment rate changes, or the date system changes are operationalized by a State, whichever date occurs latest. Additionally, one commenter suggested extending the requirement for updates to the payment rate transparency publication to 2 months instead of 1 month as proposed.

Response: In response to comments, we have revised the regulatory language to account for SPAs with prospective effective dates. As finalized in this rule, § 447.203(b)(1)(vi) now states, “[t]he agency is required to include the date the payment rates were last updated on the

State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment." We are adding this language as a technical change to account for States submitting SPAs with prospective effective dates as the proposed regulatory language would have required State to publish payment rates in the payment rate transparency publication that were approved, but not yet effective. We thank the commenter for pointing out this possibility, and we believe this change will ensure a State's payment rate transparency publication is as current as possible, and accurate once published.

However, we have not included regulatory language to account for system changes with a delayed operationalization date as suggested by this commenter. In accordance with §§ 430.10 and 430.20 and part 447, subpart B, States are required to pay the approved State plan payment rates in their State plan effective on or after the approved effective date. Therefore, payment of any rate outside of the approved State plan would result in a State plan compliance issue, and non-compliance is not a circumstance we would accommodate in regulations. We have also not extended the timeframe from 1 month to 2 months for States to update their payment rate transparency publications after a payment rate change. States are aware that a payment rate change is forthcoming and its requested effective date when they submit a SPA, and as such, we believe 1 month is more than sufficient to update the payment rate transparency publication. We invite States to reach out to CMS for technical guidance regarding any technological or operational limitations that may impact a State's compliance with the payment rate transparency publication requirement.

Comment: We received a few comments expressing concern about which bundled payment rates would be subject to the payment rate transparency publication as well as concern about the burden imposed on States from operational challenges to break down bundled payment

rates into constituent services and rates allocated to each constituent service in the bundle. These commenters also requested clarification on how States will be required to publish bundled payment rates in the payment rate transparency publication. Commenters requested clarification regarding the following instances where bundled payment rates are used by States: team-based services, provider-specific rates (for example, PPS rates typically paid for FQHC and RHC services or an encounter rate typically paid to clinics for clinic services (we assume commenters meant clinic services as defined in § 440.90) and CCBHC services), and per diem rates paid for facility or institutional (that is, hospital and nursing facility) services. These commenters stated that this requirement would be burdensome, operationally difficult, or not feasible because individual rates for constituent services within the bundle do not exist or bundled rates are established on a provider-specific basis using provider-specific historical cost data and inflationary adjustments. These commenters requested further clarification regarding a definition of constituent services, how States should unbundle rates and services from a bundled rate, as well as additional explanation of the value CMS believes this requirement will contribute to the Medicaid program. They encouraged CMS to explicitly exempt facility and institutional providers from the payment rate transparency publication requirements.

Response: Bundled payments are a versatile payment methodology that States can utilize within and across numerous Medicaid benefit categories. Bundled payments are generally developed using State-specific assumptions about the type, quantity, and intensity of services included in the bundle, and generally are based on the payment rates for the individual constituent services when they are furnished outside the bundled rate.

In this final rule, we clarify bundled payment rates that are subject to the requirement in the payment rate transparency publication provision that States identify how much of the bundled fee schedule payment rate is allocated to each constituent service under the State's payment methodology. In the case of a bundled payment methodology, the State must publish the Medicaid FFS bundled payment rate and, where the bundled payment rate is based on fee

schedule payment rates for each constituent service, must identify each constituent service included within the rate and how much of the bundled payment rate is allocated to each constituent service under the State's methodology.

To explain further, the bundled payment rates that are subject to this requirement are State-developed payment rates that provide a single payment rate for furnishing a bundle of services, including multiple units of service, multiple services within a single benefit category, or multiple services across multiple benefit categories. In any of these instances, multiple providers and provider types could contribute to a bundle of services, which is what we interpret the comment about team-based services to mean. Bundled payment rates that are based on fee schedule payment rates for each constituent service are subject to the requirement to identify each constituent service included within the rate and how much of the bundled payment rate is allocated to each constituent service under the State's methodology.

States can develop bundled payment rates for multiple units of a single service, for example, by setting a daily rate for up to 4 hours of personal care services a day that includes multiple 15-minute units of personal care services for which there is a fee schedule payment rate. States can also develop a bundled payment rate for multiple services within a single benefit category. For example, within the rehabilitative services Medicaid benefit, a daily rate for assertive community treatment, which can include constituent services set at fee schedule payment rates for assessments, care coordination, crisis intervention, therapy, and medication management, is considered a bundled rate. Finally, States can also develop a bundled payment rate for one or more services across multiple benefit categories. For example, a daily rate that includes constituent services set at fee schedule payment rates for up to 2 hours of personal care services, up to 2 hours of targeted case management services, and 1 hour of physical therapy services is considered a bundled rate. As all of these examples describe bundled payment rates comprised of constituent services that are based on fee schedule payment rates, they are subject to the bundled rate breakdown requirement in the payment rate transparency provision. Later in

this response, we will discuss how States are required to allocate the bundled payment rate to each constituent service under the State’s methodology.

Within a bundled payment rate, a constituent service is a Medicaid-covered service included in a bundle of multiple units of service and/or multiple services. These constituent services within the bundled payment rate must correspond to service descriptions in section 3.1-A of the State plan, which describes covered services. When initially adding a bundled payment rate to the State plan, States are required to separately list out each constituent service included in the bundle to ensure that non-covered services are not included in the bundled rate.²⁰⁴ For example, a bundle for assertive community treatment covered under the rehabilitative services State plan benefit should not include room and board, as rehabilitative services are not covered in institutional settings. Therefore, “room and board” is a non-covered service under the rehabilitative services benefit and would not be a constituent service in the bundled payment rate.

We also clarify payment rates that pay for various services and could be considered a bundled payment rate that are not subject to the requirement in the payment rate transparency publication provision. For purposes of the requirement of this final rule, this bundled payment rate breakdown requirement only applies to bundled payment rates that are based on fee schedule payment rates for each constituent service. Payment rate methodologies that do not utilize fee schedule payment rates for each constituent service to create a single State-developed bundled payment rate to pay for a combination of services, including multiple units of the same service, multiple services within a single benefit category, or multiple services across multiple benefit categories, are not subject to the bundled rate breakdown requirement in the payment rate transparency publication provision. For example, prospective payment system rates that States use to pay for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric

²⁰⁴ <https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf>.

facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are not subject to the bundled rate breakdown requirement, because these PPS rates (as previously mentioned, in the context of payment rates to hospitals and nursing facilities, the terms “encounter rate” or “per diem rate” can also be used to describe the prospective payment system rate received by these providers) do not utilize fee schedule payment rates to create a single payment rate to pay for a bundle of services. These PPS payment methodologies generally pay providers an amount derived based on a formula that accounts for the resources required to treat a patient, such as the patient’s condition (that is, illness severity or clinical diagnosis), the provider’s operating costs (that is, labor, supplies, insurance), and adjustment factors (that is, cost of living, case-mix, State determined factors), such as when an individual has an inpatient hospital stay for knee replacement surgery. While these PPS rates generally are subject to the payment rate transparency publication requirement in this final rule because they are typically known in advance of a provider delivering a service to a beneficiary, they are not subject to the breakdown requirement to the extent they do not utilize exclusively fee schedule payment rates to create a single payment rate for the bundle of services. Therefore, if we were to require States to also break down PPS rates, it would significantly increase burden on States and might not result in the public clearly understanding the amount that any given provider could expect to receive for the furnishing the services to a Medicaid beneficiary, as PPS rates are generally not determined based only on payment rates for constituent services within the meaning of this final rule. We believe a fee schedule payment rate for each constituent service is needed to enable the State to perform a straightforward and reliable allocation of the bundled payment rate to each included service. Therefore, because PPS rates are not determined based on fee schedule payment rates for each constituent service within the meaning of this final rule, States do not need to identify each constituent service included within a PPS rate and how much of the PPS rate is allocated to each constituent service under the State’s methodology. In response to the comment asking about FQHC and RHC PPS rates, please see the discussion earlier in this

section explaining why these rates are carved out of this requirement due to the statutory floor for rates and consideration of potentially undue burden on States.

Regarding whether payment rates for CCBHC services are subject to the bundled payment rate breakdown requirement, PPS rates for CCBHC demonstration services authorized under section 223 of the Protecting Access to Medicare Act of 2014 are not subject to the payment rate transparency publication requirement, including the bundled rate breakdown requirement, because these payments rates are outside of Medicaid FFS State plan authority. For CCBHC services covered and paid for under Medicaid FFS State plan authority, States that use Medicaid FFS fee schedule rates within the meaning of this rule to pay for CCBHC services must include these payment rates in the payment rate transparency provisions. Additionally, Medicaid FFS fee schedule rates that are bundled payment rates within the meaning of this rule paid to clinics (as defined in § 440.90), are subject to the bundled rate breakdown requirement.

Based on this, if a State determines a bundled payment rate is subject to the bundled payment rate breakdown requirement, we will now discuss how to allocate the bundled payment rate to each constituent service under the State's methodology. States have flexibility in determining the assumptions regarding the type, quantity, intensity, and price of the constituent services that they factor into the initial development of a bundled rate.²⁰⁵ When States establish the payment rate for a bundle, States may include the current fee schedule payment rates for the constituent services to determine the total bundled rate. For example, a State might pay a \$480 bundled rate for assertive community treatment, based on the application of a small discount factor to the fee schedule payment rates for all of the constituent services (assessments, care coordination, crisis intervention, therapy, and medication management). In this scenario, the State's fee schedule payment rates might be \$50 for an assessment, \$30 for care coordination,

²⁰⁵ For new bundled rates, CMS requests information on how States developed the rates, including: assumptions regarding the type, quantity, intensity, and price of the component services typically provided to support the economy and efficiency of the rate. <https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf>.

\$200 for crisis intervention, \$200 for 2 hours of individual therapy, and \$20 for medication management. Separately, the State would pay a total of \$500 for all of these services; however, the State might determine that a provider likely would realize efficiencies from providing the services together in a coordinated fashion, and so might reduce the bundled payment rate by 4 percent to account for these expected savings. Thus, the State's bundled payment rate would be \$480, which would be allocated as follows: $\$480 * (\$50 / \$500) = \48 for assessment; $\$480 * (\$30 / \$500) = \28.80 for care coordination; $\$480 * (\$200 / \$500) = \192 for crisis intervention; $\$480 * (\$200 / \$500) = \192 for 2 hours of individual therapy; and $\$480 * (\$20 / \$500) = \19.20 for medication management. In this example, the State would identify each of these constituent services and use these allocation amounts to meet the requirements finalized in paragraph (b)(1)(iv).

In response to commenters' request for an explanation of the value CMS believes the bundled payment rate breakdown requirement will contribute to the Medicaid program, our rationale is the same as for this payment rate publication requirement generally. Bundled rates are not inherently transparent, and in order to achieve the same goal of transparency in service of ensuring adequate access to covered care and services, it is important for interested parties to know what is covered in a bundled rate and how much of the bundle is attributable to each constituent service, which provides information relevant to whether the bundled rate is adequate in relation to its constituent services and enables comparison to how the constituent services are paid when furnished outside the bundle. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

In response to commenters' concerns that the bundled payment rate breakdown provision would be burdensome, operationally difficult, or not feasible because individual rates for constituent services within the bundle do not exist, we are providing guidance on how States are expected to address these circumstances. We acknowledge there are instances where States may have bundled payment rates that have been in place for many years, even decades, and the State currently does not have available information about how the payment rates were developed. Therefore, the State may lack historical data to perform a reasonable allocation of the bundled payment rate to constituent services. We also recognize there are instances where States utilizing bundled payment rates do not permit providers to bill for the constituent services separately. In this instance, States may no longer regularly update the fee schedule amounts for the constituent services included in the bundled payment rate because the bundle is primarily how the services are delivered and billed by providers. Therefore, the current fee schedule payment rates for the constituent services do not reflect how the State would pay for the constituent services outside of the bundle.

States have flexibility in determining how best to allocate the bundled payment rate to each constituent service in these scenarios. Should a State not have certain historical data about the bundled payment rate available, we are offering a few solutions for the State to consider. If a State can reasonably calculate missing rates, we expect them to do so for the purposes of completing the bundled payment rate allocation. For example, a State may have a bundled payment rate that includes five constituent services, which the State knows was calculated by summing the undiscounted fee schedule payment rates for each of the five constituent services. Today, the State may be unable to locate the fee schedule amount for one of the constituent services. In this instance, we would expect the State to reasonably deduce the allocated rate for the fifth constituent service by summing the four known rates for the four constituent services and subtracting that amount from the total bundled payment rate. If a State cannot calculate a missing portion of a bundled payment rate, they may use current fee schedule rates. For

example, a State may have a bundled payment rate, but it does not have historical information about how the bundled payment rate was originally calculated from the constituent services. In this instance, we would expect the State to use the current fee schedule rates for the constituent services included in the bundle to allocate the bundled payment rate for the payment rate transparency publication. Regardless of the approach States utilize to allocate the bundled payment rate to the constituent services, we expect States to include a description of how the bundled payment rate was allocated in the payment rate transparency publication to ensure that a member of the public can readily determine the amount that Medicaid would pay for the bundled service and understand how the State has accomplished a reasonable allocation of this amount to each constituent service included in the bundle, as required in § 447.203(b)(1)(iii).

In situations where the State cannot reasonably deduce how to allocate the bundled payment rate to the constituent services included in the bundle or the current fee schedule rates for the constituent services do not serve as a reasonable proxy to determine the allocation of the bundled payment rate to its constituent services, we invite States to reach out to us for technical assistance on how to comply with § 447.203(b)(1)(iv) on a case-by-case basis. We expect this guidance to provide States with relief from burden associated with allocating the bundled payment rate to constituent services when historical information is unavailable, including in certain situations raised by commenters where individual historical rates for constituent services within the bundle are no longer available. Regardless of how a State chooses to address a lack of data related to a bundled payment rate, we expect the State to update the payment rate transparency publication with an accurate allocation information following the effective date or CMS approval date of a SPA, a section 1915(c) HCBS waiver amendment, or similar amendment amending the bundled payment rate in question in accordance with § 447.203(b)(1)(vi). These processes require the State to provide information about the fee schedule payment rates for the constituent services included in the bundle, therefore making available the necessary data to perform an allocation for the payment rate transparency

publication.

We also invite States to contact CMS for technical assistance if they have a bundled payment methodology that does not clearly align with the previous descriptions and examples of bundled payment rates that are and are not subject to the bundled payment rate breakdown requirement. We also encourage States to review our existing Bundled Rate Payment Methodology resource on Medicaid.gov for more information about bundled payment methodologies.²⁰⁶

Regarding commenters' concerns about burden on States to break down institutional services bundled payment rates into constituent services in the payment rate transparency publication, we understand these concerns were primarily about operational challenges States would face if rates paid to hospitals and nursing facilities, as well as cost-based rates generally, were subject to this provision. As previously discussed in this response, PPS rates that are not determined based on fee schedule payment rates for each constituent service within the meaning of this final rule are not subject to the bundled rate breakdown requirement in § 447.203(b)(1)(iv); however, PPS rates generally are considered Medicaid FFS fee schedule payment rates in the context of this rule and are required to be published in the payment rate transparency publication under § 447.203(b)(1) as finalized in this rule. Also previously discussed in this response, PPS rates for FQHCs and RHCs are not subject to the bundled rate breakdown requirement in § 447.203(b)(1)(iv) because these payment rates are not subject to the payment rate transparency publication requirement under § 447.203(b)(1).

In this final rule, we are revising the regulatory language to make clear what bundled payment rates are subject to the constituent service allocation, or breakdown, requirement. We proposed in § 447.203(b)(1) to provide that the State must, "...in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much

²⁰⁶ <https://www.medicaid.gov/sites/default/files/state-resource-center/downloads/spa-and-1915-waiver-processing/bundled-rate-payment-methodology.pdf>.

of the bundled payment rate is allocated to each constituent service under the State's methodology.” We are finalizing § 447.203(b)(1)(iv) to state, “In the case of a bundled payment methodology, **the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must** identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State’s methodology.” (new language identified in bold). We also deleted “or similar” from “In the case of a bundled payment methodology...” because we determined that this language is unnecessary and potentially confusing; instead, in this final rule, we are clarifying specifically which bundled payment rates are subject to the requirement to identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State’s methodology.

Comment: Several commenters offered suggestions and recommendations for the proposed payment rate transparency requirements. These suggestions and recommendations include linking together FFS and managed care plan web pages for full transparency, allowing State contractors to publish the State’s payment rates, requiring the published format of the payment rates be ready for data analysis, requiring States to publish information about payment rate models and methodologies (that is, payment rate development information, potentially including cost factors and assumptions underlying a rate, such as wages, employee-related expenses, program-related expenses, and general and administrative expenses) as well as the frequency and processes for rate reviews, and requiring States publish additional granular data, particularly for dental services (for example, utilization, median payment rates, and service frequency).

Response: We appreciate commenters' suggestions and recommendations for the payment rate transparency publication requirement. While the transparency provisions in the Managed Care final rule (as published elsewhere in this **Federal Register**) and this final rule

share a similar goal, we are not incorporating the suggestion to require States to link together FFS and managed care plan web pages for full transparency because there is often no relationship between FFS Medicaid payment rates and managed care plan provider rates, as the rates are determined through different processes, subject to different Federal requirements, and States, managed care plans, and CMS assess access to care differently for FFS and managed care. Therefore, we believe that requiring States link their FFS payment rate transparency publication websites with managed care plan web pages would not provide beneficiaries, providers, CMS, and other interested parties with relevant payment information for the purposes of assessing access to care issues to better ensure compliance of FFS payment rates with section 1902(a)(30)(A) of the Act.

As discussed in an earlier response to comments in this section, we have revised the regulatory language in § 447.203(b)(1) from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. Specifically, in § 447.203(b)(1), we deleted the language requiring that the website where Medicaid fee-for-service fee schedule payment rates be published be “developed and maintained by the single State agency.” As finalized, § 447.203(b)(1) requires the State “...publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.” We continue to require that “The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency’s website.” in § 447.203(b)(1)(ii).

We are not incorporating the suggestion to require the format of the payment rate transparency publication be ready for any particular form of data analysis. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the

associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. Transparency will provide us and other interested parties with information necessary that is not currently available at all or not available in a clear and accessible format for us to ensure the payment rates for consistency with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. The payment rate transparency publication is the first step in ensuring payment rate data is transparent, then the comparative payment rate analysis is the next step in analyzing the payment rate data relative to Medicare as a benchmark. Additionally, given the requirements that the payment rate transparency publications be publicly available, clear, and accessible, we anticipate that various interested parties will be able to adapt the published information manually or through technological means so that it is suited to any analysis they wish to perform.

We are not incorporating the suggestion to require States to publish information about payment rate models and methodologies (that is, payment rate development information, potentially including cost factors and assumptions underlying a rate, such as wages, employee-related expenses, program-related expenses, and general and administrative expenses), the frequency and processes for rate reviews, or additional granular data, particularly for dental services (for example, utilization, median payment rates, and service frequency), because we want our initial focus to be on establishing the new payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. While the payment rate transparency publication does not require additional granular data outside of payment rate variations by population (pediatric and adult), provider type, and geographical location, we would like to note that utilization in the form of the number of

Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service is required to be included in the comparative payment rate analysis and payment rate disclosure; however, these requirements do not include dental services. We acknowledge that the commenters' suggestions would add relevant and beneficial context to the payment rate information required to be published by States in this final rule. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. While we are not adopting all of these suggestions and recommendations, we note that States have the flexibility to add the elements described to their payment rate transparency publications if they so choose.

We believe that there are minimal qualities that the website containing the payment rate transparency publication necessarily must include, such as being able to function quickly and as an average user would expect; requiring minimal, logical navigation steps; taking reasonable steps to provide meaningful access to individuals with limited English proficiency; and ensuring accessibility for persons with disabilities in accordance with section 504 of the Rehabilitation Act and Title II of the ADA. An example of this includes a single webpage clearly listing the names of the State's published fee schedules (such as Physician Fee Schedule, Rehabilitation Services Fee Schedule, etc.)) as links that transport the user to the relevant State fee schedule file, which file should be in a commonly accessible file format that generally can be viewed within a web browser without requiring the user to download a file for viewing in separate software. In this example, there is no unnecessary burden (including requiring payment (paywall)) creation of an account and/or password to view the webpage, or need to install additional software to view the files) on the individual to trying to view the published fee schedules. We invite States to reach out to CMS for technical guidance regarding compliance with the payment rate transparency publication requirement. We also encourage States to review the subregulatory guidance, which includes an example of what a compliant payment rate

transparency publication might look like, that we will issue prior to the effective date of this final rule.

Comment: A few commenters suggested narrowing the scope of the payment rate transparency requirement. Commenters recommended narrowing the scope by requiring publication of payment rate transparency information only about a representative subset of services, a State's most common provider types and covered services, or the same CMS-published list of E/M codes that we proposed for the comparative payment rate analysis requirement. A subset of these commenters suggested that, once States have acclimated to the requirements of payment rate transparency, then CMS could expand the requirement gradually to include all Medicaid FFS payment rates, to ease burden on States.

Response: We appreciate the commenters' suggestions on narrowing the scope of the payment rate transparency requirement; however, we are not changing the scope in this final rule. As previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. While we understand the broad scope of included rates will require some work for many States to implement, we believe the time between the effective date of this final rule and the applicability date of July 1, 2026, for the first publication of payment rate transparency information is sufficient for these requirements. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter suggested requiring States identify an additional level of payment rate variation within the population (pediatric and adult) where, within the pediatric

population, Medicaid and CHIP pay different rates, which should be disclosed separately in the payment rate transparency publication.

Response: We appreciate the commenter's suggestion; however, we are not including a requirement that States break down payment rates to include separate Medicaid and CHIP payment rate information within the pediatric population payment rate reporting. Regulations applicable to CHIP under 42 CFR part 457 and relevant guidance are beyond the scope of this rulemaking. After obtaining implementation experience with these new policies, we will consider proposing to require States to identify additional levels of payment rate variations in the Medicaid FFS payment rate transparency publication through future rulemaking.

Comment: One commenter suggested applying the payment rate transparency requirements to all Medicaid HCBS programs.

Response: To the extent a State's Medicaid HCBS program utilizes Medicaid FFS fee schedule payment rates within the meaning of this final rule, as discussed in detail earlier in this section, those payment rates would be subject to payment rate transparency publication requirements described in § 447.203(b)(1). Additionally, we are finalizing a similar provision to the Medicaid FFS fee schedule payment rate transparency requirement for HCBS direct care worker compensation elsewhere in this final rule. The HCBS Payment Adequacy and Reporting requirements in this final rule require that States report annually, in the aggregate for each service, on the percent of payments for homemaker, home health aide, personal care, and habilitation services that are spent on compensation for direct care workers, and separately report on payments for such services when they are self-directed and facility-based.

Comment: One commenter suggested collecting provider-level data on all payments, not just fee schedule payment rates, as well as the source(s) of non-Federal share for payments, to determine net Medicaid payments (total Medicaid provider payments received minus the provider's contributions to the non-Federal share through mechanisms including provider-related donations, health care-related taxes, intergovernmental transfers, and certified public

expenditures) to each provider.

Response: Existing UPL and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 of the Consolidated Appropriations Act, 2021 (CAA) (Pub L. 116-260),) already require States to submit provider-level payment data for certain services to CMS. Therefore, we are not incorporating the suggestion to collect provider-level data on all payments because this would be duplicative of existing requirements and because that is not the intention of the payment rate transparency publication requirement. While we do collect information about the non-Federal share through SPA reviews, regulatory requirements regarding collection of non-Federal share data are beyond the scope of this rulemaking.

Comment: A couple of commenters stated that dually eligible beneficiaries and their providers face unique issues when accessing and delivering Medicaid services (such as beneficiaries facing worse outcomes and having complex needs that require providers to coordinate and deliver specialized care) and requested CMS include additional provisions in the payment rate transparency publication requirements specifically for this group. One commenter suggested CMS require the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure address the experience of people who are dual-eligible and include factors related to Medicare coverage. Another commenter suggested requiring that the payment rates be disaggregated for the purposes of comparing providers serving dually eligible beneficiaries from those serving Medicare-only or Medicaid-only beneficiaries to ensure differences in access to care and payment rates are documented. The commenter also recommended the payment rate transparency publication identify when Medicaid is the primary or secondary payer in the context of a State's lesser-of payment policies (that is, for dually eligible Qualified Medicare Beneficiaries, States are obligated to pay Medicare providers for deductibles and co-insurance after Medicare has paid; however, States limit those payments to the lesser of the Medicaid rate for the service or the Medicare co-insurance amount).

Response: We appreciate the commenters' concern for and suggestions on how we might evaluate access to care for dually eligible beneficiaries. We are not incorporating the suggestion to require the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure address the experience of people who are dual-eligible and include factors related to Medicare coverage because these provisions focus on requiring States to publish and analyze quantitative data (such as, payment rates, claims volume, beneficiary counts) to assess access to care, rather than qualitative data (such as, surveys on beneficiary experience). We are also not incorporating the suggestion to identify when Medicaid is the primary or secondary payer in the context of a State's lesser-of payment policies in the payment rate transparency publication because we remain focused on the transparency of States' payment rates, rather than States' payment policies, as a method of assessing consistency with section 1902(a)(30)(A) of the Act. Additionally, we are not incorporating the suggestion to require States disaggregate their Medicaid FFS fee schedule payment rates for providers serving dually eligible beneficiaries from those serving Medicare-only or Medicaid-only beneficiaries because we want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues. We believe that payment rate breakdowns by population (pediatric and adult), provider type, and geographical location will provide a sufficient amount of transparency to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties.

Monitoring access to care is an ongoing priority of the agency and we will continue to work with States and other interested parties as we seek to expand access monitoring in the

future, including potentially through future rulemaking. However, we remain focused on maintaining a balance in Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

Comment: A couple of commenters recommended that the payment rate transparency requirements under § 447.203(b) be applied to payment rates for services delivered to beneficiaries through managed care to ensure managed care plan rates are published publicly.

Response: While we appreciate the value in transparency of provider payment rates in managed care delivery systems, regulations applicable to managed care under 42 CFR parts 438 and 457 are beyond the scope of this rulemaking.

Comment: One commenter requested CMS work with States to correct deficient payment rates once identified by the transparency requirements.

Response: To clarify, the provisions in this final rule do not require States to change their provider payment rates. The goal of the payment rate transparency publication is to ensure all States publish their Medicaid FFS fee schedule payment rates in a format that is publicly accessible and where all Medicaid FFS fee schedule payment rates can be easily located and understood.

Transparency, particularly the requirement that States must publicly publish their Medicaid FFS fee schedule payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We will utilize the information in the payment rate transparency publication during SPA reviews and other situations when States are proposing provider payment rate changes for services included in the publication and when the public process in § 447.204 is used to raise access to care issues related to possible deficient payment rates for services included in the publication.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(1) as proposed, apart from the following changes:

- Updated the organizational structure of (b)(1) to add romanettes.
- Added clarifying language to the proposed language stating what Medicaid FFS payment rates need to be published.

++ In paragraph (b)(1), the proposed language was revised from “The State agency is required to publish all Medicaid fee-for-service payment rates...” to finalize the language as “The State agency is required to publish all Medicaid fee-for-service **fee schedule** payment rates...” (new language identified in bold)

++ In paragraph (b)(1)(i), the proposed language was revised from “Published Medicaid fee-for-service payment rates include fee schedule payment rates...” to finalize the language as “**For purposes of paragraph (b)(1), the payment rates that the State agency is required to publish are** Medicaid fee-for-service payment rates...” (new language identified in bold)

- Deleted the proposed language specifying that the payment rate transparency must be developed and maintained on the State Medicaid agency’s website. The proposed language was revised from “The State agency is required to publish all Medicaid fee-for-service payment rates on a website developed and maintained by the single State agency that is accessible to the general public” to finalize the language as “The State agency is required to publish all Medicaid fee-for-service payment rates on a website that is accessible to the general public.” in paragraph (b)(1).

- Revised the proposed language about a member of the public being able to readily determine the payment amount for a service from “Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service” to finalize the language as “Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily

determine the amount that Medicaid would pay for a given service.” in paragraph (b)(1)(iii).

(new language identified in bold)

- Revised the proposed language about bundled payment rates from “...in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology” to:

- ++ Delete “or similar” from “In the case of a bundled or similar payment methodology...”

- ++ Add “the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must ...”

The language is finalized as “In the case of a bundled payment methodology, **the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must** identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State’s methodology.” in paragraph (b)(1)(iv).

(new language identified in bold)

- Revised the applicability date for this section from the proposed January 1, 2026, to require that the initial publication of the Medicaid FFS payment rates shall occur no later than July 1, 2026, and include approved Medicaid FFS payment rates in effect as of July 1, 2026, in paragraph (b)(1)(vi).

- Revised the proposed language about updating the publication after SPA approval from “The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the

provider payment rate or methodology.” to finalize the language as “The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current, where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment.” in paragraph (b)(1)(vi). (new language identified in bold)

b. Comparative Payment Rate Analysis and Payment Rate Disclosure § 447.203(b)(2) through (5)

In paragraph (b)(2), we proposed to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain specified services, and a payment rate disclosure for certain HCBS. We specified the categories of services that States would be required to include in a comparative payment rate analysis and payment rate disclosure of Medicaid payment rates. Specifically, we proposed that for each of the categories of services in paragraphs (b)(2)(i) through (iii), each State agency would be required to develop and publish a comparative payment rate analysis of Medicaid payment rates as specified in proposed § 447.203(b)(3). We also proposed that for each of the categories of services in paragraph (b)(2)(iv), each State agency would be required to develop and publish a payment rate disclosure of Medicaid payment rates as specified in proposed § 447.203(b)(3). We proposed for both the comparative payment rate analysis and payment rate disclosure that, if the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The categories of services listed in paragraph (b)(2) include: primary care services; obstetrical and gynecological services; outpatient mental health and substance use disorder services; and personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.

In paragraph (b)(2), we proposed to require States separately identify the payment rates in the comparative payment rate analysis and payment rate disclosure, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. These proposed breakdowns of the Medicaid payment rates, similar to how we proposed payment rates would be broken down in the payment rate transparency publication under proposed § 447.203(b)(1), would apply to all proposed categories of services listed in paragraph (b)(2): primary care services, obstetrical and gynecological services, outpatient mental health and substance use disorder services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

We acknowledged that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we have included language “if the rates vary” and “as applicable” in the proposed regulatory text. We included this language in the proposed regulatory text to ensure the comparative payment rate analysis and payment rate disclosure capture all Medicaid payment rates, including when States pay varied payment rates by population (pediatric and adult), provider type, and geographical location. We also included proposed regulatory text for the payment rate disclosure to ensure that the average hourly payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary, as later discussed in connection with § 447.203(b)(3)(ii). For States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location and pay a single Statewide payment rate for a single service, then the comparative payment rate analysis and payment rate disclosure would only need to include the State’s single Statewide payment rate.

We proposed to include a breakdown of Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, on the Medicaid side of the

comparative payment rate analysis in paragraph (b)(2) to align with the proposed payment rate transparency provision, to account for State Medicaid programs that pay variable Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, and to help ensure the State's comparative payment rate analyses accurately align with Medicare. Following the initial year that the proposed provisions proposed would be in effect, these provisions would align with and build on the payment rate transparency requirements described in § 447.203(b)(1), because States could source the codes and their corresponding Medicaid payment rates that the State already would publish to meet the payment rate transparency requirements.

We explained that these proposed provisions are intended to help ensure that the State's comparative payment rate analysis contains the highest level of granularity in each proposed aspect by considering and accounting for any variation in Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as previously required in the AMRP process under § 447.203(b)(1)(iv) and (v), and (b)(3). Additionally, Medicare varies payment rates for certain NPPs (nurse practitioners, physician assistants, and clinical nurse specialists) by paying them 85 percent of the full Medicare PFS amount and varies their payment rates by geographical location through calculated adjustments to the pricing amounts to reflect the variation in practice costs from one geographical location to another; therefore, we explained that the comparative payment rate analysis accounting for these payment rate variations is crucial to ensuring the Medicaid FFS payment rates accurately align with FFS Medicare PFS rates.²⁰⁷ Medicare payment variations for provider type and geographical location would be directly compared with State Medicaid payment rates that also apply the same payment variations, in addition to payment variation by population (pediatric and adult) which is unique to Medicaid, yet an important payment variation to take into consideration when striving for transparency of Medicaid payment rates. For States that do not pay varied payment rates by population

²⁰⁷ https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_Physician_FINAL_SEC.pdf.

(pediatric and adult), provider type, or geographical location and pay a single Statewide payment rate for a single service, Medicare payment variations for provider type and geographical location would be considered by calculating a Statewide average of Medicare PFS rates which is later discussed in this final rule.

Similar to the payment rate transparency publication, we acknowledged that there may be additional burden associated with our proposal that the payment rate transparency publication and the comparative payment rate analysis include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' payment rates vary based on these groupings. However, we believe that any approach to requiring a comparative payment rate analysis would involve some level of burden that is greater for States that choose to employ these payment rate differentials, since any comparison methodology would need to take account – through a separate comparison, weighted average, or other mathematically reasonable approach – of all rates paid under the Medicaid program for a given service. In all events, we believe this proposal would create an additional level of granularity in the analysis that is important for ensuring compliance with section 1902(a)(30)(A) of the Act. We noted that multiple types of providers, for example, physicians, physician assistants, and nurse practitioners, are delivering similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each State.

Section 1902(a)(30)(A) requires “...that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,” and we noted our belief that having sufficient access to a variety of provider types is important to ensuring access for Medicaid beneficiaries meets this statutory standard. For example, a targeted payment rate reduction to nurse practitioners, who are often paid less than 100 percent of the State's physician fee schedule rate, could have a negative impact on access to care for services provided by nurse practitioners,

but this reduction would not directly impact physicians or their willingness to participate in Medicaid and furnish services to beneficiaries. By proposing that the comparative payment rate analysis include a breakdown by provider type, where States distinguish payment rates for a service by provider type, we explained that the analysis would capture this payment rate variation among providers of the same services and provide us with a granular level of information to aid in determining if access to care is sufficient, particularly in cases where beneficiaries depend to a large extent on the particular provider type(s) that would be affected by the proposed rate change for the covered service(s).

We identified payment rate variation by population (pediatric and adult), provider type, and geographical location as the most commonly applied adjustments to payment rates that overlap between FFS Medicaid and Medicare and could be readily broken down into separately identified payment rates for comparison in the comparative payment rate analysis. For transparency purposes and to help to ensure the comparative payment rate analysis is conducted at a granular level of analysis, we explained our belief that it is important for the State to separately identify their rates, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. We solicited comments on the proposal to require the comparative payment rate analysis to include, if the rates vary, separate identification of payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the comparative payment rate analysis in proposed § 447.203(b)(2).

We acknowledged that States may apply additional payment adjustments or factors, for example, the Consumer Price Index, Medicare Economic Index, or State-determined inflationary factors or budget neutrality factors, to their Medicaid payment rates other than population (pediatric and adult), provider type, and geographical location. We stated that we expect any other additional payment adjustments and factors to already be included in the State's published Medicaid fee schedule rate or calculable from the State plan, because § 430.10 requires the State plan to be a "comprehensive written statement...contain[ing] all information necessary for CMS

to determine whether the plan can be approved to serve as a basis for...FFP...” Therefore, for States paying for services with a fee schedule payment rate, the Medicaid fee schedule is the sole source of information for providers to locate their final payment rate for Medicaid services provided to Medicaid beneficiaries under a FFS delivery system. For States with a rate-setting methodology where the approved State plan describes how rates are set based upon a fee schedule (for example, payment for NPPs are set a percentage of a certain published Medicaid fee schedule), the Medicaid fee schedule would again be the source of information for providers to identify the relevant starting payment rate and apply the rate-setting methodology described in the State plan to ascertain their Medicaid payment.²⁰⁸ We solicited comments on any additional types of payment adjustments or factors States make to their Medicaid payment rates as listed on their State fee schedules that should be identified in the comparative payment rate analysis that we have not already discussed in § 447.203(b)(i)(B) of this final rule, and how the inclusion of any such additional adjustments or factors should be considered in the development of the Medicare PFS rate to compare Medicaid payment rates to, as later described in § 447.203(b)(3)(i)(C), of this final rule.

In paragraphs (b)(2)(i) through (iv), we proposed that primary care services, obstetrical and gynecological services, and outpatient behavioral health services would be subject to a comparative payment rate analysis of Medicaid payment rates and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be subject to a payment rate disclosure of Medicaid payment rates. We begin with a discussion about the importance of primary care services, obstetrical and gynecological services, and outpatient behavioral health services as proposed in § 447.203(b)(2)(i) through (iii), and the reason for their inclusion in this proposed requirement. Then, we will discuss the importance and justification for including personal care, home health aide, and homemaker

²⁰⁸ <https://www.medicaid.gov/state-resource-center/downloads/spa-and-1915-waiver-processing/fed-req-pymt-methodologies.docx>.

services provided by individual providers and providers employed by an agency as proposed in § 447.203(b)(2)(iv).

In § 447.203(b)(2)(i) through (iii), we proposed to require primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services be included in the comparative payment rate analysis, because we believe that these categories of services are critical preventive, routine, and acute medical services in and of themselves, and that they often serve as gateways to access to other needed medical services, including specialist services, laboratory and x-ray services, prescription drugs, and other mandatory and optional Medicaid benefits that States cover. Including these categories of services in the comparative payment rate analysis would require States to closely examine their Medicaid FFS payment rates to comply with section 1902(a)(30)(A) of the Act. As described in the recent key findings from public comments on the February 2022 RFI that we published, payment rates are a key driver of provider participation in the Medicaid program.²⁰⁹ By proposing that States compare their Medicaid payment rates for primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services to Medicare payment rates, States would be required to analyze if and how their payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

In the proposed rule, we noted our belief that Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to a beneficiary because Medicare delivers services through a FFS delivery system across all geographical regions of the US and historically, the vast majority of physicians accept new Medicare patients, with extremely low rates of physicians opting out of

²⁰⁹ Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf>.

the Medicare program, suggesting that Medicare’s payment rates are generally consistent with a high level of physician willingness to accept new Medicare patients.²¹⁰ Additionally, Medicare payment rates are publicly published in an accessible and consistent format by CMS making Medicare payment rates an available and reliable comparison point for States, rather than private payer data which typically is considered proprietary information and not generally available to the public. Therefore, we explained that the proposed requirement that States develop and publish a comparative payment rate analysis would enable States, CMS, and other interested parties to closely examine the relationship between State Medicaid FFS payment rates and those paid by Medicare. This analysis would continually help States to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under section 1902(a)(30)(A) of the Act that payments be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted our belief that the comparative payment rate analysis would provide States, CMS, and other interested parties with clear and concise information for identifying when there is a potential access to care issue, such as Medicaid payment rates not keeping pace with changes in corresponding Medicare rates and decreases in claims volume and beneficiary utilization of services. As discussed later in this section, numerous studies have found a relationship between Medicaid payment rates and provider participation in the Medicaid program and, given the statutory standard of ensuring access for Medicaid beneficiaries, a comparison of Medicaid payment rates to other payer rates, particularly Medicare payment rates as justified later in this rule, is an important barometer of whether State payment rates and policies are sufficient for meeting the statutory access standard under section 1902(a)(30)(A) of the Act.

²¹⁰ Physicians and practitioners who do not wish to enroll in the Medicare program may “opt-out” of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. See <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits>.

We proposed to focus on these particular services because they are critical medical services and of great importance to overall beneficiary health. Beginning with primary care, these services provide access to preventative services and facilitate the development of crucial doctor-patient relationships. Primary care providers often deliver preventive health care services, including immunizations, screenings for common chronic and infectious diseases and cancers, clinical and behavioral interventions to manage chronic disease and reduce associated risks, and counseling to support healthy living and self-management of chronic diseases; Medicaid coverage of preventative health care services promotes disease prevention which is critical to helping people live longer, healthier lives.²¹¹ Accessing primary care services can often result in beneficiaries receiving referrals or recommendations to schedule an appointment with physician specialists, such as gastroenterologists or neurologists, that they would not be able to obtain without the referral or recommendation by the primary care physician. Additionally, primary care physicians provide beneficiaries with orders for laboratory and x-ray services as well as prescriptions for necessary medications that a beneficiary would not be able to access without the primary care physician. Research over the last century has shown that the impact of the doctor-patient relationship on patient's health care experience, health outcomes, and health care costs exists²¹² and more recent studies have shown that the quality of the physician-patient relationship is positively associated with functional health among patients.²¹³ Another study found that higher primary care payment rates reduced mental illness and substance use disorders among non-elderly adult Medicaid enrollees, suggesting that positive spillover from increasing primary care rates also positively impacted behavioral health outcomes.²¹⁴ Lastly, research has shown that a reduction in barriers to accessing primary care services has been associated with helping

²¹¹ <https://www.medicaid.gov/medicaid/benefits/prevention/index.html>.

²¹² Cockerham, W. C. (2021). *The Wiley Blackwell Companion to Medical Sociology* (1st ed.). John Wiley & Sons.

²¹³ Olaisen, R. H., Schluchter, M. D., Flocke, S. A., Smyth, K. A., Koroukian, S. M., & Stange, K. C. (2020). Assessing the longitudinal impact of physician-patient relationship on Functional Health. *The Annals of Family Medicine*, 18(5), 422–429. <https://doi.org/10.1370/afm.2554>.

²¹⁴ Maclean, Johanna Catherine, McCleallan, Chandler, Pesko, Michael F., and Polsky, Daniel. (2023). Medicaid reimbursement rates for primary care services and behavioral health outcomes. *Health economics*, 1-37. <https://doi.org/10.1002/hec.4646>.

reduce health disparities and the risk of poor health outcomes.^{215,216} These examples illustrate how crucial access to primary care services is for overall beneficiary health and to enable access to other medical services. We solicited comments on primary care services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i).

Similar to primary care services, both obstetrical and gynecological services and outpatient behavioral health services provide access to preventive and screening services unique to each respective field. A well-woman visit to an obstetrician–gynecologist often provides access to screenings for cervical and breast cancer; screenings for Rh(D) incompatibility, syphilis infection, and hepatitis B virus infection in pregnant persons; monitoring for healthy weight and weight gain in pregnancy; immunization against the human papillomavirus infection; and perinatal depression screenings among other recommended preventive services.^{217,218}

Behavioral health care promotes mental health, resilience, and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities. Outpatient behavioral health services can overlap with preventative primary care and obstetrical and gynecological services, for example screening for depression in adults and perinatal depression screenings, but also provide unique preventive and screening services such as screenings for unhealthy alcohol use in adolescents and adults, anxiety in children and adolescents, and eating disorders in adolescents and adults, among other recommended preventive services.²¹⁹

²¹⁵ Starfield, B., Shi, L., & Macinko, J. (2005). Contribution of primary care to health systems and health. *The Milbank quarterly*, 83(3), 457–502. <https://doi.org/10.1111/j.1468-0009.2005.00409.x>.

²¹⁶ <https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-primary-care>.

²¹⁷ Rh(D) incompatibility is a preventable pregnancy complication where a woman who is Rh negative is carrying a fetus that is Rh positive (Rh factor is a protein that can be found on the surface of red blood cells). When the blood of an Rh-positive fetus gets into the bloodstream of an Rh-negative woman, her body will recognize that the Rh-positive blood is not hers. Her body will try to destroy it by making anti-Rh antibodies. These antibodies can cross the placenta and attack the fetus's blood cells. This can lead to serious health problems, even death, for a fetus or a newborn. Prevention of Rh(D) incompatibility requires screening for Rh negative early in pregnancy (or before pregnancy) and, if needed, giving a medication to prevent antibodies from forming.

²¹⁸ <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/10/well-woman-visit>.

²¹⁹ https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P.

The US is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and outpatient behavioral health services, respectively, at the forefront.^{220,221} According to Medicaid and CHIP Payment and Access Commission (MACPAC), “Medicaid plays a key role in providing maternity-related services for pregnant women, paying for slightly less than half of all births nationally in 2018.”²²² Given Medicaid’s significant role in maternal health during a time when maternal mortality rates in the US continue to worsen and the racial disparities among mothers continues to widen,^{223,224} accessing obstetrical and gynecological care, including care before, during, and after pregnancy is crucial to positive maternal and infant outcomes.²²⁵ We solicited comments on obstetrical and gynecological services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(ii).

Improving access to behavioral health services is a critical, national issue facing all payors, particularly for Medicaid which plays a crucial role in mental health care access as the single largest payer of services and has a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to behavioral health services.^{226,227} Several studies have found an association between reducing the uninsured rate through increased Medicaid enrollment and improved and expanded access to critically needed behavioral health services.²²⁸ Numerous studies have found positive outcomes associated with Medicaid expansion: increases in the insured rate and access to care and medications for adults with depression, increases in coverage rates and a greater likelihood of being diagnosed with a mental health condition as well as the use of prescription medications for

²²⁰ <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>.

²²¹ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/>.

²²² <https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid%E2%80%99s-Role-in-Financing-Maternity-Care.pdf>.

²²³ <https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm>.

²²⁴ <https://www.nytimes.com/2022/02/23/health/maternal-deaths-pandemic.html?smid=url-share>.

²²⁵ <https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf>.

²²⁶ <https://www.medicaid.gov/medicaid/access-care/downloads/coverage-and-behavioral-health-data-spotlight.pdf>.

²²⁷ <https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html>.

²²⁸ <https://www.cbpp.org/research/health/to-improve-behavioral-health-start-by-closing-the-medicaid-coverage-gap>.

a mental health condition for college students from disadvantaged backgrounds,²²⁹ and a decrease in delayed or forgone necessary care in a nationally representative sample of non-elderly adults with serious psychological distress.²³⁰ While individuals who are covered by Medicaid have better access to behavioral health services compared to people who are uninsured, some coverage gaps remain in access to behavioral health care for many people, including those with Medicaid.

In the proposed rule, we noted that some of the barriers to accessing behavioral health treatment in Medicaid reflect larger system-wide access problems: overall shortage of behavioral health providers in the United States and relatively small number of psychiatrists who accept any form of insurance or participate in health coverage programs.²³¹ Particularly for outpatient behavioral health services for Medicaid beneficiaries, one reason physicians are unwilling to accept Medicaid patients is because of low Medicaid payment rates.²³² One study found evidence of low Medicaid payment rates by examining outpatient Medicaid claims data from 2014 in 11 States with a primary behavioral health diagnosis and an evaluation and management (E/M) procedure code of 99213 (Established patient office visit, 20-29 minutes) or 99214 (Established patient office visit, 30-39 minutes) and found that psychiatrists in nine States were paid less, on average, than primary care physicians.²³³ These pieces of research and data about the importance of outpatient behavioral health services and the existing challenges beneficiaries face in trying to access outpatient behavioral health services underscore how crucial access to outpatient behavioral health services is, and that adequate Medicaid payment rates for these services is likely to be an important driver of access for beneficiaries. We solicited comments on outpatient behavioral health services as one of the proposed categories of services subject to the

²²⁹ Cowan, Benjamin W. & Hao, Zhuang. (2021). Medicaid expansion and the mental health of college students. *Health economics*, 30(6), 1306-1327. https://www.nber.org/system/files/working_papers/w27306/w27306.pdf.

²³⁰ Novak, P., Anderson, A. C., & Chen, J. (2018). Changes in Health Insurance Coverage and Barriers to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act. *Administration and policy in mental health*, 45(6), 924-932. <https://doi.org/10.1007/s10488-018-0875-9>.

²³¹ <https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/>

²³² <https://www.healthaffairs.org/doi/10.1377/forefront.20190401.678690/full/>.

²³³ Mark, Tami L., Parish, William, Zarkin, Gary A., and Weber, Ellen (2020). Comparison of Medicaid Reimbursements for Psychiatrists and Primary Care Physicians. *Psychiatry services* 71(9), 947-950. <https://doi.org/10.1176/appi.ps.202000062>.

comparative payment rate analysis requirements in proposed § 447.203(b)(2)(iii) which we are finalizing as “Outpatient mental health and substance use disorder services.”

In § 447.203(b)(2)(iv), we proposed to require personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in the payment rate disclosure requirements proposed in § 447.203(b)(3)(ii). We noted that many HCBS providers nationwide are facing workforce shortages and high staff turnover that have been exacerbated by the COVID-19 pandemic, and these issues and related difficulty accessing HCBS can lead to higher rates of costly, institutional stays for beneficiaries.²³⁴ As with any covered service, the supply of HCBS providers has a direct and immediate impact on beneficiaries’ ability to access high quality HCBS, therefore, we included special considerations for LTSS, specifically HCBS, through two proposed provisions in § 447.203. The first provision in proposed paragraph (b)(2)(iv) would require States to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency to be included in the payment rate disclosure in proposed paragraph (b)(3)(ii). The second provision in paragraph (b)(6), discussed in the next section, would require States to establish an interested parties’ advisory committee to advise and consult on rates paid to certain HCBS providers. We explained that this provision is intended to help contextualize lived experience of direct care workers and beneficiaries who receive the services they deliver by providing direct care workers, beneficiaries and their authorized representatives, and other interested parties with the ability to make recommendations to the State Medicaid agency regarding the sufficiency of Medicaid payment rates for these specified services to help ensure sufficient provider participation so that these HCBS are accessible to beneficiaries consistent with section 1902(a)(30)(A) of the Act.

²³⁴ <https://www.kff.org/coronavirus-covid-19/event/march-30-web-event-unsung-heroes-the-crucial-role-and-tenuous-circumstances-of-home-health-aides-during-the-pandemic/>; <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

The proposed payment rate disclosure would require States to publish the average hourly payment rates made to individual providers and to providers employed by an agency, separately, if the rates vary, for each category of services specified in § 447.203(b)(2)(iv). No comparison to Medicare payment rates would be required in recognition that Medicare generally does not cover and pay for these services, and when these services are covered and paid for by Medicare, the services are very limited and provided on a short-term basis, rather than long-term basis as with Medicaid HCBS. While Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance), Medicare does not cover personal care or homemaker services.²³⁵

We proposed to require these services be subject to a payment rate disclosure because this rule aims to standardize data and monitoring across service delivery systems with the goal of improving access to care. To remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e), where we proposed to require annual State reporting on access and payment adequacy metrics for homemaker, home health aide, and personal care services, we proposed to include these services, provided by individual providers and providers employed by an agency in the FFS payment rate disclosure proposed in 447.203(b)(2). We explained that we selected these specific services because we expect them to be most commonly conducted in individuals' homes and general community settings and, therefore, constitute the vast majority of FFS payments for direct care workers delivering services under FFS. We acknowledged that the proposed analyses required of States in the HCBS provisions at § 441.311(d)(2) and (e) and in the FFS provisions at § 447.203(b)(2) are different, although, unique to assessing access in each program and delivery system. We proposed to include personal care, home health aide, and homemaker services for consistency with HCBS access and payment adequacy provisions, and also to include these services in the proposed provisions of § 447.203(b)(2) to require States to

²³⁵ <https://www.medicare.gov/coverage/home-health-services>.

conduct and publish a payment rate disclosure. We noted our belief the latter proposal is important because the payment rate disclosure of personal care, home health aide, and homemaker services would provide CMS with sufficient information, including average hourly payment rates, claims volume, and number of Medicaid enrolled beneficiaries who received a service as specified in proposed § 447.203(b)(3)(ii), from States for ensuring compliance with section 1902(a)(30)(A) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Additionally, we explained that this proposal to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency is supported by the statutory mandate at section 2402(a) of the Affordable Care Act. Among other things, section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that ensure that there is an adequate number of qualified direct care workers to provide self-directed services. We solicited comments on personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the payment rate disclosure requirements in proposed § 447.203(b)(2)(iv).

After discussing our proposed categories of services for the comparative payment rate analysis and payment rate disclosure requirements, we discussed the similarities and differences between the proposed rule and services previously included in the AMRP requirements. We explained that while the proposed rule would eliminate the previous triennial AMRP process, there are some similarities between the service categories for which we proposed to require a comparative payment rate analysis or payment rate disclosure in § 447.203(b)(2) and those subject to the previous AMRP requirements under § 447.203(b)(5)(ii). Specifically, § 447.203(b)(5)(ii)(A) previously required the State agency to use data collected through the

previous AMRP process to provide a separate analysis for each provider type and site of service for primary care services (including those provided by a physician, FQHC, clinic, or dental care). We proposed the comparative payment rate analysis include primary care services, without any parenthetical description. We explained our belief this is appropriate because the proposed rule includes a comparative payment rate analysis that is at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, the specifics for which are discussed later in this section. This approach requires States to perform less sub-categorization of the data analysis, and as discussed later, the analysis would exclude FQHCs and clinics.

We explained that the previous AMRP process also includes in § 447.203(b)(5)(ii)(C) behavioral health services (including mental health and substance use disorder); however, we proposed that the comparative payment rate analysis only would include outpatient behavioral health services to narrow the scope of the analysis by excluding inpatient behavioral health services (including inpatient behavioral health services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals). While we acknowledged that behavioral health services encompass a broad range of services provided in a wide variety of settings, from outpatient screenings in a physician's office to inpatient hospital treatment, we proposed to narrow the scope of behavioral health services to outpatient services only to focus the comparative payment rate analysis on ambulatory care provided by practitioners in an office-based setting without duplicating existing requirements, or analysis that must be completed to satisfy existing requirements, for upper payment limits (UPL) and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 of the CAA, 2021.

The proposed categories of services are delivered as ambulatory care where the patient does not need to be hospitalized to receive the service being delivered. Particularly for behavioral health services, we proposed to narrow the scope to outpatient behavioral health

services to maintain consistency within the categories of service included in the proposed comparative payment rate analysis and payment rate disclosure all being classified as ambulatory care. Additionally, as discussed further in this section of the final rule, we proposed that the comparative payment rate analysis would be conducted on a CPT/HCPCS code level, focusing on E/M codes. By narrowing the comparative payment rate analysis to E/M CPT/HCPCS codes, we proposed States' analyses includes a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii). To balance State administrative burden with our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act, we also proposed to limit the services to those delivered primarily by physicians and NPPs in an office-based setting for primary care, obstetrical and gynecological, and outpatient behavioral health services. By excluding facility-based services, particularly inpatient behavioral health services, we explained our intent to ensure the same E/M CPT/HCPCS code-level methodology could be used for all categories of services included in the proposed comparative payment rate analysis, including the use of E/M CPT/HCPCS codes used for outpatient behavioral health services. Rather than fee schedule rates, States often pay for inpatient behavioral health services using prospective payment rate methodologies, such as DRGs, or interim payment methodologies that are reconciled to actual cost.²³⁶ These methodologies pay for a variety of services delivered by multiple providers that a patient receives during an inpatient hospital stay, rather than a single ambulatory service billed by a single provider using a single CPT/HCPCS code. Variations in these payment methodologies and what is included in the rate could complicate the proposed comparison to FFS Medicare rates for the services identified in paragraphs (b)(2)(i) through (iii) and could frustrate comparisons between States and sometimes even within a single State. Therefore, we explained that we do not believe the E/M CPT/HCPCS code level methodology

²³⁶ [https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_\(DRGs\).pdf](https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf).

proposed for the comparative payment rate analysis would be feasible for inpatient behavioral health services or other inpatient and facility-based services in general.

While we considered including inpatient behavioral health services as one of the proposed categories of services in the comparative payment rate analysis, we ultimately did not because we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual UPL and supplemental payment reporting requirements under section 1903(bb) of the Act. SMDL 13-003 discusses the annual submission of State UPL demonstrations for inpatient hospital services, among other services, including a complete data set of payments to Medicaid providers and a reasonable estimate of what Medicare would have paid for the same services.^{237,238} UPL requirements go beyond the proposed requirements by requiring States to annually submit the following data for all inpatient hospital services, depending on the State's UPL methodology, on a provider level basis: Medicaid charges, Medicaid base payments, Medicaid supplemental payments, Medicaid discharges, Medicaid case mix index, Medicaid inflation factors, other adjustments to Medicaid payments, Medicaid days, Medicare costs, Medicare payments, Medicare discharges, Medicare case mix index, Medicare days, UPL inflation factors, Medicaid provider tax cost, and other adjustments to the UPL amount. If we proposed and finalized inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis, then this final rule would require States to biennially submit the following data for only inpatient behavioral health services on a CPT/HCPCS code level basis: base Medicaid FFS fee schedule payment rate for select E/M CPT/HCPCS codes (accounting for rate variation based on population (pediatric and adult), provider type, and geographical location, as applicable), the corresponding Medicare payment rates, Medicaid base payment rate as a percentage of Medicare payment rate, and the number of Medicaid-paid claims. While the UPL requires aggregated total payment and cost

²³⁷ <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf>.

²³⁸ If a State's payment methodology describes payment at no more than 100 percent of the Medicare rate for the period covered by the UPL, then the State does not need to submit a demonstration. See FAQ ID: 92201.
https://www.medicaid.gov/faq/index.html?search_api_fulltext=ID%3A92201&sort_by=field_faq_date&sort_order=DESC.

data at the provider level and the proposed comparative payment rate analysis calls for more granular base payment data at the CPT/HCPCS code level, the UPL overall requires aggregate Medicaid provider payment data for both base and supplemental payments as well as more detailed data for calculating what Medicare would have paid as the upper payment amount. Therefore, we explained that proposing to require States include Medicaid and Medicare payment rate data for inpatient behavioral health services in the comparative payment rate analysis would be duplicative of existing UPL requirements that are inclusive of and more comprehensive than the payment information proposed in the comparative payment rate analysis.

Additionally, section 1903(bb) of the Act requires us to establish a Medicaid supplemental payment reporting system that collects detailed information on State Medicaid supplemental payments, including total quarterly supplemental payment expenditures per provider; information on base payments made to providers that have received a supplemental payment; and narrative information describing the methodology used to calculate a provider's payment, criteria used to determine which providers qualify to receive a payment, and explanation describing how the supplemental payments comply with section 1902(a)(30)(A) of the Act. Section 1903(bb)(1)(C) of the Act requires us to make State-reported supplemental payment information publicly available. For States making or wishing to make supplemental payments, including for inpatient behavioral health services, States must report supplemental payment information to us, and we must make that information public and, therefore, transparent. Although the proposed rule sought to increase transparency, with the proposed provisions under § 447.203(b)(1) through (5) focusing on transparency of FFS base Medicaid FFS fee schedule payment rate, including inpatient behavioral health services as a category of service in § 447.203(b)(2) subject to the comparative payment rate analysis would be duplicative of the existing upper payment limit and supplemental payment reporting requirements, which capture and make transparent base and supplemental payment information for inpatient behavioral health services. However, we solicited comments regarding our decision not to

include inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2) in the final rule, should we finalize the comparative payment rate analysis proposal.

The AMRP process also previously included in § 447.203(b)(5)(ii)(D) pre- and post-natal obstetric services including labor and delivery; we proposed to include these services in the comparative payment rate analysis requirements under proposed § 447.203(b)(2)(ii), but we explained in the proposed rule that we intended to broaden the scope of this category of services to include both obstetrical and gynecological services. This expanded proposed provision would capture a wider array of services, both obstetrical and gynecological services, for States and CMS to assess and ensure access to care in Medicaid FFS is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required by with section 1902(a)(30)(A) of the Act. Lastly, similar to previous § 447.203(b)(5)(ii)(E), which specifies that home health services were included in the previous AMRP process, we proposed to include personal care, home health aide, and homemaker services, provided by individual providers and providers employed by an agency. This refined proposed provision would help ensure a more standardized effort to monitor access across Medicaid delivery systems, including for Medicaid-covered LTSS. We explained our belief that this proposal also would address public comments received in response to the February 2022 RFI.²³⁹ Many commenters highlighted the workforce crisis among direct care workers and the impact on HCBS. Specifically, commenters indicated that direct care workers receive low payment rates, and for agency-employed direct care workers, home health agencies often cite low Medicaid payment as a barrier to raising wages for workers. Commenters suggested that States should be collecting and reporting to CMS the average of direct care worker wages while emphasizing the importance of data transparency and timeliness. We explained that we were responding to these public

²³⁹ Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf>.

comments by proposing to require States to transparently publish a payment rate disclosure that collects and reports the average hourly rate paid to individual providers and providers employed by an agency for services provided by certain direct care workers (personal care, home health aide, and homemaker services).

In public comments that we received during the public comment period for the 2015 final rule with comment period, many commenters requested that we require States to publish access to care analyses for pediatric services, including pediatric primary care, behavioral health, and dental care. At the time, we responded that pediatric services did not need to be specified in the required service categories because States were already required through § 447.203(b)(1)(iv) to consider the characteristics of the beneficiary population, “including . . . payment variations for pediatric and adult populations,” within the previous AMRPs.²⁴⁰ Although we proposed to eliminate the previous AMRP requirements, we noted that the proposed rule would continue to include special considerations for pediatric populations that are addressed in the discussion of proposed § 447.203(b)(2).

We proposed to eliminate the following from the previous AMRP process without replacement in the comparative payment rate analysis requirement, § 447.203(b)(5)(ii)(F): Any additional types of services for which a review is required under previous § 447.203(b)(6); § 447.203(b)(5)(ii)(G): Additional types of services for which the State or CMS has received a significantly higher than usual volume of beneficiary, provider or other interested party access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with previous § 447.203(b)(7); and § 447.203(b)(5)(ii)(H): Additional types of services selected by the State.

We proposed to eliminate § 447.203(b)(5)(ii)(F) and (G) without a direct replacement because the proposed State Analysis Procedures for Rate Reduction or Restructuring described in § 447.203(c) are inclusive of and more refined than the previous AMRP requirements for

²⁴⁰ 80 CFR 67576 at 67592.

additional types of services for which a review is required under previous § 447.203(b)(6). Specifically, as discussed later in this section, we proposed in § 447.203(c)(1) that States seeking to reduce provider payment rates or restructure provider payments would be required to provide written assurance and relevant supporting documentation that three conditions are met to qualify for a streamlined SPA review process, including that required public processes yielded no significant access to care concerns for beneficiaries, providers, or other interested parties, or if such processes did yield concerns, that the State can reasonably respond to or mitigate them, as appropriate. If the State is unable to meet all three of the proposed conditions for streamlined SPA review, including the absence of or ability to appropriately address any access concern raised through public processes, then the State would be required to submit additional information to support that its SPA is consistent with the access requirement in section 1902(a)(30)(A) of the Act, as proposed in § 447.203(c)(2). We proposed to modify this aspect of the previous AMRP process, because our implementation experience since the 2017 SMDL has shown that States typically have been able to work directly with the public (including beneficiaries and beneficiary advocacy groups, and providers) to resolve access concerns, which emphasizes that public feedback continues to be a valuable source of knowledge regarding access in Medicaid. We explained our belief that this experience demonstrates that public processes that occur before the submission of a payment SPA to CMS often resolve initial access concerns, and where concerns persist, they will be addressed through the SPA submission and our review process, as provided in proposed § 447.203(c). Rather than services affected by proposed provider rate reductions or restructurings (previous § 447.203(b)(5)(ii)(F)) and services for which the State or CMS received significantly higher than usual volume of complaints (previous § 447.203(b)(5)(ii)(G)) being addressed through the previous AMRP process, these services subject to rate reductions or restructurings and services where a high volume of complaints have been expressed would now be addressed by the State analysis procedures in proposed § 447.203(c). We noted our belief that this approach would ensure public feedback is

fully considered in the context of a payment SPA, without the need to specifically require a comparative payment rate analysis for the service(s) subject to payment rate reduction or restructuring under proposed § 447.203(b)(2).

Lastly, we proposed to eliminate previous § 447.203(b)(5)(ii)(H), requiring the previous AMRP process to include analysis regarding “Additional types of services selected by the State,” without a direct replacement because our implementation experience has shown that the majority of States did not select additional types of service to include in their previous AMRPs beyond the required services § 447.203(b)(5)(ii)(A) through (G). When assessing which services to include in the proposed rule, we determined that the absence of an open-ended type of service option, similar to § 447.203(b)(5)(ii)(H) is unlikely to affect the quality of the analysis we proposed to require and therefore, we did not include it in the proposed set of services for the comparative payment rate analysis. These proposed shifts in policy were informed by our implementation experience and our consideration of State concerns about the burden and value of the previous AMRP process.

In paragraph (b)(3), we proposed that the State agency would be required to develop and publish, consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data, a comparative payment rate analysis and payment rate disclosure. This comparative payment rate analysis is divided into two sections based on the categories of services and the organization of each analysis or disclosure. Paragraph (b)(3)(i) describes the comparative payment rate analysis for the categories of services described in paragraphs (b)(2)(i) through (iii): primary care services, obstetrical and gynecological services, and outpatient behavioral health services. Paragraph (b)(3)(ii) describes the payment rate disclosure for the categories of service described in paragraphs (b)(2)(iv): personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

Specifically, in paragraph (b)(3)(i), we proposed that for the categories of service described in paragraphs (b)(2)(i) through (iii), the State's analysis would compare the State's Medicaid FFS payment rates to the most recently published Medicare payment rates effective for the same time period for the E/M CPT/HCPCS codes applicable to the category of service. The proposed comparative payment rate analysis of FFS Medicaid payment rates to FFS Medicare payment rates would be conducted on a code-by-code basis at the CPT/HCPCS code level using the most current set of codes published by us. We explained that this proposal is intended to provide an understanding of how Medicaid payment rates compare to the payment rates established and updated under the FFS Medicare program.

We stated that we would expect to publish the E/M CPT/HCPCS codes to be used for the comparative payment rate analysis in subregulatory guidance along with the final rule, if this proposal is finalized. We proposed that we would identify E/M CPT/HCPCS codes to be included in the comparative payment rate analysis based on the following criteria: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount for the same time period of the comparative payment rate analysis.^{241,242,243}

²⁴¹ <https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management>.

²⁴² <https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-system>.

²⁴³ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched>.

The CMS-published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis would classify each E/M CPT/HCPCS code into a corresponding category of service as described in proposed § 447.203(b)(2)(i) through (iii). As previously discussed, by narrowing the comparative payment rate analysis to CMS-specified E/M CPT/HCPCS codes, we proposed States' analyses include a broad range of core services that would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii), while also limiting the services to those delivered primarily by physicians and NPPs in an office-based setting. Based on the categories of services specified in proposed § 447.203(b)(2)(i) through (iii), we stated that we would expect the selected E/M CPT/HCPCS codes to fall under mandatory Medicaid benefit categories, and therefore, that all States would cover and pay for the selected E/M CPT/HCPCS codes. To clarify, we did not narrow the list of E/M CPT/HCPCS codes on the basis of Medicare coverage of a particular code. We are cognizant that codes with N (Non-Covered), R (Restricted), or T code statuses have limited or no Medicare coverage; however, Medicare may establish RVUs, and payment amounts for these codes. Therefore, when Medicare does establish RVUs and payment amounts for codes with N (Non-Covered), R (Restricted), or T (Injections) code statuses on the Medicare PFS, we proposed to include these codes in the comparative payment rate analysis to ensure the analysis includes a comprehensive set of codes, for example pediatric services, including well child visits (for example, 99381 through 99384), that are commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii) and delivered primarily by physicians and NPPs in an office-based setting, as previously described.

We proposed that the comparative payment rate analysis would be updated no less than every 2 years. Therefore, prior to the start of the calendar year in which States would be required to update their comparative payment rate analysis, we noted our intent to publish an updated list of E/M CPT/HCPCS codes for States to use for their comparative payment rate analysis updates through subregulatory guidance. The updated list of E/M CPT/HCPCS codes would include

changes made by the AMA CPT Editorial Panel (such as additions, removals, or amendments to a code definition where there is a change in the set of codes classified as an E/M CPT/HCPCS code billable for primary care services, obstetrics and gynecological services, or outpatient behavioral services) and changes to the Medicare PFS based on the most recent Medicare PFS final rule (such as changes in code status or creation of Medicare-specific codes).²⁴⁴

We explained that we would intend to publish the initial and subsequent updates of the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. We may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes. In this instance, for codes included on our published list of E/M CPT/HCPCS codes that are affected by a correction to the most recent Medicaid PFS final rule, we may add or remove an E/M CPT/HCPCS code from the published list, as appropriate, depending on the change to the Medicare PFS. Alternatively, depending on the nature of the change, we stated that we would expect States to accurately identify which code(s) are used in the Medicaid program during the relevant period that best correspond to the CMS-identified E/M CPT/HCPCS code(s) affected by the Medicare PFS correction. We would expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the proposed requirements in paragraphs (b)(2) through (4).

We acknowledged that there are limitations to relying on E/M CPT/HCPCS codes to select payment rates for comparative payment rate analysis to aid States, CMS, and other interested parties in assessing if payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the

²⁴⁴ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices>.

geographic area. Providers across the country and within each State deliver a variety of services to patients, including individuals with public and private sources of coverage, and then bill them under a narrow subset of CPT/HCPCS codes that fit into the E/M classification as determined by the AMA CPT Editorial Panel. The actual services delivered can require a wide array of time, skills, and experience of the provider which must be represented by a single five-digit code for billing to receive payment for the services delivered. While there are general principles that guide providers in billing the most representative E/M CPT/HCPCS code for the service they delivered, two providers might perform substantially similar activities when delivering services and yet bill different E/M CPT/HCPCS codes for those activities, or bill the same E/M CPT/HCPCS code for furnishing two very different services. The E/M CPT/HCPCS code itself is not a tool for capturing the exact service that was delivered, but medical documentation helps support the billing of a particular E/M CPT/HCPCS code.

Although they do not encompass all Medicaid services covered and paid for in the Medicaid program which are subject to the requirements in section 1902(a)(30)(A) of the Act, E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. As such, to balance administrative burden on States and our enforcement responsibilities, we proposed to use E/M CPT/HCPCS codes in the comparative payment rate analysis to limit the analysis to how much Medicaid and the FFS Medicare program would pay for services that can be classified into a particular E/M CPT/HCPCS code. We solicited comments on the proposed comparative payment rate analysis requirement in § 447.203(b)(3)(i), including the proposed requirement to conduct the analysis at the CPT/HCPCS code level, the proposed criteria that we would apply in selecting E/M CPT/HCPCS codes for inclusion in the required analysis, and the proposed requirement for States to compare Medicaid payment rates for the selected E/M CPT/HCPCS codes to the most recently published Medicare non-facility payment rate as established in the annual Medicare PFS

final rule effective for the same time period, which is discussed in more detail later in this rule when describing the proposed provisions of § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i), we further proposed that the State's comparative payment rate analysis would be required to meet the following requirements: (A) the analysis must be organized by category of service as described in § 447.203(b)(2)(i) through (iii); (B) the analysis must clearly identify the base Medicaid FFS fee schedule payment rate for each E/M CPT/HCPCS code identified by us under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable; (C) the analysis must clearly identify the Medicare PFS non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid FFS fee schedule payment rate, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B); (D) the analysis must specify the Medicaid payment rate identified under paragraph (b)(3)(i)(B) as a percentage of the Medicare payment rate identified under paragraph (b)(3)(i)(C) for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B); and (E) the analysis must specify the number of Medicaid-paid claims within a calendar year for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B). We solicited comments on the proposed requirements and content of the items in proposed § 447.203(b)(3)(i)(A) through (E).

In paragraph (b)(3)(i)(A), we proposed to require States to organize their comparative payment rate analysis by the service categories described in paragraphs (b)(2)(i) through (iii). We explained that this proposed requirement is included to ensure the analysis breaks out the payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services separately for individual analyses of the payment rates for each CMS-selected E/M CPT/HCPCS code, grouped by category of service. We solicited comments on the proposed requirement for States to break out their payment rates at the CPT/HCPCS code

level for primary care services, obstetrical and gynecological services, and outpatient behavioral health services, separately, in the comparative payment rate analysis as specified in proposed § 447.203(b)(3)(i)(A).

In paragraph (b)(3)(i)(B), after organizing the analysis by § 447.203(b)(2)(i) through (iii) categories of service and CMS-specified E/M CPT/HCPCS code, we proposed to require States to clearly identify the Medicaid base payment rate for each code, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. We proposed that the Medicaid base payment rate in the comparative payment rate analysis would only include the State's Medicaid fee schedule rate, that is, the State's Medicaid base rate for each E/M CPT/HCPCS code. By specifying the services included in the comparative payment rate analysis by E/M CPT/HCPCS code, we noted that we would expect the Medicaid base payment rate in the comparative payment rate analysis to only include the State's Medicaid fee schedule rate for that particular E/M CPT/HCPCS code as published on the State's Medicaid fee schedule effective for the same time period covered by the comparative payment rate analysis. As an example, the State's Medicaid fee schedule rate as published on the Medicaid fee schedule effective for the time period of the comparative payment rate analysis for 99202 is listed as \$50.00. This rate would be the Medicaid base payment rate in the State's comparative payment rate analysis for comparison to the Medicare non-facility rate, which is discussed later in this section.

Medicaid base payment rates are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.²⁴⁵ The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is also based on RBRVS, but select a fixed percentage of

²⁴⁵ <https://www.macpac.gov/wp-content/uploads/2017/02/Medicaid-Physician-Fee-for-Service-Payment-Policy.pdf>.

the Medicare amount to pay for Medicaid services. States can develop their own PFSs, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. States often adjust their payment rates based on provider type, geography, site of services, patient age, and in-State or out-of-State provider status. Additionally, base Medicaid FFS fee schedule payment rate can be paid to physicians in a variety of settings, including clinics, community health centers, and private offices.

We acknowledged that only including Medicaid base payments in the analysis does not necessarily represent all of a provider's revenues that may be related to furnishing services to Medicaid beneficiaries, and that other revenues not included in the proposed comparative analysis may be relevant to a provider's willingness to participate in Medicaid (such as beneficiary cost sharing payments, and supplemental payments). We discussed that public comments we received on the 2011 proposed rule and responded to in the 2015 final rule with comment period regarding the previous AMRPs expressed differing views regarding which provider "revenues" should be included within comparisons of Medicaid to Medicare payment rates. One commenter "noted that the preamble of the 2011 proposed rule refers to 'payments' and 'rates' interchangeably but that courts have defined payments to include all Medicaid provider revenues rather than only Medicaid FFS rates." The commenter stated that if the final rule consider[ed] all Medicaid revenues received by providers, States may be challenged to make any change to the Medicaid program that might reduce provider revenues."²⁴⁶ We proposed to narrow the base Medicaid FFS fee schedule payment rate to the amount listed on the State's fee schedule in order for the comparative payment rate analysis to accurately and analogously compare Medicaid fee schedule rates to Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year.

²⁴⁶ 80 FR 67576 at 67581.

We explained our belief that this approach would represent the best way to create a consistent metric across States against which to evaluate access. Specifically, we did not propose to include supplemental payments in the comparative payment rate analysis. Requiring supplemental payment data be collected and included under this rule would be duplicative of existing requirements. State supplemental payment and DSH payment data are already subject to our review in various forms, such as through DSH audits for DSH payments, and through annual upper payment limits demonstrations, and through supplemental payment reporting under section 1903(bb) of the Act.^{247,248} As such, we explained that we do not see a need to add additional reporting requirements concerning supplemental payments as part of the proposals in this rulemaking to allow us the opportunity to review the data. Also, supplemental payments are often made for specific Medicaid-covered services and targeted to a subset of Medicaid-participating providers; not all Medicaid-participating providers, and not all providers of a given Medicaid-covered service, may receive supplemental payments in a State. Therefore, including supplemental payments in the comparative payment rate analysis would create additional burden for States without then also providing an accurate benchmark of how payments may affect beneficiary access due to the potentially varied and uneven distribution of supplemental payments. Accordingly, we proposed to require that States conduct the comparative payment rate analysis for only Medicaid base payment rates for selected E/M CPT/HCPCS codes. For each proposed category of service listed in paragraphs (b)(2)(i) through (iii), this would result in a transparent and parallel comparison of Medicaid base payment rates that all Medicaid-participating providers of the service would receive to the payment rates that Medicare would pay for the same E/M CPT/HCPCS codes.

²⁴⁷ CMS State Medicaid Director Letter: SMDL 13-003. March 2013. Federal and State Oversight of Medicaid Expenditures. Available at <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf>.

²⁴⁸ CMS State Medicaid Director Letter: SMDL 21-006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf>.

Additionally, in paragraph (b)(3)(i)(B), we proposed that, if the States' payment rates vary, the Medicaid base payment rates must include a breakdown by payment rates paid to providers delivering services to pediatric and adult populations, by provider type, and geographical location, as applicable, to capture this potential variation in the State's payment rates. This proposed provision to breakdown the Medicaid payment rate is first stated in proposed paragraph (b)(2) and carried through in proposed paragraph (b)(3)(i)(B) to provide clarity to States about how the Medicaid payment rate should be reported in the comparative payment rate analysis.

In paragraph (b)(3)(i)(C), we proposed to require States' comparative payment rate analysis clearly identify the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B), including separate identification of the payment rates by provider type. We did not propose to establish a threshold percentage of Medicare non-facility payment rates that States would be required to meet when setting their Medicaid payment rates. Rather, we proposed to use Medicare non-facility payment rates as established in the Medicare PFS final rule for a calendar year as a benchmark to which States would compare their Medicaid payment rates to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. We explained that benchmarking against FFS Medicare, another of the nation's large public health coverage programs, serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. Similar to Medicaid, Medicare provides health coverage for a significant number of Americans across the

country. In December 2023, total Medicaid enrollment was at 77.9 million individuals²⁴⁹ while total Medicare enrollment was at 66.8 million individuals.^{250,251} Both the Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States. As previously described, Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for covered, non-covered, and limited coverage services generally are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. Medicare also ensures that their payment rate data are publicly available in a format that can be analyzed. The accessibility and consistency of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, compared to negotiated private health insurance payment rates that typically are considered proprietary information and, therefore, not generally available to the public, makes Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.

Additionally, Medicare is widely accepted nationwide according to recent findings from the National Electronic Health Records Survey. In 2019, 95 percent of physicians accepting new patients overall, and 89 percent of office-based physicians, were accepting new Medicare patients, and the percentage of office-based physicians accepting new Medicare patients has remained stable since 2011 when the value was 88 percent, with modest fluctuations in the years in between.²⁵² In regards to physician specialties that align with the categories of services in this

²⁴⁹ <https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf>.

²⁵⁰ Total Medicare enrollment equals the Tot_Benes variable in the Medicare Monthly Enrollment Data for December (Month) 2023 (Year) at the national level (Bene_Geo_Lvl). Tot_Benes is a count of all Medicare beneficiaries, including beneficiaries with Original Medicare and beneficiaries with Medicare Advantage and Other Health Plans. We utilized the count of all Medicare beneficiaries because Original Medicare, Medicare Advantage, and other Health Plans offer fee-for-service payments to providers. See the Medicare Monthly Enrollment Data Dictionary for more information about the variables in the Medicare Monthly Enrollment Data: https://data.cms.gov/sites/default/files/2023-02/1ec24f76-9964-4d00-9e9a-78bd556b7223/Medicare%20Monthly%20Enrollment_Data_Dictionary%2020230131_508.pdf.

²⁵¹ <https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment>.

²⁵² <https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/>.

rule, 81 percent of general practice/family medicine physicians and 81 percent of physicians specializing in internal medicine were accepting new Medicare patients, 93 percent of physicians specializing obstetrics and gynecology were accepting new Medicare patients, and 60 percent of psychiatrists were accepting new Medicare patients in 2019. Although the percentage of psychiatrists who accept Medicare is lower than other types of physicians providing services included in the comparative payment rate analysis, this circumstance is not unique to Medicare amongst payers. For example, 60 percent of psychiatrists were also accepting new privately insured patients in 2019.²⁵³ Therefore, the decreased rate of acceptance by psychiatrists relative to certain other physician specialists does not make Medicare an inappropriate benchmark when evaluated against other options for comparison.²⁵⁴

Historically, Medicare has low rates of physicians formally opting out of the Medicare program with 1 percent of physicians consistently opting out between 2013 and 2019 and of that 1 percent of physicians opting out of Medicare, 42 percent were psychiatrists.²⁵⁵ This information suggests that Medicare's payment rates generally are consistent with a high level of physician willingness to accept new Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. For the reasons previously described, we proposed to use Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a national benchmark for States to compare their Medicaid payment rates in the comparative payment rate analysis because we believe that the Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. We solicited comments on the proposed use of Medicare non-facility payment rates as established in the annual Medicare PFS

²⁵³ <https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/>.

²⁵⁴ <https://www.kff.org/medicare/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/>.

²⁵⁵ Physicians and practitioners who do not wish to enroll in the Medicare program may "opt-out" of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states that neither one can receive payment from Medicare for the services that were performed. See 2022 opt-out affidavit data published by the Centers for Medicare & Medicaid services: <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits>.

final rule for a calendar year as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

In paragraph (b)(3)(i)(C), we proposed to require States to compare their Medicaid payment rates to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period as the same set of E/M CPT/HCPCS codes paid under Medicaid as specified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type. We proposed to require States to compare their payment rates to the corresponding Medicare PFS non-facility rates because we are seeking a payment analysis that compares Medicaid payment rates to Medicare payment rates at comparable location of service delivery (that is, in a non-clinic, non-hospital, ambulatory setting such as a physician's office). States often pay physicians operating in an office based on their Medicaid fee schedule whereas they may pay physicians operating in hospitals or clinics using an encounter rate. The Medicaid fee schedule rate typically reflects payment for an individual service that was rendered, for example, an office visit that is billed as a single CPT/HCPCS code. An encounter rate often reflects reimbursement for total facility-specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter. For example, the same encounter rate may be paid for a beneficiary who has an office visit with a physician, a dental examination and cleaning from a dentist, and laboratory tests and for a beneficiary who receives an office visit with a physician and x-rays. Encounter rates are typically paid to facilities, such as hospitals, FQHCs, RHCs, or clinics, many of which function as safety net providers that offer a wide variety of medical

services. Within the Medicaid program, encounter rates can vary widely in the rate itself and services paid for through the encounter rate. We explained that States demonstrating the economy and efficiency of their encounter rates would be an entirely different exercise to the fee schedule rate comparison proposed in this rule because encounter rates are often based on costs unique to the provider, and States often require providers to submit cost reports to States for review to support payment of the encounter rate. Comparing cost between the Medicaid and Medicare program would require a different methodology, policies, and oversight than the comparative payment rate analysis requirement that we proposed due to the differences within and between each program. While the Medicare program has a broad, national policy for calculating encounter rates for providers, including prospective payment systems for hospitals, FQHCs, and other types of facilities, Medicare calculates these encounter rates differently than States may calculate analogous rates in Medicaid. Therefore, we explained that disaggregating each of their encounter rates and services covered in each encounter rate to compare to Medicare's encounter rates would be challenging for States.

From that logic, we likewise determined that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year would afford the best point of comparison because it is the most accurate and most analogous comparison of a service-based access analysis using Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis, as opposed to an encounter rate which could include any number of services or specialties. The Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year is described as "... the fee schedule amount when a physician performs a procedure in a non-facility setting such as the office" and "[g]enerally, Medicare gives higher payments to physicians and other health care professionals for procedures performed in their offices [compared to those performed elsewhere] because they must supply

clinical staff, supplies, and equipment.”²⁵⁶ As such, we stated our belief that the Medicaid fee schedule best represents the payment intended to pay physicians and non-physician practitioners for delivery of individual services in an office (non-facility) setting, and the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year represents the best equivalent to that amount and consideration.

For the purposes of the comparative payment rate analysis, we explained in the proposed rule that we would expect States to source the Medicare non-facility payment rate from the published Medicare fee schedule amounts that are established in the annual Medicare PFS final rule through one or both of the following sources: the Physician Fee Schedule Look-Up Tool²⁵⁷ on cms.gov or Excel file downloads of the Medicare PFS Relative Value with Conversion Factor files²⁵⁸ for the relevant calendar year from cms.gov. We acknowledge that the Physician Fee Schedule Look-Up Tool is a display tool that functions as a helpful aid for physicians and NPPs as a way to quickly look up PFS payment rates, but does not provide official payment rate information. While we encouraged States to begin sourcing Medicare non-facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee Schedule Guide for instructions on using the Look-Up Tool in the proposed rule, we would like to clarify in this final rule that States should first download and review the Medicare PFS Relative Value with Conversion Factor File where States can find the necessary information for calculating Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. With the publication of this final rule, we have also issued subregulatory guidance, which includes an instructional guide for identifying, downloading, and using the relevant Excel files for calculating the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States will need to include in their comparative payment rate analysis.

²⁵⁶ <https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf>.

²⁵⁷ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup>.

²⁵⁸ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files>.

Statutory provisions at section 1848 of the Act and regulatory provisions at 42 CFR 414.20²⁵⁹ require that most physician services provided in Medicare are paid under the Medicare PFS. The fee schedule amounts are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT) using resource-based inputs to establish relative value units (RVUs) in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average.^{260, 261}

For many services, the Medicare PFS also includes separate fee schedule amounts based on the site of service (non-facility versus facility setting). The applicable PFS the rate for a service, facility or non-facility, is based on the setting where the beneficiary received the face-to-face encounter with the billing practitioner, which is indicated on the claim form by a place of service (POS) code. We proposed States use the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year in the comparative payment rate analysis. We directed States to the Excel file downloads of the “PFS Relative Value Files” which include the RVUs, GPCIs, and the “National Physician Fee Schedule Relative Value File Calendar Year 2023” file which contains the associated relative value units (RVUs), a fee schedule status indicator, and various payment policy indicators needed for payment adjustment (for example, payment of assistant at surgery, team surgery, or bilateral surgery). We stated that we would expect States to use the formula for the Non-Facility Pricing Amount in “National Physician Fee Schedule Relative Value File Calendar Year 2023” file to calculate the “Non-Facility Price” using the RVUs, GPCIs, and conversion factors for codes not available in the Look-Up Tool.

²⁵⁹ The Medicare Claims Processing Manual contains additional information about physician service payments in Medicare that are based on the cited statutory and regulatory requirements. <https://www.cms.gov/regulations-and-guidance/manuals/internet-only-manuals-ioms-items/cms018912>.

²⁶⁰ <https://www.cms.gov/regulations-and-guidance/manuals/downloads/clm104c12.pdf>.

²⁶¹ <https://www.cms.gov/medicare/physician-fee-schedule/search/overview>.

We explained that Medicaid FFS fee-schedule payment rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as “the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.” Therefore, the State’s Medicaid base payment rates used for comparison should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to align with the inclusion of expected beneficiary cost sharing in Medicare’s non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year.²⁶²

In paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule must be effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the base Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B). We included this language to ensure the comparative payment rate analysis is as accurate and analogous as possible by proposing that the Medicaid and Medicare payment rates that are effective during the same time period for the same set of E/M CPT/HCPCS codes. As later described in this rule, in paragraph (b)(4), we proposed the initial comparative payment rate analysis and payment rate disclosure of Medicaid payment rates would be a retroactive analysis of payment rates that are in effect as of January 1, 2025, with the analysis and disclosure published no later than January 1, 2026. For example, the first comparative payment rate analysis a State develops and publishes would compare base Medicaid FFS fee schedule payment rate in effect as of January 1, 2025, to the Medicare non-facility

²⁶² According to the Medicare Physician Fee Schedule Guide, for most codes, Medicare pays 80% of the amount listed and the beneficiary is responsible for 20 percent.

payment rates as established in the annual Medicare PFS final rule effective January 1, 2025, to ensure the Medicare non-facility payment rates are effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B).

Additionally, in paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rates as established in the annual Medicare PFS final rule used for the comparison must be for the same geographical location as the Medicaid FFS fee schedule payment rate. For States that pay Medicaid payment rates based on geographical location (for example, payment rates that vary by rural or non-rural location, by zip code, or by metropolitan statistical area), we proposed that States' comparative payment rate analyses would need to use the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same geographical location as the Medicaid FFS fee schedule payment rate to achieve an equivalent comparison. We stated that we would expect States to review Medicare's published listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and identify the comparable Medicare locality area for the same geographical area as the Medicaid FFS fee schedule payment rate.²⁶³

We recognized that States that make Medicaid payment based on geographical location may not use the same locality areas as Medicare. For example, a State may use its own State-determined geographical designations, resulting in 5 geographical areas in the State for purposes of Medicaid payment while Medicare recognizes 3 locality areas for the State based on Metropolitan Statistical Area (MSA) delineations determined by the US Office of Management and Budget (OMB) that are the result of the application of published standards to Census Bureau data.²⁶⁴ In this instance, we would expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by

²⁶³ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality>.

²⁶⁴ <https://www.census.gov/programs-surveys/metro-micro/about/delineation-files.html>.

each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as established in the annual Medicare PFS final rule in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. Alternatively, as discussed in the next paragraph, the State could determine to use the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. We solicited comments on the proposed use of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted our awareness that States may not determine their payment rates by geographical location. For States that do not pay Medicaid payment rates based on geographical location, we proposed that States compare their Medicaid payment rates (separately identified by population, pediatric and adult, and provider type, as applicable) to the Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code. The Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar

year for a particular CPT/HCPCS code would be calculated as a simple average or arithmetic mean where all Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code for a particular State would be summed and divided by the number of all Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for a particular CPT/HCPCS code for a particular State. This calculated Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year would be calculated for each CPT/HCPCS code subject to the comparative payment rate analysis using the Non-Facility Price for each locality in the State as established in the annual Medicare PFS final rule for a calendar year. As previously mentioned, Medicare has published a listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area, and we would expect States to use this listing to identify the Medicare locality areas in their State. For example, the Specific Medicare Administrative Contractor (MAC) for Maryland is 12302 and there are two Specific Locality codes, 1230201 for BALTIMORE/SURR. CNTYS and 1230299 for REST OF STATE. After downloading and reviewing the CY 2023 Medicare PFS Relative Value Files to identify the Medicare Non-Facility Price(s) for CY 2023 for 99202 in the Specific MAC locality code for Maryland (12302 MARYLAND), the following information can be obtained: Medicare Non-Facility Price of \$77.82 for BALTIMORE/SURR. CNTYS and \$74.31 for REST OF STATE.²⁶⁵ These two Medicare Non-Facility Price(s) would be averaged to obtain a calculated Statewide average for Maryland of \$76.07.

For States that do not determine their payment rates by geographical location, we proposed that States would use the Statewide average of the Medicare Non-Facility Price(s) as listed on the PFS, as previously described, because it ensures consistency across all States' comparative payment rate analysis, aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non-facility payment rates as

²⁶⁵ <https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=1&H1=99202&C=43&M=5>.

established in the annual Medicare PFS final rule for a calendar year that States use in their comparative payment rate analysis accurately reflect how Medicare pays for services. We explained that this proposal would ensure that all States' comparative payment rate analyses consistently include Medicare geographical payment rate adjustments as proposed in paragraph (b)(3)(i)(C). As previously discussed, we proposed that States that do pay varying rates by geographical location would need to identify the comparable Medicare locality area for the same geographical area as their Medicaid FFS fee schedule payment rate. However, for States that do not pay varying rates by geographical location, at the operational level, the State is effectively paying a Statewide Medicaid payment rate, regardless of geographical location, that cannot be matched to a Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year in a comparable Medicare locality area for the same geographical area as the Medicaid FFS fee schedule payment rate. Therefore, to consistently apply the proposed provision that the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year must be for the same geographical location as the Medicaid FFS fee schedule payment rate, States that do not pay varying rates by geographical location would be required to calculate a Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year to compare the State's Statewide Medicaid payment rate.

Additionally, we proposed that States that do not determine their payment rates by geographical location should use the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year to align the implementing regulatory text with the statute's geographic area requirement in section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that Medicaid payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Therefore, the proposed provisions of this rule, which are implementing

section 1902(a)(30)(A) of the Act, must include a method of ensuring we have sufficient information for determining sufficiency of access to care as compared to the general population in the geographic area. As we have proposed to use Medicare non-facility payment rates as a benchmark for comparing Medicaid FFS fee schedule payment rate, we believe that utilizing a Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for States that do not pay varying rates by geographical location would align the geographic area requirement of section 1902(a)(30)(A) of the Act, treating the entire State (throughout which the Medicaid base payment rate applies uniformly) as the relevant geographic area.

We considered requiring States weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate, but we did not propose this due to the additional administrative burden this would create for States complying with the proposed comparative payment rate analysis as well as limited availability of Medicare beneficiary and claims data necessary to weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year in this manner. As proposed, States that do not determine their payment rates by geographical location would be required to consider Medicare's geographically determined payment rates by Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. We explained our belief that an additional step to weight the Statewide average by the proportion of the Medicare beneficiary population covered by each rate would not result in a practical version of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for purposes of the comparative payment rate analysis. Additionally, requiring only States that do not determine their payment rates by geographical location to weight Medicare payment rates in this manner would result in additional administrative burden for such States that is not imposed on States that

do determine their Medicaid payment rates by geographical location. Additionally, in order to accurately weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate, States would likely require Medicare-paid claims data for each code subject to the comparative payment rate analysis, broken down by each of the comparable Medicare locality areas for the same geographical area as the Medicaid FFS fee schedule payment rate that are included in the Statewide average of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year. While total Medicare beneficiary enrollment data broken down by State and county level is publicly available on data.cms.gov, Medicare-paid claims data broken down by the Medicare locality areas used in the Medicare PFS and by code level is not published by CMS and would be inaccessible for the State to use in weighting the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the proportion of the Medicare beneficiary population covered by each rate. Accordingly, we explained our belief that, for States that do not determine their Medicaid payment rates by geographical location, calculating a simple Statewide average of the Medicare non-facility rates in the State would ensure consistency across all States' comparative payment rate analyses, align with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensure the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States use in their comparative payment rate analyses accurately reflect how Medicare pays for services. We solicited comments regarding our decision not to propose requiring States that do not pay varying Medicaid rates by geographical location to weight the Statewide average of the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year by the distribution of Medicare beneficiaries in the State.

Furthermore, in paragraph (b)(3)(i)(C), we proposed that the Medicare non-facility payment rate as established in the annual Medicare PFS final rule must separately identify the payment rates by provider type. We previously discussed that some States and Medicare pay a percentage less than 100 percent of their fee schedule payment rates to NPPs, including, for example, nurse practitioners, physician assistants, and clinical nurse specialists. To ensure a State's comparative payment rate analysis is as accurate as possible when comparing their Medicaid payment rates to Medicare, we proposed that States include a breakdown of Medicare's non-facility payment rates by provider type. The proposed breakdown of Medicare's payment rates by provider type would be required for all States, regardless of whether or how the State's Medicaid payment rates vary by provider type, because it ensures the comparative payment rate analysis accurately reflects this existing Medicare payment policy on the Medicare side of the analysis. Therefore, every comparative payment rate analysis would include the following Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same set of E/M CPT/HCPCS codes paid under Medicaid as described in § 447.203(b)(3)(i)(B): the non-facility payment rate as established in the annual Medicare PFS rate as the Medicare payment rate for physicians and the non-facility payment rate as listed on Medicare PFS rate multiplied by 0.85 as the Medicare payment rate for NPPs.

As previously mentioned in this final rule, Medicare pays nurse practitioners, physician assistants, and clinical nurse specialists at 85 percent of the Medicare PFS rate. Medicare implements a payment policy where the fee schedule amounts, including the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, are reduced to 85 percent when billed by NPPs, including nurse practitioners, physician assistants, and clinical nurse specialists, whereas physicians are paid 100 percent of the fee schedule amounts Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year.²⁶⁶ As proposed, States' comparative payment rate analysis would

²⁶⁶ <https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf>.

need to match their Medicaid payment rates for each provider type to the corresponding Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for each provider type, regardless of the State paying varying or the same payment rates to their providers for the same service. As an example of a State that pays varying rates based on provider type, if a State's Medicaid fee schedule lists a rate of \$100.00 when a physician delivers and bills for 99202, then the \$100.00 Medicaid base payment rate would be compared to 100 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. If the same State's Medicaid fee schedule lists a rate of \$75 when a nurse practitioner delivers and bills for 99202 (or the State's current approved State plan language states that a nurse practitioner is paid 75 percent of the State's Medicaid fee schedule rate), then the \$75 Medicaid base payment rate would be compared to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year multiplied by 0.85. Both Medicare non-facility payments rates would need to account for any applicable geographical variation, including the Non-Facility Price Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for each relevant locality area or the calculated Statewide average of the Non-Facility Price Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for all relevant areas of a State, as previously discussed in this section, for an accurate comparison to the corresponding Medicaid payment rate. Alternatively, if a State pays the same \$80 Medicaid base payment rate for the service when delivered by physicians and by nurse practitioners, then the \$80 would be listed separately for physicians and nurse practitioners as the Medicaid base payment rate and compared to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for physicians and the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year multiplied by 0.85 for nurse practitioners.

This granular level of comparison provides States with the opportunity to benchmark their Medicaid payment rates against Medicare as part of the State's and our process for ensuring compliance with section 1902(a)(30)(A) of the Act. For example, a State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 80 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year and their Medicaid base payment rate for nurse practitioners is 71 percent of the Medicare non-facility payment rate for NPPs, because the State pays a reduced rate to nurse practitioners. Although Medicare also pays a reduced rate to nurse practitioners, the reduced rate the State pays to nurse practitioners compared to Medicare's reduced rate is still a lower percentage than the physician rate. However, another State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 95 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year and their Medicaid base payment rate for nurse practitioners is 110 percent of the Medicare non-facility payment rate because the State pays all providers the same Medicaid base payment rate while Medicare pays a reduced rate of 85 percent of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year when the service is furnished by an NPP. By conducting this level of analysis through the comparative payment rate analysis, States would be able to pinpoint where there may be existing or potential future access to care concerns rooted in payment rates. We solicited comments on the proposed requirement for States to compare their Medicaid payment rates to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year, effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid FFS fee schedule payment rate, that correspond to the Medicaid FFS fee schedule payment rate identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type, as proposed in § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i)(D), we proposed to require States specify the Medicaid base payment rate identified under proposed § 447.203(b)(3)(i)(B) as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule identified under proposed § 447.203(b)(3)(i)(C) for each of the services for which the Medicaid base payment rate is published under proposed § 447.203(b)(3)(i)(B). For each E/M CPT/HCPCS code that we select, we proposed that States would calculate each Medicaid base payment rate as specified in paragraph (b)(3)(i)(B) as a percentage of the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule specified in paragraph (b)(3)(i)(C). Both rates would be required to be effective for the same time period of the comparative payment rate analysis. As previous components of the proposed comparative payment rate analysis have considered variance in payment rates based on population the service is delivered to (adult or pediatric), provider type, and geographical location to extract the most granular and accurate Medicaid and Medicare payment rate data, we proposed that States would calculate the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule in the comparative payment rate analysis to obtain an informative metric that can be used in the State's and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. As previously discussed, benchmarking against Medicare serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. We proposed that States would calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule because it is a common, simple, and informative statistic that can provide us with a gauge of how Medicaid payment rates compare to Medicare non-facility payment rates in the same geographic area. Initially and over time, States, CMS, and other interested parties would be able to compare the State's Medicaid payment rates as a percentage

of Medicare's non-facility payment rates to identify how the percentage changes over time, in view of changes that may take place to the Medicaid and/or the Medicare payment rate. We explained that being able to track and analyze the change in percentage over time would help States and CMS identify possible access concerns that may be related to payment insufficiency.

We noted that the organization and content of the comparative payment rate analysis, including the expression of the Medicaid base payment rate as a percentage of the Medicare payment rate, can provide us with a great deal of information about access in the State. For example, we would be able to identify when and how the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for E/M CPT/HCPCS codes for primary care services may decrease over time if Medicare adjusts its rates and a State does not and use this information to more closely examine for possible access concerns. This type of analysis would provide us with actionable information to help ensure consistency with section 1902(a)(30)(A) of the Act by using Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year paid across the same geographical areas of the State as a point of comparison for payment rate sufficiency as a critical element of beneficiary access to care. When explaining the rationale for proposing to use Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for comparison earlier in this rule, we emphasized the ability to demonstrate to States that certain Medicaid payment rates have not kept pace with changes to Medicare non-facility payment rates and how the comparative payment rate analysis would help them identify areas where they also might want to consider rate increases that address market changes. We solicited comments on the proposed requirement for States to calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as described in proposed § 447.203(b)(3)(i)(D). We also solicited comments on any challenges States might encounter when comparing their Medicaid payment rates to Medicare

non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year under proposed § 447.203(b)(3)(i)(D), particularly for any of the proposed categories of service in paragraphs (b)(2)(i) through (iii), as well as suggestions for an alternative comparative analysis that might be more helpful, or less burdensome and equally helpful, for States, CMS, and other interested parties to assess whether a State's Medicaid payment rates are consistent with the access standard in section 1902(a)(30)(A) of the Act.

We noted our awareness in the proposed rule that provider payment rates are an important factor influencing beneficiary access; as expressly indicated in section 1902(a)(30)(A) of the Act, insufficient provider payment rates are not likely to enlist enough providers willing to serve Medicaid beneficiaries to ensure broad access to care; however, there may be situations where access issues are principally due to other causes. For example, even if Medicaid payment rates are generally consistent with amounts paid by Medicare (and those amounts have been sufficient to ensure broad access to services for Medicare beneficiaries), Medicaid beneficiaries may have difficulty scheduling behavioral health care appointments because the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population. Therefore, a State's rates may be consistent with the requirements of section 1902(a)(30)(A) of the Act even when access concerns exist, and States and CMS may need to examine other strategies to improve access to care beyond payment rate increases. By contrast, comparing a State's Medicaid behavioral health payment rates to Medicare may demonstrate that the State's rates fall far below Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, which would likely impede beneficiaries from accessing needed care when the demand already exceeds the supply of providers within a State. In that case, States may need to evaluate budget priorities and take steps to ensure behavioral health rates are consistent with section 1902(a)(30)(A) of the Act.

Lastly, in paragraph (b)(3)(i)(E), we proposed to require States to specify in their comparative payment rate analyses the number of Medicaid-paid claims and the number of

Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under paragraph (b)(3)(i)(B).

The previous components of the comparative payment rate analysis focus on the State's payment rate for the E/M CPT/HCPCS code and comparing the Medicaid base payment rate to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for the same code (separately, for each Medicaid base payment rate by population (adult or pediatric), provider type, and geographic area, as applicable). This component examines the Medicaid-paid claims volume of each E/M CPT/HCPCS code included in the comparative payment rate analysis relative to the number of Medicaid enrolled beneficiaries receiving each service within a calendar year. We proposed to limit the claims volume data to Medicaid-paid claims, and the number of beneficiaries would be limited to Medicaid-enrolled beneficiaries who received a service in the calendar year of the comparative payment rate analysis, where the service would fall into the list of CMS-identified E/M CPT/HCPCS code(s). In other words, a beneficiary would be counted in the comparative payment rate analysis for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraphs (b)(2)(i) through (iii) for which the State has a Medicaid base payment rate (the number of Medicaid-enrolled beneficiaries who received a service). A claim would be counted in the comparative payment rate analysis for a particular calendar year when that beneficiary had a claim submitted on their behalf by a provider who billed one of the codes from the list of CMS-identified E/M CPT/HCPCS code(s) to the State and the State paid the claim (number of Medicaid-paid claims). With the proposal, we explained that we were seeking to ensure the comparative payment rate analysis reflects actual services received by beneficiaries and paid for by the State or realized access.²⁶⁷

²⁶⁷ Andersen, R.M., and P.L. Davidson (2007). Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

We considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We considered this detail in order to identify the unique, or deduplicated, number of beneficiaries who received a service that falls into one of the categories of services described in in paragraph (b)(2)(i) through (iii) in a calendar year. For example, if a beneficiary has 6 visits to their primary care provider in a calendar year and the provider bills 6 claims with 99202 for the same beneficiary, then the beneficiary and claims for 99202 would only be counted as one claim and one beneficiary. Therefore, we chose not to propose this aspect because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. We solicited comments regarding our decision not to propose that States would identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed in § 447.203(b)(3)(i)(E).

We also considered but did not propose to require States to identify the total Medicaid-enrolled population who could potentially receive a service within a calendar year for each of the services for which the Medicaid base payment rate is published under paragraph (b)(3)(i)(B), in addition to the proposed requirement for States to identify the number of Medicaid-enrolled beneficiaries who received a service. This additional data element in the comparative payment rate analysis would reflect the number of Medicaid-enrolled beneficiaries who could have received a service, or potential access, in comparison to the number of Medicaid-enrolled beneficiaries who actually received a service. We did not propose this aspect because this could result in additional administrative burden on the State, as we already collect and publish similar data through Medicaid and CHIP Enrollment Trends Snapshots published on Medicaid.gov. We

also solicited comments regarding our decision not to propose that States would identify the total Medicaid-enrolled population who could receive a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed in § 447.203(b)(3)(i)(E).

We proposed to include beneficiary and claims information in the comparative payment rate analysis to contextualize the payment rates in the analysis, and to be able to identify longitudinal changes in Medicaid service volume in the context of the Medicaid beneficiary population receiving services, since utilization changes could be an indication of an access to care issue. For example, a decrease in the number of Medicaid-paid claims for primary care services furnished to Medicaid beneficiaries in an area (when the number of Medicaid-enrolled beneficiaries who received primary care services in the area is constant or increasing) could be an indication of an access to care issue. Without additional context provided by the number of Medicaid enrolled beneficiaries who received a service, changes in claims volume could be attributed to a variety of changes in the beneficiary population, such as a temporary loss of coverage when enrollees disenroll and then re-enroll within a short period of time.

Further, if the Medicaid base payment rate for the services with decreasing Medicaid service volume has failed to keep pace with the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year over the period of decrease in utilization (as reflected in changes in the Medicaid base payment rate expressed as a percentage of the Medicare non-facility payment rate as required under proposed § 447.203(b)(3)(i)(D)), then we would be concerned and would further scrutinize whether any access to care issue might be caused by insufficient Medicaid payment rates for the relevant services. With each biennial publication of the State's comparative payment rate analysis, as proposed in § 447.203(b)(4), discussed later in this section, States and CMS would be able to compare the number of paid claims in the context of the number of Medicaid enrolled beneficiaries receiving services within a calendar year for the services subject to the comparative

payment rate analysis with previous years' comparative payment rate analyses. Collecting and comparing the number of paid claims data in the context of the number of Medicaid enrolled beneficiaries receiving services alongside Medicaid base payment rate data may reveal trends where an increase in the Medicaid base payment rate is correlated with an increase in service volume and utilization, or vice versa with a decrease in the Medicaid base payment rate correlated with a decrease in service volume and utilization. As claims utilization and number of Medicaid enrolled beneficiaries receiving services are only correlating trends, we acknowledge that there may be other contextualizing factors outside of the comparative payment rate analysis that affect changes in service volume and utilization, and we would (and would expect States and other interested parties to) take such additional factors into account in analyzing and ascribing significance to changes in service volume and utilization. We are solicited comments on the proposed requirement for States to include the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as specified in proposed § 447.203(b)(3)(i)(E).

We noted our belief that the comparative payment rate analysis proposed in paragraph (b)(3) is needed to best enable us to ensure State compliance with the requirement in section 1902(a)(30)(A) of the Act that payments are sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. As demonstrated by the findings of Sloan, et al,²⁶⁸ which have since been supported and expanded upon by numerous researchers, multiple studies

²⁶⁸ Sloan, F. et al "Physician Participation in State Medicaid Programs." *The Journal of Human Resources*, Volume 13, Supplement: National Bureau of Economic Research Conference on the Economics of Physician and Patient Behavior, 1978, p. 211-245. https://www.jstor.org/stable/145253?seq=1#metadata_info_tab_contents. Accessed August 16, 2022.

examining the relationship between Medicaid payment and physician participation,^{269,270} at the State level,²⁷¹ and among specific provider types,^{272,273} have found a direct, positive association between Medicaid payment rates and provider participation in the Medicaid program. While multiple factors may influence provider enrollment (such as administrative burden), section 1902(a)(30)(A) of the Act specifically concerns the sufficiency of provider payment rates. Given this statutory requirement, a comparison of Medicaid payment rates to other payer rates is an important barometer of whether State payment policies are likely to support the statutory standard of ensuring access for Medicaid beneficiaries such that covered care and services are available to them at least to the extent that the same care and services are available to the general population in the geographic area.

The AMRP requirements previously addressed this standard under section 1902(a)(30)(A) of the Act by requiring States to compare Medicaid payment rates to the payment rates of other public and private payers in current § 447.203(b)(1)(v) and (b)(3). While we proposed to eliminate the previous AMRP requirements, we noted our belief that our proposal to require States to compare their Medicaid payment rates for services under specified E/M CPT/HCPSC codes against Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the same codes, as described in § 447.203(b)(3), would well position States and CMS to continue to meet the statutory access requirement. Some studies

²⁶⁹ Chen, A. “Do the Poor Benefit from More Generous Medicaid Policies” SSRN Electronic Journal, January 2014., p. 1-46. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2444286. Accessed June 16, 2022.

²⁷⁰ Holgash, K. and Martha Heberlein, “Physician Acceptance of New Medicaid Patients: What Matters and What Doesn’t” *Health Affairs*, April 10, 2019. <https://www.healthaffairs.org/doi/10.1377/forefront.20190401.678690/#:~:text=Physicians%E2%80%99%20acceptance%20of%20new%20Medicaid%20patients%20is%20only,of%20Medicaid%20patients%20already%20in%20the%20physician%E2%80%99s%20care>. Accessed June 16, 2022.

²⁷¹ Fakhraei, H. “Payments for Physician Services: An analysis of Maryland Medicaid Reimbursement Rates” *International Journal of Healthcare Technology and Management*, Volume 7, Numbers 1-2, January 2005, p. 129-142. https://www.researchgate.net/publication/228637758_Payments_for_physician_services_An_analysis_of_Maryland_Medicaid_reimbursement_rates. Accessed June 16, 2022.

²⁷² Berman, S., et al. “Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients,” *Pediatrics*, Volume 110, Issue 2, August 2002, p. 239-248. <https://publications.aap.org/pediatrics/article-abstract/110/2/239/64380/Factors-That-Influence-the-Willingness-of-Private?redirectedFrom=fulltext?autologincheck=redirected>. Accessed June 16, 2022.

²⁷³ Suk-fong S., Tang, et al “Increased Medicaid Payment and Participation by Office-Based Primary Care Pediatricians,” *Pediatrics*, Volume 141, number 1, January 2018, p. 1-9. <https://publications.aap.org/pediatrics/article/141/1/e20172570/37705/Increased-Medicaid-Payment-and-Participation-by>. Accessed June 16, 2022.

examining the relationship between provider payments and various access measures have quantified the relationship between the Medicaid-Medicare payment ratio and access measures. Two studies observed that increases in the Medicaid-Medicare payment ratio is associated with higher physician acceptance rates of new Medicaid patients and with an increased probability of a beneficiary having an office-based physician as the patient’s usual source of care.^{274,275} We explained that these studies led us to conclude that Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are likely to be a sufficient benchmark for evaluating access to care, particularly ambulatory physician services, based on provider payment rates.

By comparing FFS Medicaid payment rates to corresponding FFS Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year, where Medicare is a public payer with large populations of beneficiaries and participating providers whose payment rates are readily available, we aim to establish a uniform benchmarking approach that allows for more meaningful oversight and transparency and reduces the burden on States and CMS relative to the previous AMRP requirements that do not impose specific methodological standards for comparing payment rates and that contemplate the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. We noted that this aspect of the proposal specifically responds to States’ expressed concerns that the previous AMRP requirement to include “actual or estimated levels of provider payment available from other payers, including other public and private payers” was challenging to accomplish based on the general unavailability of this information, as discussed elsewhere in this final rule.

Following the 2011 proposed rule, and as addressed by us through public comment response in the 2015 final rule with comment period, States expressed concerns that private payer payment rates were proprietary information and not available to them and that large private

²⁷⁴ Holgash, K. and Martha Heberlein, *Health Affairs*, April 10, 2019.

²⁷⁵ Cohen, J. W., *Inquiry*, Fall 1993.

plans did not exist within some States so there were no private payer rates to compare to, therefore, the State would need to rely on State employee health plans or non-profit insurer rates.²⁷⁶ States also expressed that other payer data, including public and private payers, in general may be unsound for comparisons because of a lack of transparency about the payment data States would have compared their Medicaid payment rates to. We discussed how, since 2016, we have learned a great deal from our implementation experience of the previous AMRP process. We have learned that very few States were able to include even limited private payer data in their previous AMRPs. States that were able include private payer data were only able to do so because the State had existing Statewide all payer claiming or rate-setting systems, which gave them access to private payer data in their State, or the State previously based their State plan payment rates off of information about other payers (such as the American Dental Association's Survey of Dental Fees) that gave them access to private payer data.²⁷⁷ Based on our implementation experience and concerns from States about the previous requirement in § 447.203(b)(1)(v) to obtain private payer data, we proposed to require States only compare their Medicaid payment rates to Medicare's, for which payment data are readily and publicly available.

Next, in paragraph (b)(3)(ii), we proposed that for each category of services described in proposed paragraph (b)(2)(iv), the State agency would be required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates differ. The payment rate disclosure would be required to meet specified requirements. We explained that we intended this proposal to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) and to take specific action regarding direct care workers per Section 2402(a) of the Affordable Care Act. HCBS and direct care workers

²⁷⁶ Alaska Department of Health and Social Services, Comment Letter on 2011 Proposed Rule (July 7, 2011), <https://www.regulations.gov/comment/CMS-2011-0062-0102>.

²⁷⁷ <https://www.medicaid.gov/sites/default/files/2019-12/co-amrp-2016.pdf>, <https://www.medicaid.gov/sites/default/files/2019-12/md-amrp-16.pdf>, <https://www.medicaid.gov/sites/default/files/2019-12/sd-amrp-16.pdf>.

that deliver these services are unique to Medicaid and often not covered by other payers, which is why we proposed a different analysis of payment rates for providers of these services that does not involve a comparison to Medicare. As previously stated, Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance); however, Medicare does not cover personal care or homemaker services. Therefore, comparing personal care and homemaker services to Medicare, as we proposed in paragraph (b)(3)(i) for other specified categories of services, would not be feasible for States, and a comparison of Medicaid home health aide payment rates to analogous rates for Medicare would be of limited utility given the differences in circumstances when Medicaid and Medicare may pay for such services.

As previously discussed, private payer data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Even if private payer payment rate data were more readily available, like Medicare, many private payers do not cover HCBS as HCBS is unique to the Medicaid program, leaving Medicaid as the largest or the only payer for personal care, home health aide, and homemaker services. Given Medicaid's status as the most important payer for HCBS, we believe that scrutiny of Medicaid HCBS payment rates themselves, rather than a comparison to other payer rates that frequently do not exist, is most important in ascertaining whether such Medicaid payment rates are sufficient to enlist adequate providers so that the specified services are available to Medicaid beneficiaries at least to the same extent as to the general population in the geographic area. We acknowledge that individuals without insurance may self-pay for medical services provided in their home or community; however, similar to private payer data, self-pay data is unlikely to be available to States. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS. Through the proposed payment rate disclosure, Medicaid payments rates would be transparent and comparable among

States and would assist States to analyze if and how their payment rates are compliant with section 1902(a)(30)(A) of the Act.

As noted previously in this section, we proposed to require States to express their rates separately as the average hourly payments made to individual providers and providers employed by an agency, if the rates differ, as applicable for each category of service specified in proposed § 447.203(b)(2)(iv). We noted our belief that expressing the data in this manner would best account for variations in types and levels of payment that may occur in different settings and employment arrangements. Individual providers are often self-employed or contract directly with the State to deliver services as a Medicaid provider while providers employed by an agency are employed by the agency, which works directly with the Medicaid agency to provide Medicaid services. These differences in employment arrangements often include differences in the hourly rate a provider would receive for services delivered, for example, providers employed by an agency typically receive benefits, such as health insurance, and the cost of those benefits is factored into the hourly rate that the State pays for the services delivered by providers employed by an agency (even though the employed provider does not retain the entire amount as direct monetary compensation). However, these benefits are not always available for individual providers who may need to separately purchase a marketplace health plan or be able to opt into the State-employee health plan, for example. Therefore, the provider employed by an agency potentially could receive a higher hourly rate because benefits are factored into the hourly rate they receive for delivering services, whereas the individual provider might be paid a rate that does not reflect employment benefits.

With States expressing their payment rates separately as the average hourly payment rate made to individual and agency employed providers for personal care, home health aide, and homemaker services, States, CMS, and other interested parties would be able to compare payment rates among State Medicaid programs. Such comparisons may be particularly relevant for States in close geographical proximity to each other or that otherwise may compete to attract

providers of the services specified in proposed paragraph (b)(2)(iv) or where such providers may experience similar costs or other incentives to provide such services. For example, from reviewing all States' payment rate analyses for personal care, home health aide, and homemaker services, we would be able to learn that two neighboring States have similar hourly rates for providers of these services, but a third neighboring State has much lower hourly rates than both of its neighbors. This information could highlight a potential access issue, since providers in the third State might have an economic incentive to move to one of the two neighboring States where they could receive higher payments for furnishing the same services. Such movement could result in beneficiaries in the third State having difficulty accessing covered services, compared to the general population in the tri-State geographic area.

In paragraph (b)(3)(ii), we proposed that the State's payment rate disclosure must meet the following requirements: (A) the State must organize the payment rate disclosure by category of service as specified in proposed paragraph (b)(2)(iv); (B) the disclosure must identify the average hourly payment rates, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency by population (pediatric and adult), provider type, and geographical location, as applicable; and (C) the disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(ii)(B). We solicited comments on the proposed requirements and content of the items in proposed § 447.203(b)(3)(ii)(A) through (C).

In paragraph (b)(3)(ii)(A), we proposed to require States to organize their payment rate disclosures by each of the categories of services specified in proposed paragraph (b)(2)(iv), that is, to break out the payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency, separately for individual analyses of the payment rates for each category of service and type of employment structure.

We solicited comments on the proposed requirement for States to break out their payment rates for personal care, home health aide, and homemaker services separately for individual analyses of the payment rates for each category of service in the comparative payment rate analysis, as described in proposed § 447.203(b)(3)(ii)(A).

In paragraph (b)(3)(ii)(B), we proposed to require States identify in their disclosure the Medicaid average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, as well as by population (pediatric and adult), provider type, and geographical location, as applicable. Given that direct care workers deliver unique services in Medicaid that are often not covered by other payers, we proposed to require a payment rate disclosure, instead of comparative payment rate analysis. To be clear, we did not propose to require a State's payment rate disclosure for personal care, home health aide, and homemaker services be broken down and organized by E/M CPT/HCPCS codes, nor did we propose States compare their Medicaid payment rates to Medicare for these services.

We proposed to require States to calculate their Medicaid average hourly payment rates made to providers of personal care, home health aide, and homemaker services, separately, for each of these categories of services, by provider employment structures (individual providers and agency employed providers). For each of the categories of services in paragraph (b)(3)(ii)(A), one Medicaid average hourly payment rate would be calculated as a simple average (arithmetic mean) where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates. As an example, the State's Medicaid average hourly payment rate for personal care providers may be \$10.50 while the average hourly payment rate for a home health aide is \$15.00. A more granular analysis may show that within personal care providers receiving a payment rate of \$10.50, an individual personal care provider is paid an average hourly payment rate of \$9.00, while a personal care provider employed by an agency is paid an average hourly payment rate of \$12.00 for the same type of service. Similarly for home

health aides, a more granular analysis may show that within home health aides receiving a payment rate of \$15.00, an individual home health aide is paid an average hourly payment rate of \$13.00, while a home health aide employed by an agency is paid an average hourly payment rate of \$17.00.

We explained that we understand that States may set payment rates for personal care, home health aide, and homemaker services based on a particular unit of time for delivering the service, and that time may not be in hourly increments. For example, different States might pay for personal care services using 15-minute increments, on an hourly basis, through a daily rate, or based on a 24-hour period. By proposing to require States to represent their rates as an hourly payment rate, we would be able to standardize the unit (hourly) and payment rate for comparison across States, rather than comparing to Medicare. To the extent a State pays for personal care, home health aide, or homemaker services on an hourly basis, the State would simply use that hourly rate in its Medicaid average hourly payment rate calculation of each respective category of service. However, if for example a State pays for personal care, home health aide, or homemaker services on a daily basis, we would expect the State to divide that rate by the number of hours covered by the rate.

Additionally, and similar to proposed paragraph (b)(3)(i)(E), we proposed in paragraph (b)(3)(ii)(B), that, if the States' Medicaid average hourly payment rates vary, the rates must separately identify the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable. We included this proposed provision with the intent of ensuring the payment rate disclosure contains the highest level of granularity in each element. As previously discussed, States may pay providers different payment rates for billing the same service based on the population being served, provider type, and geographical location of where the service is delivered. We solicited comments on the proposed requirement for States to calculate the Medicaid average hourly payment rate made separately to individual providers

and to agency employed providers, which accounts for variation in payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the payment rate disclosure.

In paragraph (b)(3)(ii)(C), we proposed to require that the State disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid payment rate is published under proposed paragraph (b)(3)(ii)(B), so that States, CMS, and other interested parties would be able to contextualize the previously described payment rate information with information about the volume of paid claims and number of beneficiaries receiving personal care, home health aide, and homemaker services.

We proposed that the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service be reported under the same breakdown as paragraph (b)(3)(ii), where the State provides the number of paid claims and number of beneficiaries receiving services from individual providers versus agency-employed providers of personal care, home health aide services, and homemaker services. As with the comparative payment rate analysis, we proposed the claims volume data would be limited to Medicaid-paid claims and the number of beneficiaries would be limited to Medicaid enrolled beneficiaries who received a service in the calendar year of the payment rate disclosure, where the services fall into the categories of service for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). In other words, the beneficiary would be counted in the payment rate disclosure for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraph (b)(2)(iv) for which the State has calculated average hourly payment rates (the number of Medicaid enrolled beneficiaries who received a service). A claim would be counted when that beneficiary had a claim submitted on their behalf by a provider who billed for one of the categories of services described in paragraph (b)(2)(iv) and the State paid the claim (number of Medicaid-paid claims). We noted we were

seeking to ensure the payment rate disclosure reflects actual services received by beneficiaries and paid for by the State, or realized access.²⁷⁸

Similar to the comparative payment rate analysis, we considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). We also considered but did not propose to require States to identify the total Medicaid enrolled population who could receive a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) in addition to proposing States identify the number of Medicaid enrolled beneficiaries who received a service. As discussed in the comparative payment rate discussion, we solicited comments on our decision not to require these levels of detail for the payment rate disclosure.

Also similar to the comparative payment rate analysis requirement under proposed paragraph (b)(3)(i)(E), we explained that this disclosure element would help States, CMS, and other interested parties identify longitudinal changes in Medicaid service volume and beneficiary utilization that may be an indication of an access to care issue. Again, with each biennial publication of the State's comparative payment rate analysis and payment rate disclosure, States and CMS would be able to compare the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for services subject to the payment rate disclosure with previous years' disclosures. Collecting and comparing data on the number of paid claims and number of Medicaid enrolled beneficiaries alongside Medicaid average hourly payment rate data may reveal trends, such as where a

²⁷⁸ Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In *Changing the U.S. health care system: Key issues in health services policy and management*, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

provider type that previously delivered a low volume of services to beneficiaries has increased their volume of services delivered after receiving an increase in their payment rate.

We acknowledged that one limitation of using the average hourly payment rate is that the statistic is sensitive to highs and lows, so one provider receiving an increase in their average hourly payment rate would bring up the average overall while other providers may not see an improvement. As these are only correlating trends, we also acknowledged that there may be other contextualizing factors outside of the payment rate disclosure that may affect changes in service volume and utilization. We solicited comments on the proposed requirement for States to include the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid payment rate is published under paragraph (b)(3)(ii)(B), as specified in proposed § 447.203(b)(3)(ii)(C).

Additionally, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities and in an effort to remain consistent with the proposed HCBS payment adequacy provisions at § 441.302(k) (discussed in section II.B.5 of this rule), we solicited comments on whether we should propose a similar provision that would require at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care workers. In this final rule, we want to clarify that this request for comment was distinct from the proposal at § 441.302(k) as discussed in section II.B.5 of this rule. The payment adequacy provision finalized in § 441.302(k) is applicable to rates for certain specified services authorized under section 1915(c) of the Act, as well as sections 1915(j), (k), and (i) of the Act as finalized at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. The request for comment in this section of the rule considered expanding that requirement to Medicaid FFS payments under FFS State plan authority.

In paragraph (b)(4), we proposed to require the State agency to publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payments in

effect as of January 1, 2025, as required under § 447.203(b)(2) and (b)(3), by no later than January 1, 2026. Thereafter, the State agency would be required to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data.

As previously discussed in this final rule, we proposed that the Medicaid payment rates included in the initial comparative payment rate analysis and payment rate disclosure would be those in effect as of January 1, 2025. Specifically, for the comparative payment rate analysis, we proposed States would conduct a retrospective analysis to ensure CMS can publish the list of E/M CPT/HCPCS codes for the comparative payment rate analysis and States have timely access to all information required to complete comparative payment rate analysis. As described in paragraph (b)(3)(i)(C), we proposed States would compare their Medicaid payment rates to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, therefore, the Medicare non-facility payment rates as published on the Medicare PFS for the same time period as the State's Medicaid payment rates would need to be available to States in a timely manner for their analysis and disclosure to be conducted and published as described in paragraph (b)(4). Medicare publishes its annual PFS final rule in November of each year and the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are effective the following January 1. For example, the 2025 Medicare PFS final rule would be published in November 2024 and the Medicare non-facility payment rates as established in the annual Medicare PFS final rule would be effective January 1, 2025, so States would compare their Medicaid payment rates effective as of January 1, 2025, to the Medicare PFS payment rates

effective January 1, 2025, when submitting the initial comparative payment rate analysis that we proposed would be due on January 1, 2026.

Also, previously discussed in this final rule, we noted our intent to publish the initial and subsequent updates to the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. Because the list of E/M CPT/HCPCS codes is derived from the relevant calendar year's Medicare PFS, the Medicare non-facility payment rates as established in the annual Medicare PFS final rule that the State would need to include in their comparative payment rate analysis would also be available to States. We explained that we expect approximately one full calendar year of the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year being available to States would provide the States with sufficient time to develop and publish their comparative payment rate analyses as described in paragraph (b)(4). We considered proposing the same due date and effective time period for Medicaid and Medicare payment rates where the initial publication of the comparative payment rate analysis would be due January 1, 2026, and would contain payment rates effective January 1, 2026; however, we believe a 2-month time period between Medicare publishing its PFS payment rates in November and the PFS payment rates taking effect on January 1 would be an insufficient amount of time for CMS to publish the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis and for States to develop and publish their comparative payment rate analyses by January 1. While the proposed payment rate disclosure would not require a comparison to Medicare, we proposed to use the same due date and effective period of Medicaid payment rates for both the proposed comparative payment rate analysis and payment rate disclosure to maintain consistency.

We noted our expectation the proposed initial publication timeframe would provide sufficient time for States to gather necessary data, perform, and publish the first required comparative payment rate analysis and payment rate disclosure. We determined this timeframe was sufficient based on implementation experience from the previous AMRP process, where we initially proposed a 6-month timeframe between the January 4, 2016, effective date of the 2015 final rule with comment period in the **Federal Register**, and the due date of the first AMRP, July 1, 2016. At the time, we believed that this timeframe would be sufficient for States to conduct their first review for service categories newly subject to ongoing AMRP requirements; however, after receiving several public comments from States on the 2015 final rule with comment period that State agency staff may have difficulty developing and submitting the initial AMRPs within the July 1, 2016 timeframe, we modified the policy as finalized in the 2016 final rule.²⁷⁹ Specifically, we revised the deadline for submission of the initial AMRP until October 1, 2016 and we made a conforming change to the deadline for submission in subsequent review periods at § 447.203(b)(5)(i) to October 1.²⁸⁰ We also found that, despite this additional time, some State were still late in submitting their first AMRP to us. Therefore, we noted our belief that a proposed initial publication date of January 1, 2026, thereby providing States with approximately 2 years between the effective date of the final rule and the due date of the first comparative payment rate analysis and payment rate disclosure, would be sufficient. In alignment with the proposed payment rate transparency requirements, we proposed an alternate date if this rule is finalized at a time that does not allow for States to have a period of 2 years from the effective date of the final rule and the proposed January 1, 2026, date to publish the initial comparative payment rate analysis and payment rate disclosure. We proposed an alternative date of July 1, 2026, for the initial comparative payment rate analysis and payment rate disclosure and for the initial comparative payment rate analysis and payment rate disclosure

²⁷⁹ 81 FR 21479 at 21479-21480.

²⁸⁰ 81 FR 21479 at 21480.

to include Medicaid payment rates approved as of July 1, 2025, to allow more time for States to comply with the initial comparative payment rate analysis and payment rate disclosure requirements. We acknowledged that the date of the initial comparative payment rate analysis and payment rate disclosure publication would be subject to change based on the final rule publication schedule and effective date. If further adjustment is necessary beyond the July 1, 2026, timeframe to allow more time for States to comply with the payment rate transparency requirements, then we proposed that we would adjust date of the initial payment rate transparency publication in 6-month intervals, as appropriate.

Also, in § 447.203(b)(4), we proposed to require the State agency to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. We proposed that the comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. After publication of the 2011 proposed rule, and as we worked with States to implement the previous AMRP requirements after publication of the 2015 final rule with comment period, many States expressed concerns that the previous requirements of § 447.203, specifically those in previous § 447.203(b)(6) imposed additional analysis and monitoring requirements in the case of provider rate reductions or restructurings that could result in diminished access, were overly burdensome. As described in the 2018 and 2019 proposed rules, “a number of States expressed concern regarding the administrative burden associated with the requirements of § 447.203, particularly those States with a very high beneficiary enrollment in comprehensive, risk-based managed care and a limited number of beneficiaries receiving care through a FFS delivery system.”^{281,282} Additionally, from our implementation experience, we learned that the triennial due date for updated AMRPs required by previous § 447.203(b)(5)(ii)

²⁸¹ 83 FR 12696 at 12697.

²⁸² 84 FR 33722 at 33723.

was too infrequent for States or CMS to identify and act on access concerns identified by the previous AMRPs. For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), and timely submitted its first AMRP update (the next ongoing AMRP) 3 years later, on October 1, 2019. The 2016 AMRP included data about beneficiary utilization and Medicaid-participating providers accepting new Medicaid patients from 2014 to 2015 (the most recent data available at the time the State was developing the AMRP), while the 2019 AMRP update included similar data for 2016 to 2017 (the most recent data then available). The 2019 AMRP showed that the number of Medicaid-participating providers accepting new Medicaid patients significantly dropped in 2016, and the State received a considerable number of public comments during the 30-day public comment period for the 2019 AMRP update prior to submission to us per the requirements in § 447.203(b) and (b)(2). This data lag between a drop in Medicaid-participating providers accepting new Medicaid patients in 2016 and CMS receiving the next AMRP update with information about related concerns in 2019 illustrates how the infrequency of the triennial due date for the AMRP updates could allow a potential access concern to develop without notice by the State or CMS in between the due dates of the ongoing AMRP updates. Although § 447.203(b)(7) previously required States to have ongoing mechanisms for beneficiary and provider input on access to care, and States are expected to promptly respond to concerns expressed through these mechanisms that cite specific access problems, beneficiaries and providers themselves may not be aware of even widespread access issues if such issues are not noticed before published data reveal them.

We also learned from our previous AMRP implementation experience that the timing of the ongoing AMRP submissions required by previous § 447.203(b)(5)(ii) and access reviews associated with rate reduction or restructuring SPA submissions required by § 447.203(b)(6) have led to confusion about the due date and scope of routine, ongoing AMRP updates and SPA-connected access review submissions, particularly when States were required to submit

access reviews within the 3-year period between AMRP updates when proposing a rate reduction or restructuring SPA, per the requirements in previous § 447.203(b)(6). For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in § 447.203(b)(1) through (5), then the State submitted a SPA that proposed to reduce provider payment rates for physical therapy services with an effective date of July 1, 2018, along with an access review for the affected service completed within the prior 12 months, consistent with the requirements in § 447.203(b)(6). The State's access review submission consisted of its 2016 AMRP submission, updated with data from the 12 months prior to this SPA submission, with the addition of physical therapy services for which the SPA proposed to reduce rates. Because the State submitted an updated version of its 2016 AMRP in 2018 in support of the SPA submission, the State was confused whether its next AMRP update submission was due in 2019 (3 years from 2016), or in 2021 (3 years from 2018). Based on the infrequency of a triennial due date for AMRP updates and the numerous instances of similar State confusion during the implementation process for the previous AMRPs, we identified that the triennial timeframe was insufficient for the proposed comparative payment rate analysis and payment rate disclosure.

As we considered a new timeframe for updates to the comparative payment rate analysis and payment rate disclosure to propose in this rulemaking, we initially considered proposing to require annual updates. However, we explained our belief that annual updates would add unnecessary administrative burden as annual updates would be too frequent because many States do not update their Medicaid fee schedule rates for the codes subject to the comparative payment rate analysis and payment rate disclosure on an annual basis. As proposed, the categories of services subject to the proposed comparative payment rate analysis and payment rate disclosure are for office-based visits and, in our experience, the Medicaid payment rates generally do not

change much over time due to the nature of an office visit.²⁸³ Office visits primarily include vital signs being taken and the time a patient meets with a physician or NPP; therefore, States would likely have a considerable amount of historical payment data for supporting the current payment rates for such services. Given the relatively stable nature of payment rates for office visits, our proposal aimed to help ensure the impact of the comparative payment rate analysis is maximized for ensuring compliance with section 1902(a)(30)(A) of the Act while minimizing unnecessary burden on States by holding all States to a proposed update frequency of 2 years to capture all Medicaid (and corresponding Medicare) payment rate changes.

As the proposed rule sought to reduce the amount of administrative burden from the previous AMRP process on States while also fulfilling our oversight responsibilities, we explained our belief that updating the comparative payment rate analysis and payment rate disclosure no less than every 2 years would achieve an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act. We noted our intent for the comparative payment rate analysis and payment rate disclosure States develop and publish to be time-sensitive and useful sources of information and analysis to help ensure compliance with section 1902(a)(30)(A) of the Act. If this proposal is finalized, we stated that both the comparative payment rate analysis and payment rate disclosure would provide the State, CMS, and other interested parties with cross-sectional data of Medicaid payment rates at various points in time. This data could be used to track Medicaid payment rates over time as a raw dollar amount and as a percentage of Medicare non-facility payment as established in the annual Medicare PFS final rule for a calendar year, as well as changes in the number of Medicaid-paid claims volume and number of Medicaid enrolled beneficiaries who receive a service over time. The availability of this data could be used to inform State policy

²⁸³ We acknowledged that Medicaid primary care payment increase, a provision in the Patient Protection and Affordable Care Act (ACA, Pub. L. 111-148, as amended), temporarily raised Medicaid physician fees for evaluation and management services (Current Procedural Terminology codes 99201–99499) and vaccine administration services and counseling related to children’s vaccines (Current Procedural Terminology codes 90460, 90461, and 90471–90474). This provision expired on December 31, 2014. <https://www.macpac.gov/wp-content/uploads/2015/03/An-Update-on-the-Medicaid-Primary-Care-Payment-Increase.pdf>.

changes, to compare payment rates across States, or for research on Medicaid payment rates and policies. While we noted our belief that the comparative payment rate analysis and payment rate disclosure would provide useful and actionable information to States, we explained that we did not want to overburden States with annual updates to the comparative payment rate analysis and payment rate disclosure. As we proposed to replace the previous triennial AMRP process with less administratively burdensome processes (payment rate transparency publication, comparative payment rate analysis, payment rate disclosure, and State analysis procedures for rate reductions and restructurings) for ensuring compliance with section 1902(a)(30)(A) of the Act, we stated our belief that annual updates to the comparative payment rate analysis and payment rate disclosure would negate at least a portion of the decrease in administrative burden from eliminating the previous AMRP process.

With careful consideration, we stated our belief that our proposal to require updates to the comparative payment rate analysis and payment rate disclosure to occur no less than every 2 years is reasonable. We noted our expectation that the proposed biennial publication requirement for the comparative payment rate analysis and payment rate disclosure after the initial publication date would be feasible for State agencies, provide a straightforward timeline for updates, limit unnecessary State burden, help ensure public payment rate transparency, and enable us to conduct required oversight. We solicited comments on the proposed timeframe for the initial publication and biennial update requirements for the comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(4).

Lastly, we also proposed in paragraph (b)(4) to require States to publish the comparative payment rate analysis and payment rate disclosure consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. Paragraph (b)(1) would require the website developed and maintained by the single State Agency to be accessible to the general public. We proposed States utilize the same website developed and maintained by the single State Agency to publish their Medicaid FFS payment rates and their comparative

payment rate analysis and payment rate disclosure. We solicited comments on the proposed required location for States to publish their comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(4).

In § 447.203(b)(5), we proposed a mechanism to ensure compliance with paragraphs (b)(1) through (b)(4). Specifically, we proposed that, if a State fails to comply with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of proposed § 447.203, including requirements for the time and manner of publication, that, under section 1904 of the Act and procedures set forth in regulations at 42 CFR part 430 subparts C and D, future grant awards may be reduced by the amount of FFP we estimate is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of proposed § 447.203 for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. We also proposed that unless otherwise prohibited by law, FFP for deferred expenditures would be released after the State has fully complied with all applicable requirements. We explained that this proposed enforcement mechanism is similar in structure to the mechanism that applies with respect to the Medicaid DSH reporting requirements in § 447.299(e), which specifies that State failure to comply with reporting requirements will lead to future grant award reductions in the amount of FFP CMS estimates is attributable to expenditures made for payments to the DSH hospitals as to which the State has not reported properly. We proposed this long-standing and effective enforcement mechanism because we believed it is proportionate and clear, and to remain consistent with other compliance actions we take for State non-compliance with statutory and regulatory requirements. We solicited comments on the proposed method for ensuring compliance with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements, as specified in proposed § 447.203(b)(5).

We received public comments on these proposed provisions. The following is a summary of the comments we received and our responses.

Comparative Payment Rate Analysis Comments and Responses

Comment: Among comments received on the comparative payment rate analysis, the majority of commenters generally supported the proposal to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain categories of services. These commenters specifically supported the proposed categories of services, comparing only base payment rates, breakdown of Medicaid payment rates by population (pediatric and adult), use of Medicare non-facility rates as a benchmark for comparing Medicaid rates, and number of Medicaid services as a data element in the comparative payment rate analysis. Commenters in support of the comparative payment rate analysis agreed with CMS that the analysis requirement would help to ensure necessary information, specifically Medicaid payment rates and the comparison to Medicare, is available to CMS for ensuring compliance with section 1902(a)(30)(A) of the Act and to interested parties for raising access to care concerns through public processes.

However, a couple of commenters expressed opposition to the proposed comparative payment rate analysis. Commenters in opposition stated the proposed comparative payment rate analysis requirements would be administratively burdensome on States and create challenges for States in benchmarking services to Medicare because Medicare uses a rate setting methodology that is different from each State's Medicaid program. These commenters expressed concerns about the burden associated with the comparative payment rate analysis, specifically about further burden on States that do not use the same procedure/diagnostics codes or same payment methodologies as Medicare, as well as data challenges to stratify State payment rates by population, provider type, and geographic location, and challenges of comparing community mental health center payment rates to the Medicare equivalent.

Response: We appreciate the commenters' support of the comparative payment rate

analysis at § 447.203(b)(3)(i). We are finalizing the comparative payment rate analysis provisions as proposed apart from some minor revisions that ensure clarity and consistent terminology throughout § 447.203(b), as well as update the name of “outpatient behavioral health services” to “outpatient mental health and substance use disorder services” and the compliance timeframe, as discussed earlier in this section. We list and describe the specific revisions we made to the regulatory language for the comparative payment rate analysis provision at § 447.203(b)(2) through (b)(5) at the end of this section of responses to comments.

We disagree with commenters regarding burden of the comparative payment rate analysis and challenges benchmarking services to Medicare. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters' concerns about State burden, we have described numerous flexibilities States have for compliance with this final rule. Specifically for the comparative payment rate analysis, States have flexibility to (1) utilize contractors or other third party websites to publish the payment rate transparency publication on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency's website as required in § 447.203(b)(1)(ii) of this final rule); and (2) for the requirement that States break down their payment rates by geographical location, as applicable, States have the flexibility to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. Additionally, we are providing an example list that defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were

in effect for CY 2023 and an illustrative example of a compliant comparative payment rate analysis (including to meet accessibility standards) through subregulatory guidance that we will issue prior to the effective date of this final rule.

We do not expect States to experience excessive burden or challenges in benchmarking services to Medicare because we will issue subregulatory guidance prior to the effective date of this final rule, including a hypothetical example list of the CMS-published list of E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023, where all codes on the CMS-published list of E/M CPT/HCPCS codes have an existing Medicare payment rate. By ensuring there is an existing Medicare payment rate for States to compare their Medicaid payment rate to and providing States with information about where and how to find the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year for these codes to include in their analysis (that is, through Excel file downloads of the Medicare PFS Relative Value Files),²⁸⁴ we do not expect States to face challenges with identifying the applicable Medicare benchmark rates.

Regarding States that do not use same procedure/diagnostics codes as Medicare, as described in the proposed rule, E/M CPT/HCPCS codes are comprised of primarily preventive services which are generally some of the most commonly billed codes in the U.S.,²⁸⁵ therefore, we do not believe there will be issues with States not using the same procedure/diagnostics codes as Medicare. However, we recognize that States may amend existing CPT/HCPCS codes with additional numbers or letters for processing in their own claims system. If a State does not use the exact code included in the CMS-published list of E/M CPT/HCPCS codes, then we expect the State to review the CMS-published list of E/M CPT/HCPCS codes and identify which of their codes are most comparable for purposes of the comparative payment rate analysis. We

²⁸⁴ 88 FR 27960 at 28012

²⁸⁵ 88 FR 27960 at 28009

anticipate States may need to review code descriptions as part of the process of identifying which codes on the CMS-published list of E/M CPT/HCPCS codes are comparable to the codes that States utilizes.

Regarding States that expect to experience challenges benchmarking services to Medicare because they do not use the same payment methodologies as Medicare, while Medicare and State Medicaid agencies may use different methodologies to determine the rate published on their fee schedules, the comparative payment rate analysis only requires the base Medicaid FFS fee schedule payment rates as published on the State's fee schedule and Medicare's rate as published on the PFS for a particular code to be published in the analysis. The methodology to determine the payment rate is not relevant to the comparative payment rate analysis, therefore, having different methodologies to determine the rate does not affect a States' ability to comply with the comparative payment rate analysis requirements. Under the comparative payment rate analysis requirements we are finalizing in this final rule, Medicare rates serve as a benchmark to which States will compare certain of their base Medicaid FFS fee schedule payment rates to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act.

Regarding commenters' concerns about data challenges to stratify State payment rates by population, provider type, and geographic location for the comparative payment rate analysis, we acknowledge that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we proposed and are finalizing language noting "if the rates vary" and "as applicable" in the regulatory text. Therefore, States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location will not need to list varied rates based on factors that the State does not use in its rates. For example, a State that pays different rates by population (pediatric and adult) but does not vary the rates by provider type or geographic location will list separate payment rates for services furnished to a pediatric and to an adult beneficiary, but will not list separate rates based

on provider type or geographical location. If the State pays a single Statewide payment rate for a single service, the State will only include the State's single Statewide payment rate in the comparative payment rate analysis. For States that do pay varied payment rates by population (pediatric and adult), provider type, and geographical location, in accordance with § 430.10 and given that States are the stewards of setting and maintaining Medicaid FFS payment rates, States are required to maintain sufficient records about current payment rates, including when payment rates vary, to enable them to meet the comparative payment rate analysis requirements of this final rule.

Regarding the commenter's concerns about comparing community mental health center payments to Medicare rates, we would like to clarify that mental health services provided in a facility-based setting, such as FQHC, RHC, CCBHC, or clinics (as defined in § 440.90) are excluded from the comparative payment rate analysis due to the challenges we expect States to face in disaggregating their rates (including PPS rates paid to FQHCs or RHCs which are often paid encounter, per visit, or provider-specific rates and all-inclusive per-visit rates, encounter rates, per visit rates, or provider-specific rates paid to clinics (as defined in § 440.90)) for comparison to Medicare, as discussed in the proposed rule.²⁸⁶

Comment: We received a comment requesting clarification about the entity responsible for publishing the comparative payment rate analysis.

Response: The State agency is required to publish a hyperlink where the comparative, as well as the payment rate disclosure and payment rate transparency publication, on the State Medicaid agency's website. As finalized in this rule, § 447.203(b)(3) requires that States' comparative payment rate analysis, as well as payment rate disclosure, must be published consistent with the publication requirements in paragraphs (b)(1) and (b)(1)(ii). Paragraph (b)(1) requires the State "...publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public." As discussed in an earlier response to

²⁸⁶ 88 FR 27960 at 28011-28012

comments in this section, this language has been revised from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. We continue to require that “[t]he website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency’s website.” in § 447.203(b)(1)(ii).

Comment: One commenter requested clarification regarding how the comparative payment rate analysis will be organized, particularly if the FFS rates included in the analysis would be organized by CPT code.

Response: As finalized by this rule, § 447.203(b)(3)(i) requires that “State[s] must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS...” As such, the publication is required to be organized at the CPT level. However, to the extent there are differences in a State’s rates based on population (pediatric and adult), provider type, and geographical location, the publication may need to have multiple CPT-level rate comparisons to account for each differing rate.

Comment: One commenter raised concerns regarding the accessibility of the comparative payment rate analysis due to the extensive amount of data, which may be overwhelming and difficult for individuals to understand, for example individuals with disabilities and those who use screen readers. The commenter recommended that CMS require the analysis and disclosure be contained in a designated website, rather than linked from the State Medicaid agency’s website to avoid creating potential confusion. They further recommended CMS require States include plain language descriptions of the published payment rate data to ensure the analysis is accessible for individuals with disabilities.

Response: We understand the concern that the amount of data in the analysis could prove overwhelming to some individuals. However, we believe it is important for these data to be

easily reached for those interested parties that are trying to locate it. Transparency, particularly the requirement that States must publicly publish their payment rates, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties. Therefore, as finalized in this rule, § 447.203(b)(1) requires the State “...publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.” As discussed in an earlier response to comments in this section, this language has been revised from what we originally proposed to permit States the flexibility to continue to utilize contractors and other third parties for developing and publishing their fee schedules on behalf of the State. We continue to require at § 447.203(b)(1)(ii) that the website where the State agency publishes its Medicaid FFS payment rates must be easily reached from a hyperlink on the State Medicaid agency’s website.

As described in the proposed rule, longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State’s website containing Medicaid FFS payment rate information. We invite States to reach out to CMS for technical guidance regarding compliance with the comparative payment rate analysis. We also encourage States to review the subregulatory guidance, which includes an example of what a compliant comparative payment rate analysis might look like, that will be issued prior to the effective date of this final rule.

Comment: A couple of commenters suggested that the proposed breakdown of the comparative payment rate analysis would result in an overwhelming volume of information for the average individual viewing the data. One commenter suggested requiring States to report the aggregate fee schedule rate, instead of breaking down a State’s payment rates by categories of services in addition to population, provider type and geographic location to ensure data is

accessible and meaningful to someone viewing the data.

Response: We understand the commenters' concerns about the potential for the comparative payment rate analysis to contain a large amount of information. However, the level of detail we are requiring will afford States, CMS, and the public the best opportunity to assess individual rates and how they might impact access to certain services. Our hope is that the requirements and guidance around the elements to include, and the consistency this will create across States, will make the data readily navigable and understandable, even though a high volume of information may need to be presented to account for the array of services subject to the comparative payment rate analysis requirement and the potential complexity of the State's payment rate structure.

We assume the commenter who suggested an aggregated fee schedule rate meant we should only require States publish a single Statewide payment rate or a calculated Statewide average Medicaid payment rate if they do have varying payment rates for a service by population (pediatric and adult), provider type, and/or geographic location. We are not adopting this suggestion because only requiring an aggregated fee schedule rate would lose the opportunity for States, CMS, and the public to contextualize payment rates and how they might be impacting access for different populations in different geographical areas, or for beneficiaries seeking services from particular provider types. However, we note that States have the flexibility to add an aggregated fee schedule rate in addition to breaking down a State's payment rates for a given service by population (pediatric and adult), provider type, and geographic location, as applicable, with their comparative payment rate analysis if they so choose. If a State utilizes this flexibility to include this or optional additional information, then required data elements in § 447.203(b)(2) through (3) must be listed first on the State's website to ensure the analysis presents payment rate information in a clear and accurate way, particularly for States that do pay varied rates based on population (pediatric and adult), provider type, and/or geographic location and opted to include an aggregated fee schedule rate (that is, a calculated Statewide average Medicaid payment rate).

The previous AMRP process established a transparent data-driven process to measure access to care in States; however, during the implementation period, we found that States produced varied AMRPs that were difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. With this final rule, we are focusing on payment rate transparency and streamlining information States are required to publish. Therefore, we expect the comparative payment rate analysis to be easier to understand and more consistent across States than the previous AMRPs.

Comment: A few commenters suggested narrowing the scope of the comparative payment rate analysis to a representative subset of services or commonly used services with a Medicare equivalent. On the other hand, one commenter stated that limiting the scope of the comparative payment rate analysis to E/M codes would not be adequate to meaningfully assess access to care for all services under the proposed categories of services.

Response: We appreciate the commenters' suggestions on the scope of the comparative payment rate analysis. Prior to the effective date of this final rule, we will issue subregulatory guidance, including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. The initial CMS-published list of the E/M CPT/HCPCS codes to be published no later than July 1, 2025, will contain a finite number of E/M CPT/HCPCS codes subject to the initial comparative payment rate analysis. While the commenters did not specify their recommendation for what a representative subset of services would include or how they would identify commonly provided services with a Medicare equivalent, we believe the criteria we used to select the E/M CPT/HCPCS codes for the comparative payment rate analysis²⁸⁷ fulfills these commenters' suggestion for a representative set of commonly provided services with Medicare payment rates for comparison. We believe the categories of services included in the rule (primary care services, obstetrical and gynecological

²⁸⁷ 88 FR 27960 at 28008

services, and outpatient mental health and substance use disorder services) are a representative subset of Medicaid services available to beneficiaries that are of great importance to overall beneficiary health, as described in the proposed rule.²⁸⁸ Additionally, E/M CPT/HCPCS codes are some of the most commonly billed codes and one of the criteria in the CMS-published list of the E/M CPT/HCPCS codes is that the Medicare PFS has a payment amount on the fee schedule, therefore, we believe our list of codes includes commonly used services with a Medicare equivalent payment rate.

Also as previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. For consistency, we are using the same description of Medicaid FFS fee schedule payment rates to describe the payment rates that need to be included in the comparative payment rate analysis in paragraph (b)(3)(ii)(B) of this section which would also consider bundled payment rates to be Medicaid FFS fee schedule payment rates for the purposes of the comparative payment rate analysis. We would also like to clarify that while prospective payment system rates for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are subject to the payment rate transparency publication, these rates are effectively excluded from the comparative payment rate analysis because of the criteria we discussed in the proposed rule that we used to identify which CPT/HCPCS codes would be subject to the analysis (that is, the code is classified as an E/M CPT/HCPCS code by the AMA CPT Editorial Panel and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate

²⁸⁸ 88 FR 27960 at 28003

analysis).²⁸⁹ Prospective payment system rates are generally used to pay for institutional services (for example, hospitals and nursing facilities) where E/M services are not provided. Prospective payment system rates are also not listed on the Medicare PFS because they do not pay for a single code, and therefore, they would not have a code or a payment rate on the PFS. Also, as discussed in an earlier response to comments, PPS rates for FQHCs and RHCs are not subject to the payment rate transparency publication requirement under § 447.203(b)(1). Rather than further broadening the services subject to the comparative payment rate analysis requirement, we want our initial focus of this rulemaking to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues.

We disagree with the commenter that our scope of services subject to the comparative payment rate analysis will not provide a meaningful assessment of access. To reemphasize, we believe this list of codes, including primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services, are critical medical services and of great importance to overall beneficiary health, as described in the proposed rule.²⁹⁰ We acknowledge that the code list is limited to services delivered in an ambulatory setting, such as a physician's office, and services that are paid a Medicaid FFS fee schedule rate within the meaning of this final rule. Therefore, the code list for the comparative payment rate analysis excludes services delivered in a facility setting and/or services States pay for using a prospective payment system, for example hospitals, nursing facilities, FQHCs, and RHCs; however, we believe these limitations are appropriate to balance administrative burden on States and our enforcement responsibilities. As previously discussed, we believe that asking States to

²⁸⁹ 88 FR 27960 at 28008.

²⁹⁰ 88 FR 27960 at 28003

disaggregate their prospective payment system rates for facility-based services to compare to Medicare's prospective payment system rates often would be challenging for States. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters suggested aligning the proposed categories of services with Medicaid service categories as defined in statute and regulation to minimize confusion and ambiguity about the services subject to the comparative payment rate analysis. Another commenter suggested, rather than requiring a specified set of services, that CMS require the comparative payment rate analysis based on the percentage of services paid for by the State (that is, each State would include the services they pay the most for in their Medicaid program).

Response: We understand commenters' concerns about possible confusion of the categories of services subject to the comparative payment rate analysis that do not align directly with a Medicaid services category. Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023. The initial CMS-published list of the E/M CPT/HCPCS codes actually subject to the comparative payment rate analysis will be published no later than July 1, 2025. We believe this list of codes will eliminate any confusion and ambiguity commenters expressed in response to the proposed rule because it will contain the actual E/M CPT/HCPCS codes subject to the initial comparative payment rate analysis. We will only be including codes that satisfy all the defined criteria set forth in this rule. This list will be updated every other year after 2025, that is, July 1, 2027, 2029, so on and so forth. We expect States to review the CMS-published list of the E/M

CPT/HCPCS codes to identify the base Medicaid FFS fee schedule payment rate as specified in § 447.203(b)(3)(i)(B) that is required to be included in the comparative payment rate analysis.

We are not adopting the commenter's suggestion to require the comparative payment rate analysis be based on the percentage of services paid for by the State (that is, each State would include the services they pay the most for in their Medicaid program), rather than requiring a specified set of services. In the comparative payment rate analysis, we are striving for consistency and comparability between States and Medicare, therefore, we have decided to require States use the same categories of services and CMS published list of E/M CPT/HCPCS codes for the analysis.

Comment: A couple of commenters suggested alternative terms for the categories of services in the proposed rule. One commenter recommended using the terms “substance use disorder and mental health services” in place of “behavioral health services” and requiring the comparative payment rate analysis include separate analyses for each condition. Another commenter suggested using gender-inclusive language such as “reproductive and sexual health services” in place of “obstetrical and gynecological services” as a category of services in the comparative payment rate analysis.

Response: We appreciate the commenters' suggestions. We understand and appreciate the commenter's request for further granularity in the comparative payment rate analysis by specifying “substance use disorder and mental health services” in place of “behavioral health services.” We have decided to revise the outpatient behavioral health services category of service in § 447.203(b)(2)(iii) and finalize it as “Outpatient mental health and substance use disorder services.” While this revision does not change the criteria used to identify the discrete codes included in the BETOS E/M family grouping and families and subfamilies for the CMS published list of E/M CPT/HCPCS subject to the comparative payment rate analysis, this revision does ensure this final rule is consistent with the services in the Managed Care final rule (as published elsewhere in this **Federal Register**) for consistency across Medicaid FFS and

managed care delivery systems and reflects a more granular level of service description as suggested by the commenter.

We agree with the importance of gender-inclusive language, where appropriate. However, current medical and procedural terminology generally still uses the terminology "obstetrical and gynecological services." We determined consistent language would provide interested parties the most clarity. Additionally, we selected obstetrical and gynecological services as a category of service due Medicaid's key role in providing and paying for maternity-related services for pregnant women during a maternal health crisis in the US.²⁹¹ We acknowledge that using the term "reproductive and sexual health services" would be inclusive of more services, that is, male reproductive services in addition to pregnancy and female reproductive services. However, if we were to utilize the term "reproductive and sexual health services" then this would expand the number of services that would be subject to comparative rate analysis and increase burden on States complying with the analysis. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Therefore, we are finalizing "obstetrical and gynecological services" as a category of service in § 447.203(b)(2)(ii) subject to the comparative payment rate analysis. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters raised concerns about inpatient behavioral health services not being a category of service in the comparative payment rate analysis. One of those commenters disagreed with CMS' justification that including inpatient behavioral health services

²⁹¹ 88 FR 27960 at 28004

would be duplicative of the information captured through UPL demonstrations because UPL demonstrations do not include the same level of analysis as proposed in the comparative payment rate analysis. In particular, the commenter stated that UPL demonstrations do not ensure hospital base payments are adequate, do not track if Medicaid payments align with Medicare payment rate increases, and the new supplemental payment reporting requirements established by the CAA, 2021 focus on supplemental payments, rather than base payments. Additionally, one commenter recommended that, if inpatient behavioral health services are not subject to the comparative payment rate analysis, CMS take alternative steps to assess access to inpatient behavioral health services, such as monitoring care transitions between inpatient and outpatient facilities during temporary or permanent transitions to inpatient care.

Response: We understand the commenters' concerns about excluding inpatient behavioral health services from the categories of services subject to the comparative payment rate analysis. We acknowledge the importance of inpatient behavioral health services in the spectrum of behavioral health services for which coverage is available under the Medicaid program. As discussed in the proposed rule, we recognize that Medicaid plays a crucial role in mental health care access as the single largest payer of these services with a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to mental health and substance use disorder services.²⁹² In this final rule, we are revising the outpatient behavioral health services category of service in § 447.203(b)(2)(iii) and finalizing it as "Outpatient mental health and substance use disorder services." While the scope of the comparative payment rate analysis requirement is limited to outpatient mental health and substance use disorder services, to the extent States pay for inpatient behavioral health services (including inpatient services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals) with a Medicaid FFS fee schedule payment rate that falls within the meaning of this rule, as discussed

²⁹² 88 FR 27960 at 28004

in an earlier response to comments in this section, then those payment rates would be subject to the payment rate transparency publication. In addition to subjecting certain inpatient behavioral health payment rates to the payment rate transparency publication requirement, we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual UPL demonstrations and supplemental payment reporting requirements under section 1903(bb) of the Act. We recognize UPL data are not an exact duplicate of the data required under the policies we are finalizing in this rule. With this final rule, our focus is on improving our oversight of Medicaid payment rates to identify where rates may be negatively impacting access to care while minimizing burden imposed on States, which requires us to prioritize areas of focus. Although the UPL and the supplemental payment reporting requirements under section 1903(bb) of the Act represent a different array of data, they still afford us an opportunity for payment oversight. Therefore, we chose to focus on services and rates not covered by those requirements.

We disagree with the commenter that UPL demonstrations do not ensure hospital base payments are adequate and do not track if Medicaid payments align with Medicare payment rate increases. We began requiring annual UPL demonstrations in 2013 to ensure CMS and States have a better understanding of the variables surrounding rate levels, supplemental payments and total providers participating in the Medicare and Medicaid programs and the funding supporting each of the payments subject to UPL demonstrations.²⁹³ UPL demonstrations are a comparison of total Medicaid payments for a particular benefit category to a reasonable estimate of what Medicare would have paid. Therefore, UPL demonstrations fundamentally track if Medicaid payments align with Medicare payment rates at an aggregate level and provide CMS with important information for assessing if payment rates comply with economy and efficiency provisions at section 1902(a)(30)(A) of the Act, specifically how total Medicaid payments compare to what Medicare would have paid for similar services where Medicare acts as a

²⁹³ <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf>.

payment limit, or ceiling, for economic and efficient. We do acknowledge that the new supplemental payment reporting requirements under section 1903(bb) of the Act focus on supplemental payments, rather than base payments; however, base payment data continues to be collected through UPL demonstrations, providing us, in the aggregate, with detailed information about both base and supplemental payments for hospitals.

Additionally, the comparative payment rate analysis utilizes Medicare rates as a benchmark to which States will compare their Medicaid FFS fee schedule payment rate to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. We are not requiring States to meet a threshold percentage of Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year or align with Medicare payment rate increases.

We acknowledge the commenter's request for CMS to take alternative steps to assess access to inpatient behavioral health services, such as monitoring care transitions between inpatient and outpatient facilities during temporary or permanent transitions to inpatient care. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate. We are committed to helping States and their providers undertake efforts to improve transitions and improve medical and LTSS coordination by providing technical assistance, resources, and facilitating the exchange of information about promising practices of high quality, high impact,

and effective care transition models and processes and we encourage States to review existing resources about improving care transitions on Medicaid.gov.²⁹⁴

Comment: Some commenters submitted comments about behavioral health services as a category of service in the comparative payment rate analysis. A few commenters suggested particular or additional categories of services for behavioral health services, including inpatient behavioral health services, substance use disorder services, mental health services, intensive outpatient services, partial hospitalization care, opioid treatment programs, services delivered by providers who do not bill E/M codes, and specialist services provided to individuals with chronic diseases and disabilities. These commenters also suggested including codes outside of the E/M category, such as “H” HCPCS codes that psychologists, social workers, and marriage and family therapists often bill to ensure a comprehensive analysis of behavioral health services in the comparative payment rate analysis.

Response: We appreciate commenters' suggestion for the comparative payment rate analysis. As stated previously, we are excluding inpatient behavioral health services because existing UPL and supplemental payment reporting requirements under section 1903(bb) of the Act provide for payment oversight for inpatient behavioral health services, and with the provisions of this final rule, we chose to focus on services and payment rates not covered by those requirements. Additionally, we are not considering behavioral health services, now called outpatient mental health and substance use disorder services in this final rule, outside the E/M category as suggested by commenters because E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. If we were to expand outside of E/M category of codes, then it is possible Medicare may not have rates established on the Medicare PFS for States to compare their base Medicaid FFS fee

²⁹⁴ <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/improving-care-transitions/index.html>.

schedule payment rates too in the comparative payment rate analysis. Based on the criteria used to narrow the scope of the comparative payment rate analysis, we are requiring that the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis as well as the code must be included in the BETOS Classification System which only includes Psychotherapy – Group and Psychotherapy – Nongroup (family) under the E/M (category), Behavioral Health Services (subcategory). Psychotherapy is a type of treatment, or service, that can help individuals experiencing a wide array of mental health conditions and emotional challenges, including substance use disorder and mental health.²⁹⁵ While the CMS published list of E/M CPT/HCPCS codes will not specifically include intensive outpatient services, partial hospitalization care, opioid treatment programs, services delivered by providers who do not bill E/M codes, specialist services provided to individuals with chronic diseases and disabilities, or H codes for Alcohol and Drug Abuse Treatment²⁹⁶ as suggested by commenters, we believe the services included on the CMS published list of E/M CPT/HCPCS codes are critical medical services and of great importance to overall beneficiary health, as described in the proposed rule.²⁹⁷ As previously discussed, the CMS published list of E/M CPT/HCPCS codes narrows the scope of the comparative payment rate analysis to selected services delivered in an ambulatory setting, such as a physician’s office, and services that are paid a Medicaid FFS fee schedule rate within the meaning of this final rule to balance administrative burden on States and our enforcement responsibilities. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters expressed concerns regarding the exclusion of

²⁹⁵ <https://www.psychiatry.org/patients-families/psychotherapy>.

²⁹⁶ <https://www.aapc.com/codes/hcpcs-codes-range/>.

²⁹⁷ 88 FR 27960 at 28003

facility-based services from the comparative payment rate analysis. These commenters requested CMS consider additional provisions for services that are delivered by facility-based providers, which are often paid via an encounter rate, reimbursement of actual cost, or cost-based payment methodologies. One commenter suggested requiring States that pay for behavioral health services using cost-based payment methodologies publish the provider's payment rate compared to provider's actual incurred cost because States are already collecting this information from providers as it is necessary for the State's cost-based payment methodology.

Response: We appreciate the commenter's suggestions. We assume by encounter rate that the commenters were referring more broadly to PPS rates paid to both institutional facilities, such as hospitals and nursing facilities which are often paid encounter or per diem rates, as well as non-institutional facilities, such as FQHCs or RHCs which are often paid encounter, per visit, or provider-specific rates, as discussed in detail in an earlier response to comments in this section. We did not propose and are not finalizing in this rule the requirement that States disaggregate each of their PPS rates (including encounter, per diem, per visit, and provider-specific rates) and services covered in each rate to compare to Medicare's prospective payment system rates when Medicare pays a prospective payment system rate for the same service. Likewise, we also did not propose and are not finalizing in this rule the requirement that States publish cost reports or provider's unique cost information when the State's methodology is reimbursement of actual cost or cost-based methodologies and services covered in the reimbursement methodology to compare to actual incurred cost. Therefore, any policies that require States to disaggregate each of their PPS rates and services covered in each PPS rate or publish cost reports or provider's unique cost information in order to compare to Medicare's prospective payment system rates or the commenter's suggestion to compare to actual incurred cost, would be challenging for States because we would require a different methodology, policies, and oversight relative to the comparative payment rate analysis, as discussed in the

proposed rule.²⁹⁸ As we are seeking an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act, requiring States to publish cost-based Medicaid payments as well as actual, incurred cost for each unique provider would impose more burden on States that was not accounted for in the proposed rule. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: Several commenters recommended changes to the analysis, such as additional categories of services or revisions to the proposed categories of services subject to the comparative payment rate analysis. While some commenters generally recommended expanding the categories of services, including all mandatory Medicaid services, other commenters recommended specific additional categories of services, provider types, or costs such as supplies. Those recommendations included: physician specialist services and specialty/specialist care (for example, cancer care); subspecialty services (for example, pediatric ophthalmology); services provided by NPPs; services delivered in clinics and other settings; prosthetic supplies (for example, ostomy and urological supplies), home health services (for example, homemaker and home health aide), sexual and reproductive health services (for example, midwives, doulas, providers who primarily serve the sexual and reproductive health needs of people assigned male at birth, etc.); dental and oral health services (including pediatric dentistry), ground emergency medical transportation services; cell and gene therapies; hospital and emergency department services; vaccine administration services; and habilitation and rehabilitation services provided by physical therapists. Commenters also suggested processes to add services when certain criteria are met, for example, adding any service to the comparative payment rate analysis when access concerns are raised or identified.

Response: We thank the commenters for the many recommendations for additional or

²⁹⁸ 88 FR 27960 at 28012.

alternate categories of service. In order to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same), we are finalizing this rule with a narrow scope of categories of services subject to the comparative payment rate analysis and not including additional categories of services suggested by commenters. As discussed in the proposed rule, we chose primary care services, obstetrical and gynecological services, and outpatient behavioral health services (which we are finalizing as outpatient mental health and substance use disorder services) because they are critical medical services and of great importance to overall beneficiary health.²⁹⁹ Primary care providers often deliver preventative health care services, write referrals or recommendations to schedule an appointment with physician specialists, and write orders for lab and x-ray services and prescriptions that a beneficiary would not be able to access without the primary care provider, therefore, access to a primary care provider is often a gateway to accessing other care. Obstetrical and gynecological providers and behavioral health providers also deliver preventive services respective to their field, such as well-woman visits and screenings for behavioral health conditions (such as alcohol disorders, anxiety, and eating disorders), respectively. As described in the proposed rule, the U.S. is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and mental health and substance use disorder services at the forefront.³⁰⁰

We clarify that we did propose to include in the comparative payment rate analysis a couple of the services commenters suggested: care delivered by NPPs, and sexual and reproductive health services (to the extent these are included within the category of obstetrical and gynecological services). If a State's base Medicaid FFS fee schedule payment rate varies by provider type for a particular code subject to the comparative payment rate analysis, then the

²⁹⁹ 88 FR 27960 at 28003

³⁰⁰ 88 FR 27960 at 28004.

payment rates must be separately identified by provider type, including, but not limited to, physician, nurse practitioner, and physician assistant, as specified in § 447.203(b)(3)(i)(B). While we are not including the broader category of sexual and reproductive health services, obstetrical and gynecological services are one of the categories of services subject to the analysis. Lastly, homemaker and home health aide services are subject to the payment rate disclosure, but not the comparative payment rate analysis because of a lack of comparable Medicare payment rate.

Finally, we are not including the following services suggested by commenters in the comparative payment rate analysis: services delivered in clinics and other settings (as the commenter did not specify, we assume the commenter meant settings similar to clinics (as defined in § 440.90)), sexual and reproductive health services (for example, midwives, doulas, providers who primarily serve the sexual and reproductive health needs of people assigned male at birth, etc.) to the extent these are not included within the category of obstetrical and gynecological services, hospital and emergency department services, and medical supplies. Our current access strategy focuses broadly on Medicaid FFS fee schedule payment rates for outpatient practitioner services. As described in the proposed rule, encounter rates (generally based on total facility-specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter) are typically paid to facilities, such as hospitals, FQHCs, RHCs, and clinics, and proposing States demonstrate the economy and efficiency of their encounter rates would be an entirely different exercise to the comparative payment rate analysis.³⁰¹ Therefore, we are not including services delivered in clinics and other settings (as the commenter did not specify, we assume the commenter meant settings similar to clinics (as defined in § 440.90)) or hospital and emergency department services in the comparative payment rate analysis. As previously stated, obstetrical and

³⁰¹ 88 FR 27960 at 28012.

gynecological services are one of the categories of services subject to the analysis, but we are not including the broader category of sexual and reproductive health services because our focus in this rule is ensuring access to care to services that can most directly respond to the maternal health crisis occurring the U.S. As Medicaid plays a key role in providing and paying for maternity-related services for pregnant women, obstetrical and gynecological services generally represent the services received before, during, and after pregnancy.³⁰² We note that one of the criteria used to narrow the CMS published list of E/M CPT/HCPCS codes requires that the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for obstetrics and gynecological services; this includes prostate cancer screenings (G0102). Additionally, our current access strategy focuses on Medicaid FFS fee schedule payment rates for the provision of outpatient practitioner services, rather than medical supplies.

We are also not including the suggestion to create processes to add services to the comparative payment rate analysis when certain criteria are met, for example, adding any service to the comparative payment rate analysis when access concerns are raised or identified, because these situations will generally trigger the processes in § 447.203(c) which include similar requirements to the comparative payment rate analysis (that is, requiring State publish or submit information to CMS about Medicaid payment rates, number of Medicaid beneficiaries receiving services, and number of Medicaid services furnished/paid claims). Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A few commenters submitted specific CPT/HCPCS codes and services for CMS' consideration when developing the CMS-published list of E/M CPT/HCPCS codes subject

³⁰² 88 FR 27960 at 28004.

to the comparative payment rate analysis. These codes and services included specific obstetric codes including surgical procedures billed by providers of obstetric-gynecological services, reproductive care codes, pediatric ophthalmology codes including surgical procedures and clinical evaluations, vaccine administration, and other E/M codes. We also received requests to require analysis of the most frequently billed surgical codes for obstetrical-gynecological services, as well as behavioral health services that do not have E/M codes or a Medicare analog.

Response: We appreciate the commenters' suggestions. Prior to the effective date of this final rule, we will issue subregulatory guidance including a hypothetical example list of the E/M CPT/HCPCS codes that would be subject to the comparative payment rate analysis, if the comparative rate analysis requirements were applicable with respect to payment rates in effect for CY 2023. This example list defines the categories of services subject to the comparative payment rate analysis through the finite number of E/M CPT/HCPCS codes in the list, if it were in effect for CY 2023. Several of the commenter's suggested codes are included in the example list; however, this list is subject to change when the first CMS-published list of the E/M CPT/HCPCS codes subject to the comparative payment rate analysis for CY 2025 is published no later than July 1, 2025. Of the specific codes suggested by commenters, we can confirm that the following codes would be included in the CMS published list of E/M CPT/HCPCS codes subject to the analysis, if it were in effect for CY 2023: CPT 59400 – 59612, 58300 – 58301, 59120 – 59160, 59812 - 59857, 99401 – 99404, 90832 – 90853, 90791 – 90792, 96158, and 96165. Because of the criteria outlined in the proposed rule intended to narrow the scope of codes subject to the comparative payment rate analysis, CPT 59852 and 59857, peer support services, psychosocial rehab, and assertive community treatment, as well as vaccine administration codes are excluded from the comparative payment rate analysis due to their classification outside of the BETOS Classification System as E/M codes that are primary care, obstetrical and gynecological services, or outpatient mental health and substance use disorder services. Additionally, pediatric ophthalmology surgical procedures and the top 10 surgical

codes billed by obstetrician-gynecologists to the Medicaid program are excluded from the analysis because one of the criteria used to narrow the scope of the comparative payment rate analysis was that for a code to be included on the CMS published list of E/M CPT/HCPCS codes, the code has to be included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule). E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. Therefore, we narrowed the scope of codes to just E/M codes and surgical codes fall outside of this scope. As described in the proposed rule, the following criteria were used to identify the E/M CPT/HCPCS codes to be included in the comparative payment rate analysis: the code is effective for the same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the AMA CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services (now called outpatient mental health and substance use disorder services in this final rule); and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established RVU and payment amount for the same time period of the comparative payment rate analysis. As discussed in an earlier response to comments in this section, the revision from outpatient behavioral services to outpatient mental health and substance use disorder services does not change the criteria used to identify the discrete codes included in the BETOS E/M family grouping and families and subfamilies for the CMS published list of E/M CPT/HCPCS subject to the comparative payment

rate analysis. While the payment rate transparency publication does not require a comparison to the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year, it does require transparency of Medicaid payment rates by requiring States publicly publish all Medicaid FFS fee schedule payment rates, which will often include a number of the services requested by commenters to be subject to the comparative payment rate analysis. Our primary goal with the payment rate transparency publication is ensuring Medicaid payment rates are publicly available in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A few commenters suggested additional data elements and analyses for the comparative payment rate analysis. A couple of commenters suggested data elements specifically for comparing FQHC and non-FQHC settings: number of primary care claims provided in FQHC and non-FQHC settings, number of patients served in FQHC and non-FQHC settings, total spending in FQHC and non-FQHC settings. Commenters also suggested data elements specifically for nursing facility payments, such as comparing payments to total cost of care, examining the relationship between payments and quality of care and health disparities in nursing facilities, and trend data on medical inflation and practice costs.

Response: We appreciate commenters' suggestions for the comparative payment rate analysis. As described in the proposed rule, we excluded encounter rates often paid for facility-based services, including FQHC and nursing facility services, from the comparative payment rate

analysis due to the challenges we expect States to face in disaggregating encounter rates for comparison to Medicare. While we are not adopting these suggestions, we note that States have the flexibility to add the elements described to their comparative payment rate analysis if they so choose. We would encourage any State choosing to disclose additional comparative payment rate analysis for facility-based services also to publish detailed information about the State's methodology for disaggregating its payment rates, as applicable, and identifying analogous Medicare payment rates for comparison.

Comment: We received a few comments in response to our consideration of requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We received one comment that opposed requiring the unique number of claims and beneficiaries while a few commenters encouraged CMS to require this data element to improve the collection and quality of data on Medicaid service utilization.

Response: We appreciate the commenters' feedback. As described in the proposed rule, we considered but did not propose requiring States to identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year.³⁰³ Upon further review, we determined the request regarding unique beneficiaries was inaccurately framed, as a beneficiary would not duplicate. Nevertheless, we decided not to require States to identify the number of **unique** Medicaid-paid claims (bold added to highlight the difference between data element we considered and the data element we are finalizing in this rule). Instead, we are finalizing the comparative payment rate analysis to require States to include the number of Medicaid-paid claims (which may duplicate codes) and the number of Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the base Medicaid FFS fee schedule payment rate is published

³⁰³ 88 FR 27960 at 28016.

pursuant to paragraph (b)(3)(i)(B) of this section, as proposed. Although we do see value in obtaining unique, or deduplicated, claims counts, we did not propose this data element because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. To illustrate, and to correct the example provided in the proposed rule, for a beneficiary with 6 visits to their primary care provider in a calendar year where the provider bills 6 claims with CPT code 99202 for the same beneficiary, the State is required to report 6 claims for CPT code 99202. The beneficiary count would remain 1. If 6 separate beneficiaries each received a service and the provider bills CPT code 99202 for all of them, the claims count would still be 6, but the beneficiary count would also be 6. Given that our access work is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule for any additional changes we may propose through future rulemaking.

Comment: One commenter recommended CMS allow States to have a 6-month period to account for lags in claims reporting by providers and States paying providers' claims for codes required to be in the comparative payment rate analysis.

Response: We believe the commenter was referring to the claims run out period where a State may not have received all of their providers' claims for the codes subject to the comparative payment rate analysis by the time the analysis is due, which could result in an undercount of both claims for services furnished and beneficiaries who received a service during the year. In response to comments and based on the timing of this final rule, we have revised the timeframes for the comparative payment rate analysis. The regulatory language finalized in this rule at paragraph (b)(4) now states the following, "[t]he State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates in effect as of July 1, 2025, as required under paragraphs (b)(2) and (3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the

second year following the most recent update.” Therefore, for the initial comparative payment rate analysis, States will need to include their claims and beneficiary data required in paragraph (b)(3)(i)(E) for CY 2025 in the analysis to be published no later than July 1, 2026. This timing provides a 6-month period for claims run out, as requested by the commenter.

Comment: One commenter raised concerns regarding the requirement to separately identify the base Medicaid FFS fee schedule payment rate by provider type without the inclusion of an additional analysis to assess whether the State’s rate setting process complies with the Mental Health Parity and Addiction Equity Act (MHPAEA or the Parity Act).

Response: CMS works closely with State Medicaid agencies to ensure compliance with MHPAEA in Medicaid managed care arrangements, Medicaid alternative benefit plans (managed care and FFS), and CHIP benefits (managed care and FFS) whenever changes to coverage of mental health or SUD benefits are proposed by States. Parity requirements do not apply to MH or SUD benefits for enrollees who receive only Medicaid non-ABP FFS State plan coverage; however, CMS encourages States to comply with parity for all Medicaid beneficiaries.^{304,305} Congress has not extended MHPAEA requirements to non-ABP Medicaid benefits provided solely through FFS delivery systems. Nonetheless, we encourage our State Medicaid agency partners to ensure their non-ABP FFS benefits voluntarily comply with MHPAEA. Moreover, CMS reviews State proposals regarding rate reductions or restructuring to ensure compliance with overarching requirements under section 1902(a)(30)(A) of the Social Security Act “to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.” This review thus helps promote the fundamental objective of MHPAEA to ensure access to mental health and substance use disorder treatment services.

³⁰⁴ <https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/parity/index.html>.

³⁰⁵ <https://www.medicaid.gov/sites/default/files/2023-09/cmcs-mental-health-parity-092023.pdf>.

Comment: One commenter requested clarification about the Medicare rate to be used in the comparative payment rate analysis.

Response: As finalized by this rule, § 447.203(b)(3)(i)(C) requires States to compare their base Medicaid FFS fee schedule payment rate to the Medicare non-facility payment rates as established in the annual Medicare PFS final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid FFS fee schedule payment rate, that correspond to the base Medicaid FFS fee schedule payment rate rates identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type. That is, States are required to compare their base Medicaid FFS fee schedule payment rates to the corresponding Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year. As described in the proposed rule, we expected States to source the Medicare non-facility payment rate as established in the annual Medicare PFS final rule for a calendar year from the published Medicare fee schedule amounts on the Medicare PFS through one or both of the following sources: the Physician Fee Schedule Look-Up Tool³⁰⁶ on *cms.gov* or Excel file downloads of the Medicare PFS Relative Value Files³⁰⁷ for the relevant calendar year from *cms.gov*. We acknowledge that the Physician Fee Schedule Look-Up Tool is a display tool that functions as a helpful aid for physicians and NPPs as a way to quickly look up PFS payment rates, but does not provide official payment rate information. While we encouraged States to begin sourcing Medicare non facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee Schedule Guide for instructions on using the Look-Up Tool in the proposed rule, we would like to clarify in this final rule that States should first by downloading and reviewing the Medicare PFS Relative Value with Conversion Factor File where States can find the necessary information for calculating Medicare non facility payment rates. Prior to the

³⁰⁶ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup>.

³⁰⁷ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files>.

effective date of this final rule, we will issue subregulatory guidance, which includes an instructional guide for identifying, downloading, and using the relevant Excel files for calculating the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year that States will need to include in their comparative payment rate analysis. Therefore, for the initial comparative payment rate analysis, after Medicare's publication of the CY 2025 Physician Fee Schedule rate by November 2024, we encourage States to begin sourcing Medicare non-facility payment rates as established in the annual Medicare PFS final rule for CY 2025 by downloading and reviewing the CY 2025 Medicare PFS Relative Value with Conversion Factor File from [cms.gov](https://www.cms.gov).³⁰⁸

Comment: While we received overwhelming support from commenters for proposing to use Medicare non-facility rates for comparison to Medicaid rates in the comparative payment rate analysis, some commenters expressed concerns or suggested alternative comparison points. Many commenters stated that Medicare payment rates are low and have not kept up with inflation; therefore, these commenters stated that Medicare is not an appropriate comparison point for payment rates for many services, including dental, anesthesiology, and physical therapy. Some commenters stated that there is limited comparability between Medicaid and Medicare due to the differences in coverage of services and populations (for example, Medicare's limited coverage of pediatric services, behavioral health services (including substance use disorder and mental health care), and dental care) which results in fundamentally different payment rate methodologies. A few commenters expressed that Medicare is not a perfect comparator and should not be used as the standard for adequacy of Medicaid payment rates, but agreed it was a useful starting place because Medicare rates are publicly available. One commenter stated that States aligning Medicaid payment rates with Medicare rates for psychiatrist services as well as decreasing administrative burden could help encourage more providers to enroll in Medicaid.

³⁰⁸ <https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files>.

Many commenters who opposed using Medicare non-facility rates for the comparative payment rate analysis offered alternative suggestions for States to compare their payment rates to. Several commenters suggested private payer rates. One commenter suggested Medicaid rates from geographically similar States that CMS identifies for States. A few commenters suggested rates from Federal or State employee dental plans. Two commenters suggested FAIR Health data³⁰⁹ (particularly for dental services). One commenter suggested Medicare Advantage for dental, vision, and hearing services. We also received a comment suggesting CMS develop an alternative to Medicare as a point of comparison in the comparative payment rate analysis, particularly for inpatient administered therapies that are paid using DRGs.

Response: We thank the commenters for their support of using the Medicare non-facility rates for comparison to Medicaid rates in the comparative payment rate analysis. We understand the commenters' concerns about using Medicare as a benchmark for Medicaid rates to be compared to in the comparative payment rate analysis; however, we do not agree that Medicare payment rates are low and have not kept up with inflation. As described in the proposed rule, Medicare PFS payment rates are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT),) using resource-based inputs to establish RVUs in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average.³¹⁰ The Medicare PFS is revised annually by CMS ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.³¹¹

With regard to commenters who raised concerns about using Medicare as a point of

³⁰⁹ We assume the commenter was referring to <https://www.fairhealth.org/>.

³¹⁰ 88 FR 27960 at 28012. Note this language has been revised for accuracy in this final rule,

³¹¹ <https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other>.

comparison, we disagree with the commenter that differences in coverage and populations limits comparability between Medicare and Medicaid in any way that would make Medicare an inappropriate comparator. As described in the proposed rule, Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year are utilized in this rule as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis.³¹² Medicare PFS payment rates simply serve as a point of comparison for CMS to consider in assessing if Medicaid payments are consistent with section 1902(a)(30)(A) of the Act. Differences in the methodology that Medicare uses and States use to determine their FFS fee schedule payment rates does not compromise the value of Medicare as a reliable benchmark for assessing payment rate sufficiency for enlisting providers to furnish services to an individual, as required by section 1902(a)(30)(A) of the Act. As described in the proposed rule, Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States, Medicare payment rates are publicly available, and broad provider acceptance of Medicare makes Medicare non-facility payment rates as established on the Medicare PFS for a calendar year an available and reliable comparison point for States to use in the comparative payment rate analysis.³¹³ Also as described in the proposed rule, base Medicaid FFS fee schedule payment rate are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors.³¹⁴ The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own fee schedules, typically determined based on market value or an internal process, and often do this in situations where

³¹² 88 FR 27960 at 28012.

³¹³ 88 FR 27960 at 28011.

³¹⁴ 88 FR 27960 at 28010.

there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. Again, one of the criteria for including codes on the CMS-published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis is that there must be a payment rate on the Medicare PFS so States have a Medicare payment rate to compare their Medicaid base payment to.

We also disagree with commenters that there is limited comparability between Medicaid and Medicare due to the differences in coverage of services and populations. We acknowledge that Medicare and Medicaid vary in terms of covered services and populations served; however, the Medicare PFS includes payment rates for covered, non-covered, and limited coverage services and applies the same resource-based formula to ensure all PFS rates are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. As described in the proposed rule, Medicare PFS non-facility rates serves as a reliable benchmark for assessing the level of payment sufficiency to enlist providers to furnish the relevant services to an individual for the following reasons.³¹⁵ As we have narrowed the scope of the comparative payment rate analysis to E/M CPT/HCPCS codes, Medicare PFS non-facility payment rates are comparable to Medicaid FFS fee schedule payment rates because both fee schedule rates are generally for services provided in a physician's office and specify the rate paid to a provider for delivering an individual service (that is, a single FFS payment for a single service, rather than an encounter rate paying for any number for services). The accessibility and consistent format of the published Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year makes these rates an available and reliable comparison point for States to use in the comparative payment rate analysis for the foreseeable future as the Medicare PFS is free to the public, updated on an annual basis, and posted online on an easily located website, relative to private payer rates that States would need to request access to and perhaps pay for the information. Medicare also has a low rate of physicians formally

³¹⁵ 88 FR 27960 at 28011.

opting out of the program, suggesting that Medicare's payment rates generally are consistent with a high level of physician willingness to furnish services to Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. Additionally, Medicare is another of the nation's large public health coverage programs which serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency.

We appreciate commenters' alternative suggestions to using Medicare as a benchmark in the comparative payment rate analysis; however, we are not incorporating these suggestions due to the following reasons. As discussed in the proposed rule, we learned from our implementation experience with the previous AMRP process that very few States were able to include even limited private payer data in their AMRPs due to the payment data being proprietary or unsound due to a lack of transparency about the construction of the payment data or because States did not have large private plans in their State so there were no private payer rates to compare to. This resulted in States being unable fully to comply with the previous AMRP regulations, to the extent they required an analysis that included private payer rate information.³¹⁶ Without this final rule, requiring States to compare their Medicaid rates to geographically similar States would not be possible because not all States currently post their Medicaid FFS fee schedule payment rates in a transparent and consistent format that would permit data analysis among States. While some States were able to compare their payment rates to other States' rates in their previous AMRPs, this was inconsistent across AMRPs and risked a subjective comparison where States selected which rates and States they compared themselves to. Requiring a comparison to Medicare ensures all States are using the same consistent data point to compare their rates to. Regarding the suggestion that CMS could identify the geographically similar States for States to compare their payment rates to, this would require a

³¹⁶ 88 FR 27960 at 28018.

different approach than what we proposed due to the variation across State Medicaid programs and would require careful consideration and policy development to ensure that any proposal would be consistent with the statutory requirement in section 1902(a)(30)(A) of the Act that looks to the “geographic area” in determining whether payment rates are sufficient. Similarly, we would also not require States compare their rates to rates from Federal or State employee dental plans because this information might not be generally available to State Medicaid agencies.

At this time and for the purposes of the comparative payment rate analysis, we are not advocating or requiring States source payment rate information from any particular data source other than the State’s own Medicaid agency (who is responsible for setting and paying the payment rates required in the analysis and, therefore has direct access to base Medicaid FFS fee schedule payment rates required in the analysis) and publicly available Medicare fee schedule rates (which we have previously described as an available and reliable comparison point for States to use in the comparative payment rate analysis). Therefore, we are not requiring States compare their rates to FAIR Health data because this data source is outside of the State agency and Medicare’s publicly available fee schedule rates. We would also not require States compare their rates to Medicare Advantage for dental, vision, and hearing services because these are not categories of services subject to the comparative payment rate analysis. As previously stated, only codes listed on the CMS-published list of E/M CPT/HCPCS codes are subject to the comparative payment rate analysis. The list does not include dental, anesthesiology, physical therapy, vision, and hearing services and these services, among others not on the CMS-published list of E/M CPT/HCPCS codes, are not subject to the comparative payment rate analysis requirement. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

For the previously stated reasons, we believe the Medicare payment rates for the categories of services subject to the comparative payment rate analysis are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. Therefore, we are finalizing this rule with the requirement that States use the Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year as the comparison point for States to compare their Medicaid payment rates to in the comparative payment rate analysis.

We would also like to clarify that the provisions in this final rule do not require States to change their payment rates, including requiring States to align their Medicaid payment rates with Medicare rates for psychiatrist services. Although we intend for States to consider the information produced for the payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure in an ongoing process of evaluating the State's payment rate sufficiency and when considering changing payment rates or methodologies (and we intend to make similar use of the information in performing our oversight activities and in making payment SPA approval decisions, for example), we did not propose and are not finalizing that any payment rate changes necessarily would be triggered by the proposed requirements.

Comment: Some commenters were concerned about how States would be expected to conduct the comparative payment rate analysis for services that Medicaid pays for, but Medicare does not. A few commenters suggested CMS develop a methodology for calculating a proxy rate for Medicaid services with no equivalent Medicare rate or Medicaid services that are provided very infrequently in Medicare, so Medicare rates are not a reliable comparison. Two commenters suggested working with MedPAC or MACPAC to set appropriate comparison points for services that are not covered by Medicare, for example contraceptive and pregnancy-related services.

Response: To clarify, only codes listed on the CMS-published list of E/M CPT/HCPCS codes are subject to the comparative payment rate analysis. All codes on this list have an

existing Medicare payment rate, therefore, the development of a proxy rate is unnecessary.

Codes outside of this list, including services that Medicaid pays for, but Medicare does not, are not subject to the comparative payment rate analysis requirement. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

We disagree with the commenter that Medicare rates are not a reliable comparison when services are provided infrequently to Medicare beneficiaries. As previously described, Medicare PFS payment rates are computed using a resource-based formula made up of three components of a procedure's RVU: physician work, practice expense, and malpractice as well as geographical differences in each locality area of the country.³¹⁷ The Medicare PFS is revised annually by CMS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.³¹⁸ Despite a service being covered and paid for infrequently by Medicare, the payment rates on the Medicare PFS are consistently updated with relevant data on a frequent, annual basis.

Comment: A few commenters suggested alternative update frequencies for the comparative payment rate analysis. Commenter suggestions included updates annually, every 3 years, and every 4 years. Commenters' justification ranged from more frequent than 2 years due to the need for timely publication of Medicaid data to less frequent to align with the State's existing rate study schedule or because they did not believe rates would change significantly during a 2-year period. Additionally, one commenter suggested CMS require States to document when rates have not changed between comparative payment rate analysis biennial publications.

Response: We are finalizing the payment rate transparency requirements, including the comparative payment rate analysis, with an applicability date of July 1, 2026; however, we are

³¹⁷ 88 FR 27960 at 28012

³¹⁸ <https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other>.

not changing the proposed timeframe of 2 years for States to update their publications. We believe requiring updates to the comparative payment rate analysis every 2 years balances State burden with maintaining up-to-date information. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: One commenter expressed concerns about cross walking a State's geographical areas to Medicare in the comparative payment rate analysis. The commenter stated that States may define a geographical region differently than Medicare and result in a complex and confusing analysis that would be contrary to CMS' transparency goals.

Response: As discussed in the proposed rule, we recognize that States that make Medicaid payment based on geographical location may not use the same locality areas as Medicare.³¹⁹ We expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as established in the annual Medicare PFS final rule in a calendar year in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. States could also calculate the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. While States

³¹⁹ 88 FR 27960 at 28013

have flexibility in mapping their geographical areas to Medicare's for the comparative payment rate analysis, we invite States to reach out to CMS for technical assistance.

Comment: A few commenters stated that other factors besides rates impact access to care. Commenters suggested CMS consider regional cost differences, provider shortages (including number of providers and their location), and the unique needs of specific populations (such as dually eligible beneficiaries, or beneficiaries in rural areas of a State) as factors that impact access to care.

Response: We agree with commenters that other factors besides rates impact access to care.³²⁰ After considering feedback received from States and other interested parties about the previous AMRP process issued through the 2015 final rule with comment period, as well as our obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we are finalizing a streamlined and standardized process to assess access to care that focuses on payment rate transparency. Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: A couple of commenters expressed concerns regarding the privacy of beneficiary information when it comes to the requirement that the comparative payment rate analysis and payment rate disclosure must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service. Commenters suggested CMS provide an exception when the volume of claims or beneficiaries is small.

Response: We take privacy and our obligations to protect beneficiary information very seriously. We remind States of their obligations to comply with applicable Federal and State privacy laws with respect to such information, such as the HIPAA Privacy Rule and Federal Medicaid requirements in section 1902(a)(7) of the Social Security Act and 42 CFR part 431,

³²⁰ 88 FR 27960 at 28016-28017.

subpart F. We are not requiring States to publish any beneficiary-identifiable information in the comparative payment rate analysis or payment rate disclosure. We expect States will ensure that any claims and Medicaid beneficiary data made publicly available under these requirements have been de-identified in accordance with the HIPAA Privacy Rule at 45 CFR 164.514(b).

We strongly encourage States to have policies to ensure that all information, particularly claims and beneficiary data, published in their comparative payment rate analysis and payment rate disclosure is de-identified prior to publishing on July 1, 2026. Such policies should address circumstances in which the number of Medicaid-paid claims and/or Medicaid enrolled beneficiaries is small. For example, States may consider implementing a small cell size suppression policy for publishing data on the State's website, similar to CMS' cell size suppression policy that no cell (for example, admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly.³²¹ We invite States to reach out to CMS regarding any data privacy concerns that may impact a States' compliance with the comparative payment rate analysis or payment rate disclosure requirements.

Additionally, to address privacy concerns at the individual level, we would like to share the following resources for filing civil rights and HIPAA complaints with the Office for Civil Rights:

- Filing a civil rights complaint;³²² and
- Filing a health information privacy or security complaint.³²³

Comment: A commenter raised concerns that the comparative payment rate analysis would incentivize States to raise payment rates for the categories of services subject to the analysis, but might also lead or contribute to rate cuts for other services, since the proposed rule would not provide that States may not cut some rates to make funds available to raise other rates.

Response: We understand the commenter's concerns about the effects of the comparative

³²¹ <https://resdac.org/articles/cms-cell-size-suppression-policy>

³²² <https://www.hhs.gov/civil-rights/filing-a-complaint/index.html>.

³²³ <https://www.hhs.gov/hipaa/filing-a-complaint/complaint-process/index.html>.

payment rate analysis in practice. We emphasize that the comparative payment rate analysis will afford more transparency to CMS and the public about rates for primary care, obstetrical and gynecological, and outpatient mental health and substance use disorder services, and will also provide States with an opportunity to identify where existing rates could create an access issue for the services subject to the comparative payment rate analysis requirement. If a State chooses to raise payment rates for the categories of services subject to the analysis, and in order to do so seeks to reduce rates for other services, then the State would be required to follow the State Analysis Procedures for Rate Reduction or Restructuring in § 447.203(c) to ensure the proposed rate reductions do not reduce access to care to the services for which payment rates would be reduced below the statutory standard. A public input process to raise access concerns with States is described in § 447.203(c)(4) of this final rule. We are confident our policies finalized in this rule will work in conjunction with each other to ensure ongoing and improved access to care.

Comment: A couple of commenters requested clarification regarding the circumstance whereby a comparative payment rate analysis reveals that a State's Medicaid payment rates are significantly below Medicare rates. One commenter suggested requiring States to submit a corrective action plan in those instances.

Response: Transparency, particularly the requirement that States must publicly publish their payment rates and compare their payment rates to Medicare, helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We intend to utilize the information published by States in their payment rate transparency publication and comparative payment rate analysis whenever the provisions of § 447.203(c) are invoked, when a State submits a SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access. We did not propose and are not requiring States to submit a corrective action plan when

Medicaid payment rates included in the comparative payment rate analysis are lower than Medicare payment rates. While the results of a comparative payment rate analysis would not themselves require a corrective action plan, § 447.203(c)(5) does require a State to submit a corrective action plan to remedy an access deficiency within 90 days from when it is identified to the State.

Comment: One commenter requested that CMS make UPL demonstration data and methodologies publicly available for purposes of data analysis, particularly for inpatient behavioral health services as CMS did not propose to include these services in the comparative payment rate analysis.

Response: While the comparative payment rate analysis is limited in scope to base Medicaid FFS fee schedule payment rates, the payment rate transparency publication does include PPS rates that are considered fee schedules payment rates within the meaning of this final rule, including for inpatient hospital, outpatient hospital, and nursing facility services. The PPS rates, which are generally the base payment for these services, and reported through UPLs, will be publicly available through the payment rate transparency publication. We acknowledge that supplemental payments as well as UPL data and methodologies typically are not publicly available currently. Nevertheless, UPL demonstrations provide us with an opportunity for payment oversight and we consider UPL demonstrations in assessing State compliance with the access requirement in section 1902(a)(30)(A) of the Act.³²⁴ As previously discussed in an earlier response to comments, we stated that UPL demonstrations provide CMS with important information for assessing if payment rates comply with economy and efficiency provisions at section 1902(a)(30)(A) of the Act, specifically how total Medicaid payments compare to what Medicare would have paid for similar services where Medicare acts as a payment limit, or ceiling, for economic and efficient. Requiring supplemental payments as well as UPL data and methodologies be publicly available would contribute to our transparency efforts; however, the

³²⁴ 88 FR 27960 at 28006

current reporting format of UPL data would not align with § 447.203(b)(1)(iii) which requires Medicaid FFS fee schedule payment rates be published and organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service. Therefore, we would need to develop a different methodology, policies, and oversight than what is being finalized in this rule to ensure UPL data is transparent. With this final rule, our focus is on improving our oversight of Medicaid payment rates to identify where rates may be negatively impacting access to care while minimizing burden imposed on States, which requires us to prioritize areas of focus. We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring the data required under this final rule are available to beneficiaries, providers, CMS, and other interested parties for the purpose of assessing access to care issues.

Payment Rate Disclosure Comments and Responses

Comment: We received general support for our proposal to require States to develop and publish a payment rate disclosure for certain HCBS. Commenters specifically expressed support for the proposed categories of services and calculation of the average hourly payment rate.

However, a couple of comments expressed opposition of the payment rate disclosure provision. Commenters in opposition stated the proposed payment rate disclosure requirements would be administratively burdensome for States and that it was unclear how calculating an average hourly payment rate along with publishing data about claims and beneficiaries would be valuable and informative for payment policy purposes.

Response: We appreciate the commenters' support of the payment rate disclosure provision at § 447.203(b)(3)(ii). We are finalizing the payment rate disclosure provisions with an additional category of service, habilitation, a few minor revisions for clarification purposes and consistent terminology usage within § 447.203(b), and an update to the compliance timeframe, the latter of which was discussed earlier in this section. The addition of habilitation

services to the payment rate disclosure is further discussed in a later response to comments in this section. In this final rule, we are revising the regulatory language to clarify which services and payment rates are subject to this requirement. We proposed in § 447.203(b)(3)(ii) that the State would be required to publish the “average hourly payment rate, separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary” for each category of service specified in paragraph (b)(2)(iv). We are finalizing in § 447.203(b)(3)(ii) that States are required to publish the “average hourly **Medicaid fee-for-service fee schedule** payment rates, separately identified for payments made to individual providers and **provider agencies**, if the rates vary.” (new language identified in bold). We proposed in § 447.203(b)(3)(ii)(B) that the State would be required to “identify the average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable.” We are finalizing in § 447.203(b)(3)(ii)(B) that the States are required to “identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs**, as applicable.” (new language identified in bold). For clarification and consistent terminology usage of “Medicaid fee-for-service fee schedule payment rates,” similar revisions were made in § 447.203(b)(2)(iv) and (b)(3)(ii)(B) and (C) and described in detail at the end of responses to comments in this section. We utilized the term “average hourly Medicaid fee-for-service fee schedule payment rates” in the payment rate disclosure for consistency throughout § 447.203(b) where the term Medicaid FFS fee schedule payment rates is used to describe what payment rates are subject to the payment rate transparency publication in § 447.203(b)(1)(i). Additionally, we

are incorporating the term “provider agencies” for clarification purposes to more accurately reflect what payment rate we are requiring be published. Lastly, we added the requirement that payments that include facility-related costs must be separately identified to ensure transparency of payment rates that may differ due to the inclusion of facility-related costs. Additional information about these regulatory language changes is discussed in later responses to comments in this section.

We disagree with the commenters regarding administrative burden of the payment rate disclosure. As documented in section III. of this final rule, the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties’ advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), are expected to result in a net burden reduction on States compared to the previous AMRP requirements. Additionally, as addressed in another comment response generally discussing commenters’ concerns about State burden, we have described numerous flexibilities States will have for compliance with this final rule. Specifically for the payment rate disclosure, and as discussed in a later response to comments, States have flexibility to (1) utilize contractors or other third party websites to publish the payment rate disclosure on (however, we remind States that they are still requiring to publish the hyperlink to the website where the publication is located on the State Medicaid agency’s website as required in § 447.203(b)(1)(ii) of this final rule), (2) format and organize the payment rate disclosure how they chose (that is, we are not requiring certain codes be included as required in the comparative payment rate analysis) (however, we remind States that the disclosure is still subject to the publication requirements described in proposed paragraphs (b)(1) and (b)(1)(ii) for payment rate transparency data), and (3) calculate the average hourly Medicaid FFS fee schedule payment rate as a simple average or arithmetic mean where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates, rather than a weighted

average which would impose more burden on States to calculate. Additionally, we are providing an illustrative example of a compliant payment rate disclosure (including to meet accessibility standards) through subregulatory guidance that we will issue prior to the effective date of this final rule.

We are not identifying codes for the categories of services subject to the payment rate disclosure. We are providing States with flexibility in determining which codes to include in the calculated average hourly Medicaid FFS fee schedule payment rate for the payment rate disclosure because States may use a wide variety of codes to bill and pay for personal care, home health aide, homemaker, and habilitation services, such as HCPCS codes T1019-T1022 and/or CPT codes 99500- 99602. For example, HCPCS codes T1019-T1022 for home health services includes T1019 (personal care services that are part of the individualized plan of treatment, per 15 minutes), T1020 (personal care services that are part of the individualized plan of treatment, per diem), T1021 (home health aide or certified nurse assistant, per visit), and T1022 (contracted home health agency services, all services provided under contract, per day). One State may use T1019 or T1020 depending on the unit (daily or per diem), a second State may only use T1021, and a third State may use none of these codes. We expect States to review their Medicaid FFS fee schedule payment rates for the payment rate and unit the State uses to pay for each of category of service and calculate the Medicaid average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, separately by service and provider employment structure as well as for payments that include facility-related costs, as provided in this final rule and discussed in later responses to comments in this section.

Additionally, the list of possible codes States may pay for personal care, home health aide, homemaker, and habilitation services is already limited by the available CPT/HCPCS codes, so we did not see a need to narrow the codes with a CMS-published list of E/M CPT/HCPCS like the comparative payment rate analysis. As previously discussed, we recognize

that States may amend existing CPT/HCPCS codes with additional numbers or letters for processing in their own claims system. If a State does not use CPT or HCPCS codes as published by AMA and CMS, then we expect the State to review the published lists of CPT or HCPCS codes and identify which of their codes are most comparable for purposes of the payment rate disclosure. We anticipate States may need to review code descriptions of CPT and HCPCS codes for personal care, home health aide, homemaker, and habilitation services as part of the process of identifying which CPT and HCPCS codes are comparable to the codes that States utilizes. We want to ensure the full scope of personal care, home health aide, homemaker, and habilitation services, and providers of these services, are included in the payment rate disclosure for transparency purposes, rather than narrowing the scope to certain codes and/or provider types, which would result in a limited disclosure of provider payment rates.

Regarding commenters that were unclear how calculating an average hourly payment rate along with publishing data about claims and beneficiaries would be valuable and informative for payment policy purposes, we are requiring States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). Calculating an average hourly Medicaid FFS fee schedule payment rate for categories of services subject to the payment rate disclosure will ensure a standardized unit and permit States, CMS, and other interested parties to compare payment rates among State Medicaid programs. As discussed in the proposed rule, HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we are proposing a different disclosure of payment rates for providers of these services that does not involve a comparison to Medicare.

Additionally, private payer data and self-pay data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Because

HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS that is covered by a third-party payer.³²⁵

Comment: Some commenters requested CMS clarify and add to the proposed categories of services included in the payment rate disclosure requirements. A few commenters requested clarification regarding whether services covered under waiver authority or State plan authority are subject to the disclosure requirements. A couple of commenters suggested adding regulatory language to explicitly include services provided through State plan and waiver authority in the payment rate disclosure. Another couple of commenters requested clarification specifically about self-directed services when an individual has budget authority and residential services. A few commenters encouraged CMS to require States to report payment rate variations by populations served (that is, populations receiving services under a waiver versus State plan authority) due to States varying rates for the same service furnished to different targeted populations under different coverage authorities.

A few commenters recommended additional categories of services to the proposed categories of services subject to the payment rate disclosure. While some commenters recommended expanding the categories of services generally, a number of commenters specifically recommended expanding the categories of service to include habilitation services (including residential habilitation services, day habilitation services, and home-based habilitation services).

Response: Personal care, home health aide, homemaker, and habilitation services provided under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority are subject to the payment rate disclosure described in § 447.203(b)(3)(ii). We are clarifying that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k)

³²⁵ 88 FR 27960 at 28019

State plan services included in this final rule, apply to such services included in approved section 1115 demonstration projects, unless we explicitly waive or identify as not applicable one or more of the requirements as part of the approval of the demonstration project. Please see section II.B for additional information on the inclusion of section 1115 demonstrations under the provisions of this final rule. While we appreciate the commenters' suggestion to add regulatory language to explicitly include services provided through State plan and waiver authority in the payment rate disclosure, we are not incorporating this suggestion as we previously provided clarification on which authorities are subject to the disclosure.

As previously discussed, self-directed services delivery models under which an individual beneficiary has budget authority do not constitute a fee schedule payment methodology for purposes of the payment rate transparency publication requirement, as well as the payment rate disclosure. Generally, under such self-directed services delivery models, the individual beneficiary determines a reasonable payment rate for the service in the State-authorized budget for that beneficiary. As such, these types of payment rates are excluded from the disclosure requirement. Regarding commenters' request for clarification about residential services being subject to the disclosure, as discussed in a later response to comments, personal care, home health aide, homemaker, and habilitation services, are inherently delivered in a home or community setting, outside of an institutional or residential facility. However, we acknowledge that the addition of habilitation services to the disclosure would now include residential habilitation services and we further address this in the later portion of this comment response.

We appreciate commenters' suggestion to require States report payment rate variations by populations served (that is, populations receiving services under a waiver versus State plan authority). However, that level of detailed reporting is beyond the scope of what we are seeking to implement in this current rulemaking, and would represent additional burden to States. We are requiring States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by

various factors that we believe will provide beneficial insights into these rates.

As stated in the proposed rule, we intend to standardize data and monitoring across service delivery systems with the goal of improving access to care, to the extent possible, and particularly for the payment rate disclosure requirements in § 447.203(b)(2)(iv) and (3)(ii), we intend to remain consistent with the HCBS provisions we are finalizing at § 441.311(d)(2) and (e).³²⁶ Given the addition of habilitation services to these HCBS provisions in this final rule as well as the Managed Care final rule (as published elsewhere in this **Federal Register**) provisions at § 438.207(b)(3)(ii) and after consideration of comments, we are adding habilitation services, including residential habilitation, day habilitation, and home-based habilitation services, to the payment rate disclosure requirements in § 447.203(b)(2)(iv) and (3)(ii). Specifically, the regulatory language finalized in this rule at § 447.203(b)(2)(iv) requires States to publish the average hourly Medicaid FFS payment rate for personal care, home health aide, homemaker, and habilitation services, as specified in § 440.180(b)(2) through (4) and (6) in the payment rate disclosure. We note that § 447.203(b)(2)(iv) refers to “habilitation” services, without distinguishing between residential habilitation services, day habilitation services, and home-based habilitation services. As previously discussed in section II.B., these categories will be further described in subregulatory guidance. As discussed in a later response to comments in this section, we also adding a requirement in the payment rate disclosure that States must separately identify the Medicaid FFS fee schedule payment rates for services that include facility-related costs. We believe this distinction will generally only arise for habilitation service rates, but we are applying it across all four service categories to remain consistent with the amended provisions at § 441.311(e)(2), and for consistency in reporting across all four services within the payment rate disclosure.

As discussed in the proposed rule, we initially proposed to include in the payment rate disclosure requirement only personal care, home health aide, and homemaker services because

³²⁶ 88 FR 27960 at 28005.

they are most commonly conducted in beneficiaries' homes and general community settings and, therefore, constituted the majority of FFS payments for direct care workers delivering services under FFS.³²⁷ However, and as previously stated, we agree with commenters' recommendation that the payment rate disclosure should include payment rates for habilitation services. As such, and to remain consistent with the HCBS provisions at § 441.311(d)(2) and (e) finalized in this rule, we are adding habilitation services as a category of service subject to the payment rate disclosure.

We acknowledge that habilitation services are also generally high-volume, high-cost services particularly in States where individuals with intellectual or developmental disabilities receive personal care services through habilitation. In other words, we acknowledge that some States design the delivery of and payment rates for habilitation services to include personal care services in these instances. If we were to exclude habilitation services from the payment rate disclosure provisions, then we would effectively exclude an important component of personal care services provided to individuals with intellectual or developmental disabilities from the payment rate disclosure, which would not align with our intent to ensure transparency of payment rates of personal care services within this provision. In instances where States combine the delivery and payment of habilitation services with personal care services, requiring reporting on both services supports our goal of enhancing the transparency of payment rates that support the delivery of personal care services while accommodating the potential variation in classification a State utilizes. We want to note a State has the option to indicate when a habilitation service rate includes personal care services or otherwise provide further data nuances while meeting the requirements of this final rule. In addition, this change provides clarity to States that might have reported on habilitation services under the personal care category of services in the payment rate disclosure were it not for this revision to the disclosure. Given the variation in how States deliver and pay for habilitation services, separately identifying

³²⁷ 88 FR 27960 at 28005.

habilitation as a category of service supports our payment rate transparency goals to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

As previously discussed in detail in an earlier response to comments in section II. of this final rule, including habilitation services in HCBS reporting requirements at § 441.311(d)(2) and (e), as well as the payment rate disclosure at § 447.203(b)(2) and (3)(ii), will ensure that services of particular importance to certain beneficiary populations, namely individuals with intellectual or developmental disabilities, are not excluded from our efforts to promote payment rate transparency in the interest of ensuring adequate access to care. As previously stated, in accordance with commenters' recommendation, and to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) as stated in the proposed rule,³²⁸ we are adding habilitation services to the payment rate disclosure to ensure transparency of rates that disproportionately affect access to services required by a unique population, individuals with intellectual or developmental disabilities.

Comment: A few commenters expressed concern over certain terms used in the proposed rule. Two commenters noted the terms “rates,” “payments,” “wage,” and “compensation” were used throughout the rule and were concerned about potential confusion about complying with the payment rate disclosure with the terms not clearly defined. One commenter was concerned the payment rate disclosure required States to request detailed financial records and information from provider organizations/agencies, which are often private businesses. Another couple of commenters requested a Federal-level definition or description of “provider type” and “geographical location” in the context of the payment rate disclosure.

Response: The payment rate disclosure requires States to separately identify the average

³²⁸ 88 FR 27960 at 28005.

hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). We are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable. In section II.C. of this final rule, wage is only mentioned while summarizing comments received on the February 2022 RFI.³²⁹ Likewise, compensation is only mentioned in section II.C. of this final rule while describing the difference between individual providers and provider agencies and when requesting public comments on whether we should have proposed a provision similar to the HCBS provisions we proposed at § 441.302(k)(3)(i) (where we proposed to require at least 80 percent of all Medicaid FFS payments for certain services be spent on compensation for direct care workers). Therefore, we are not requiring that States collect wage or compensation (including benefits) information from provider agencies to publish information about the compensation that the provider agency pays to its employee in the payment rate disclosure provisions at § 447.203(b)(3)(ii). We consistently used average hourly payment rate to refer to the payment rate that States are required to publish in the payment rate disclosure. As finalized in this rule, we are replacing the term “average hourly payment rate” with “average hourly Medicaid FFS fee schedule payment rate” for clarity and consistency throughout § 447.203(b).

We are not specifying a Federal definition for provider type because of the variety of provider types a State could license and pay for delivering Medicaid services. States are responsible for licensing providers in their State and have the flexibility to license a wide variety

³²⁹ Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf>.

of provider types for personal care, home health aide, homemaker, and habilitation services, including, but not limited to, personal care attendants, home health aides, certified nursing assistants, or registered nurses. We would like to ensure the full scope of providers of personal care, home health aide, homemaker, and habilitation services across States are included in the payment rate disclosure for transparency purposes.

Finally, we also are not providing a Federal definition of geographical location. Because the payment rate disclosure does not involve a comparison to Medicare (or other payer), the data need only reflect the State's specific circumstances. Different States have different methods of assigning payment rates to particular regions and are therefore best situated to determine how rates must reflect their State-determined geographical designations.

Comment: A few commenters requested clarification regarding what CMS meant by "individual providers" and "providers employed by an agency" in the payment rate disclosure. Commenters were generally unsure if States are required to publish the average hourly payment rate paid to the agency or the compensation the agency pays to its employee. One commenter requested clarification on what CMS considers "payments made to individual providers" and "payments made...to providers employed by an agency." Another commenter noted an example where agencies have multiple direct care workers as employees and was unsure from the language in the proposed rule ("providers employed by agency") what CMS considered to be the payment rate, either total compensation (including benefits) divided by total hours, or the hourly base wage of the direct care workers. One commenter specifically noted the use of the terms "direct care worker" and "provider" are both used in 42 CFR 447.203(b)(3)(ii) and stated these terms are often misaligned. The commenter explains that "direct care worker" or "home care worker" refers to personal care aides and home health aides, who provide hands-on services to those in need while "providers" are the agencies that employ direct care workers, train and screen them (health status and background checks), supervise them, schedule their services, reimburse their travel expenses, and support their professional development as well as liaise with

service recipients and their families, handle all service billing, prepare for and respond to emergencies, and ensure day-to-day compliance with State and Federal standards.

Response: We appreciate the commenters' examples to illustrate the requested areas of clarification in the rule. As previously stated, in this final rule, we are revising the language "to providers employed by an agency" in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) and finalizing the language as "provider agencies" for clarification purposes to more accurately reflect what payment rate we are requiring be published which is discussed shortly in this response to comments. To clarify, in the payment rate disclosure, we are requiring States to calculate and publish the average hourly Medicaid FFS fee schedule payment rate that States pay to individual providers and provider agencies, if the rates vary, and for payments that include facility-related costs. As described in the proposed rule and this final rule, individual providers in the context of the payment rate disclosure at § 447.203(b)(3)(ii) refers to individuals that are direct care workers and often self-employed or contract directly with the State to deliver services as a Medicaid provide; additionally, the individual provider bills the States directly and is paid directly by the State for services provided. To clarify, individual providers does not refer to providers delivering services through self-directed models with service budget authorized under 42 CFR 441.545, as these are not considered Medicaid FFS fee schedule payment rates for the purposes of the payment rate transparency publication, as well as the payment rate disclosure at § 447.203(b)(3)(ii), which was discussed in an earlier response to commenters.

Provider agency in the context of the payment rate disclosure at § 447.203(b)(3)(ii) refers to the agency contracted or enrolled with the State to deliver Medicaid services and the agency in turn employs or contracts with direct care workers as employees of the agency that works directly with the Medicaid agency to provide Medicaid services; additionally, the agency bills the State directly and is paid directly by the State for services their employees or contractors provide. Also, as previously stated, to the extent a State pays a provider agency a Medicaid FFS fee schedule payment rate (as discussed in detail in an earlier response to comments in this

section), then those payment rates are subject to the payment rate disclosure requirements at § 447.203(b)(3)(ii).

As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States collect wage or compensation (including benefits) information from provider agencies to publish information about the compensation the provider agency pays to its employee. While the comment focuses on the daily work of a “direct care worker” and the functions of a “provider” to distinguish these terms, for the purposes of this rule, we focused on the type of employment structure (that is, individual provider or provider agency) to best account for variations in types and levels of payment that may occur for different provider types. We clarify that the codified regulation text for § 447.203(b)(3)(ii) does not include the phrase “direct care worker.”

Comment: Many commenters raised concerns and requested clarification regarding CMS requiring the payment rate being an hourly unit in the payment rate disclosure. A few commenters requested CMS clearly define what to include in the average hourly payment rate (for example, wages or benefits) to ensure the average hourly payment rates are comparable across States. A couple of commenters requested clarification on how States should convert half day, per diem, or per visit payment rates into an average hourly payment rate while one commenter requested CMS permit States to publish an average payment rate in the unit the State pays to ease burden on States. Lastly, one commenter stated that services, such as adult day habilitation or assisted living waiver, that cannot be calculated as an hourly rate should be reported as daily rates.

Response: For personal care, home health aide, homemaker, or habilitation services under FFS State plan authority, including sections 1915(i), 1915(j), 1915(k) State plan services; section 1915(c) waiver authority; and under section 1115 demonstration authority, this final rule requires States to publish a payment rate disclosure that expresses the State's payment rates as the average hourly Medicaid FFS fee schedule payment rates, separately identified for payments

made to individual providers and provider agencies, if the rates vary, and for payments that include facility-related costs, as applicable. States have flexibility in operating their Medicaid programs to set payment rates and payment policies for services that cover a particular unit of time for delivering the service and, therefore, States currently pay for these services in a wide range of units, from minutes to hourly to daily to monthly units. As described in the proposed rule, because of Medicaid's status as the most important payer for HCBS and lack of other points of comparison (that is, Medicare, private payers, self-pay), transparency and comparability among States is most important for assessing compliance with section 1902(a)(30)(A) of the Act. To ensure the payment rate disclosure supports our transparency efforts to help ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes available to interested parties, we are requiring States publish their payment rates in a uniform and comparable format, that is, an average hourly Medicaid FFS fee schedule payment rate. As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable.

Regarding commenters requesting clarification on how States should convert half day, per diem, or per visit payment rates into an average hourly payment rate, we would like to clarify that States that pay for the categories of services specified in paragraph (b)(2)(iv) in a unit other than an hourly payment rate are expected to calculate an hourly payment rate using the unit of the rate the State pays for the service and the number of hours covered by that unit. For example, if a State provides home health aide services as a half day or on a per diem (daily) or per visit basis, then the State would be expected to divide their payment rate for a half day, day,

or visit by the number of hours covered by the rate, such as 8 hours for a full day, to calculate an average hourly Medicaid FFS fee schedule payment rate for the payment rate disclosure. States have flexibility in operating their Medicaid programs to set payment rates and payment policies for services that cover a particular unit of time for delivering the service. We expect States have a maximum number of hours factored into their payment rate for services set on a per diem or per visit basis and States should use that maximum number in calculating the average hourly Medicaid FFS fee schedule payment rate, which is a simple average (arithmetic mean) where all payment rates are summed, then divided by the number of all hourly payment rates. Regarding commenters who stated that services, such as adult day habilitation or assisted living waiver, that cannot be calculated as an hourly rate should be reported as daily rates, we are not incorporating this suggestion into the final rule as we would expect States to use the previously described process to calculate an hourly payment rate from a per diem (daily) rate.

As previously mentioned in an earlier response to comments, this final rule adds habilitation services to the categories of services subject to the payment rate disclosure. This final rule is also adding a requirement that States must separately identify whether the average hourly Medicaid FFS fee schedule payment rate for services includes facility-related costs in § 447.203(b)(2) and (3)(ii)(B) to remain consistent with HCBS provisions finalized in this rule at § 441.311(e)(2). We recognize that habilitation services can mean residential habilitation, day habilitation, or home-based habilitation services; as such, payment rates for habilitation services generally may include facility-related costs, as in the case of residential or day habilitation services delivered in a residential group home or day center, whereas home-based habilitation would not include facility-related costs.³³⁰ We remind States that we proposed an “as applicable” clause in § 447.203(b)(3)(ii)(B) that applies to the ways payment rates can vary (that

³³⁰ We remind States that room and board is generally only coverable and payable to an individual who has been admitted to a medical institution as an “inpatient” as defined in 42 CFR 440.2 and 435.1010. Therefore, room and board in a facility setting that provides residential or day habilitation service must be excluded from the average hourly Medicaid FFS fee schedule payment rate for habilitation services.

is, by employment structure, population (pediatric and adult), provider type, geographical location). The requirement to identify whether a payment rate includes facility-related costs would also be covered by the “as applicable” clause. As such, we would not expect States to identify facility-related costs for personal care, home health aide, homemaker, and habilitation service payment rates when they are delivered in a home-based setting. While § 447.203(b)(2) and (3)(ii)(B) requires that States must separately identify whether the average hourly Medicaid FFS fee schedule payment rate includes facility-related costs may not apply to all services and delivery sites (that is, in home or community settings), we believe this provision will help to ensure transparency of payment rates that may differ due to the inclusion of facility-related costs.

Comment: One commenter requested clarification regarding individually negotiated rates and bundled rates being included in the average hourly payment rate calculation in the payment rate disclosure.

Response: As previously described in detail in an earlier response to comments in this section, we interpret the commenter’s reference to “negotiated rates” to mean a provider payment rate where the individual provider’s final payment rate is agreed upon through negotiation with the State Medicaid agency. For consistency with the payment rate transparency publication requirement, negotiated rates are not subject to the payment rate disclosure provision because these payment rates are not subject to the payment rate transparency publication as negotiated rates are not Medicaid FFS fee schedule payment rates that are known in advance of a provider delivering a service to a beneficiary.

Also, as previously discussed in detail in an earlier response to comments in this section, for purposes of the payment rate transparency provision in § 447.203(b)(1), Medicaid FFS fee schedule payment rates are FFS payment amounts made to a provider, and known in advance of a provider delivering a service to a beneficiary by reference to a fee schedule. For consistency, we are using the same description of Medicaid FFS fee schedule payment rates to describe the payment rates that need to be included in the payment rate disclosure in paragraph (b)(3)(ii)(B)

of this section which would also consider bundled payment rates to be Medicaid FFS fee schedule payment rates for the purposes of the payment rate disclosure.

We also clarify that while PPS rates for services provided in inpatient hospitals, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and nursing facilities are subject to the payment rate transparency publication, these PPS rates are effectively excluded from the payment rate disclosure because the categories of services specified in § 447.203(b)(2)(iv), personal care, home health aide, homemaker, and habilitation services, inherently delivered in a home or community setting, outside of an institutional facility.

Comment: Many commenters suggested additional data elements and levels of analysis for the payment rate disclosure. A couple of commenters suggested additional breakdowns of the average hourly payment rates, including when a State pays different rates for higher level of need or complexity (such as paying tiered rates for a single service when provided on nights, weekends, or in a particular geographical area), demographic information (such as gender and race of the direct care worker), and type of service provided. Another commenter suggested CMS require States to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker in the payment rate disclosure to enable easier comparison of compensation between individual providers and to providers employed by an agency. One commenter suggested requiring States to publish the rates that provider agencies pay their employees to ensure payment rates are fully disclosed at the State and provider levels. One commenter suggested additional data elements be reported by States in the payment rate disclosure: Medicaid-authorized payment rates; minimum base wages that would be paid to direct care workers if the proposed 80 percent requirement is met; average Medicaid payment rates and average direct care worker wages; the minimum, maximum, and median rates of wages; and number of direct care workers employed by the agency.

Response: We appreciate commenters' suggestions for the payment rate disclosure. As

previously discussed in an earlier response to commenters, in this final rule, we are revising the proposed language “to providers employed by an agency” in in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) and finalizing it as “provider agencies” for clarification purposes to more accurately reflect what payment rate we are requiring be published, that is, the payment rate the State pays a provider agency for services its employees have delivered. While the commenters did not provide additional explanation or examples of what they meant by requiring an additional break down of the average hourly payment rate by “type of service provided,” we clarify that the payment rate disclosure requires States to publish the average hourly Medicaid FFS fee schedule payment rate for personal care, home health aide, homemaker, and habilitation services, which are types of services, separately. Additionally, while we are not explicitly requiring States break down their payment rates by higher level of need or complexity, we did propose and are finalizing the requirement to break down the average hourly Medicaid FFS fee schedule payment rate by geographical location, which was one of the examples of additional criteria the commenter provided for suggested further breakdown.

However, we are not incorporating the other suggestions to require the other, additional breakdowns of the average hourly payments rates as suggested by commenters or to require additional data elements be reported by States in the payment rate disclosure, to remain consistent across provisions of this final rule. If we were to include these suggestions only for the payment rate disclosure, then the payment rate breakdowns would be inconsistent with the payment rate transparency publication and comparative payment rate analysis in terms of requiring, for example, demographic information about the direct care worker. During the initial compliance period of this final rule and in consideration of the numerous, concurrent regulatory changes States are facing, we believe consistency, where possible, across provisions will contribute to our goal to standardize data and monitoring across service delivery systems with the goal of improving access to care.

Likewise, we are not incorporating the suggestion to identify the average portion of the

average payment rate that is used for compensation to pay the direct care worker in the payment rate disclosure. While the suggestion aligns with the intent of HCBS provisions we are finalizing in this rule at § 441.302(k) as discussed in section II.B.5 of this rule, we did not propose to require 80 percent of all payments with respect to services at § 440.180(b)(2) through (4) must be spent on compensation for direct care workers within the payment rate disclosure, as discussed in a later response to comments in this section. As we remain focused on consistency, because we are not requiring a certain percentage of all payments be spent on compensation for direct care workers, we are also not requiring at § 447.203(b)(3)(ii) that States to identify the average portion of the average payment rate that is used for compensation to pay the direct care worker.

We are also not incorporating the suggestion to require States publish the rates that provider agencies pay their employees because, similar to private payer data as a point of rate comparison, rates that provider agencies pay their employees is generally considered proprietary and this information may not be available to States. As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable.

We want our initial focus to be on establishing the new payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements, providing States with support during the compliance period, and ensuring these data are available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues. While we are not adopting these suggestions, we note that States have the flexibility to add the elements described to their payment rate disclosure publication if they so choose. We will also review how our finalized policies work in conjunction with other policies finalized in this rule to identify any potential areas for future enhancements suggested by the commenters.

Comment: One commenter suggested CMS could ease burden on States by collecting

State payment rates from Dual Special Needs Plans (D-SNPs) through Medicare Advantage, rather than requiring States to calculate and publish their average hourly payment rate for the payment rate disclosure.

Response: We appreciate the commenters' suggestion; however, D-SNPs do not provide us with the specific data elements (that is, State Medicaid payment rates, number of Medicaid-paid claims, and number of Medicaid enrolled beneficiaries) we are requiring in this rule. Some D-SNPs only cover Medicare services and do not directly pay for Medicaid services. Other D-SNPs do cover Medicaid services (either directly or through an affiliated Medicaid managed care plan), but this rule only applies to Medicaid FFS payment rates. Therefore, as D-SNPs do not collect or provide us with Medicaid payment rate information that is relevant to this rule, we will not be incorporating this suggestion. Additionally, we believe that the States, as stewards of Medicaid payment rates in the Medicaid program, would be the party best situated to publish and analyze their own payment rate information for the payment rate transparency requirements finalized in this rule, including the payment rate disclosure. States' ownership of payment rate information will ensure accurate payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures.

Comment: A few commenters suggested alternative timelines for States updating their payment rate disclosures. One commenter suggested extending the requirement for updates to the payment rate disclosure to every 3 years, instead of the proposed 2 years, to align with the State's existing data publication cycle. However, another commenter suggested the update frequency of the payment rate disclosure be every year.

Response: We are finalizing the payment rate transparency requirements, including the payment rate disclosure, with an applicability date of July 1, 2026; however, we are not changing the proposed timeframe of 2 years for States to update their payment rate disclosure. We believe requiring updates to the payment rate disclosure every 2 years appropriately balances State burden and maintaining up-to-date information in the payment rate disclosure.

Comment: Most commenters were supportive in response to our request for public comment on whether we should propose a provision to what we proposed at § 441.302(k) (where we proposed to require that at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care workers) in § 447.203(b) on the basis that this provision would help address the direct care workforce crisis and access issues. One commenter suggested that if such a provision were proposed and implemented, then CMS should implement an accountability requirement where States would be required to validate that direct care workers are receiving 80 percent of all Medicaid FFS payments.

Some commenters opposed this consideration and suggested that, if this provision is finalized, the requirement would negatively affect access to care. These commenters aligned with those in opposition to the proposed HCBS provisions at § 441.302(k), as discussed in section II.B.5 of this rule. These commenters opposed this because the policy does not consider that given low levels of payment for relevant services, the remaining 20 percent of the payment rate would be insufficient for the administrative costs (that is, staff, technology, training, travel, oversight) of running a business, provider agencies are already challenged by worker shortages, providers would withdraw from the Medicaid program or stop serving Medicaid beneficiaries, and the requirement would be ineffective without supportive policies in place to implement standards for determining sufficient Medicaid payment rates that provide competitive wages, promote quality services, and ensure compliance with all State and Federal regulations. Commenters in opposition recommended alternatives including: a lower percentage than 80 percent of all Medicaid FFS payments going to compensation for direct care workers, establishing quality outcome metrics, and focusing on wage review and transparency.

Response: We thank commenters for their input and suggestions. We also understand the commenters' concerns. Given that our work to better ensure access in the Medicaid program

is ongoing, we intend to gain implementation experience with this final rule, particularly from the HCBS provisions finalized in this rule at § 441.302(k) as discussed in section II.B.5, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

Comment: Many commenters expressed concerns about requiring States to publish the average hourly payment rate that States pay for personal care, home health aide, and homemaker services. These commenters were generally concerned that requiring States to publish this information could result in unintended consequences or be ineffective for assessing and improving access to care. The unintended consequences commenters were primarily concerned about included contributing to providers leaving areas where there are low Medicaid payment rates which could create or exacerbate access to care issues in that area and misunderstandings of the required average hourly payment rate without additional context about employee benefits (for example, paid time off, health insurance, pension, employee assistance program) that are not easily disaggregated from an hourly Medicaid service payment rate. Regarding commenter concerns that publishing the average hourly rate would be ineffective, one commenter stated that their State already publishes provider rates, and it has not resolved issues with low and unequal payment rates among providers employed by agencies.

Response: We understand commenters' concerns about the effects of the payment rate disclosure in practice. Regarding commenters' concerns that providers could leave an area where there are low Medicaid payment rates, we would like to emphasize that the payment rate disclosure requirements will afford more transparency to CMS and the public about rates for HCBS, but they will also provide States with an opportunity to identify where existing rates could create an access issue. If the difference in rates between two areas enlists more providers to one area over another, States may need to consider revisions to their payment rates to comply with section 1902(a)(30)(A) of the Act to "assure that payments ... are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such

care and services are available to the general population in the geographic area.” Therefore, if the transparency created by the payment rate disclosure requirements induces providers to switch locations, affecting access to care, we would expect States to address the rate disparities that the commenter has correctly identified are negatively impacting access.

Regarding commenters’ concerns that there could be misunderstandings of the published average hourly payment rate without additional context about employee benefits, the payment rate disclosure provisions at § 447.203(b)(3)(ii) requires States to separately identify the average hourly Medicaid FFS fee schedule payment rates for personal care, home health aide, homemaker, and habilitation services by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable, and by provider employment structures (individual providers and provider agencies). As previously discussed in an earlier response to comments in this section, we are not requiring in the payment rate disclosure provisions at § 447.203(b)(3)(ii) that States to collect wage, compensation (including benefits), or financial records and information from provider agencies or to publish information about the compensation the provider agency pays to its employee, where applicable. In other words, we are focused on payment rate transparency for personal care, home health aide, homemaker, and habilitation services rather than what the providers of these services does with their payment rate (that is, pay for employee benefits). Given that our work to better ensure access in the Medicaid program is ongoing, we intend to gain implementation experience with this final rule, and we will consider the recommendations provided on the proposed rule to help inform any future rulemaking in this area, as appropriate.

We disagree with the commenters that publishing the average hourly Medicaid FFS fee schedule payment rate of personal care, home health aide, homemaker, and habilitation providers through the payment rate disclosure requirement will be ineffective, including because one commenter’s State already publishes this information, and the commenter has not seen improvement in low and unequal payment rates among providers employed by agencies. We

believe a broad requirement for all States that provide personal care, home health aide, homemaker, and habilitation services through the FFS delivery system will help ensure consistency across delivery systems in monitoring and ensuring access to care, particularly with the HCBS provisions at § 441.311(d)(2) and (e), which require annual State reporting on access and payment adequacy metrics for the same set of services as the payment rate disclosure as well as with the Managed Care final rule (as published elsewhere in this **Federal Register**) provisions at § 438.207(b)(3)(ii) for Medicaid to require a payment analysis of the total amount paid for homemaker services, home health aide services, and personal care services and the percentage that results from dividing the total amount paid by the amount the State's Medicaid FFS program would have paid for the same claims. While the commenter did not provide additional details about their State's publication of payment rates, we believe that with a broad rate transparency requirement across delivery systems, we can reasonably expect that States, CMS, and interested parties will have transparent payment rate information available to them across delivery systems. Transparency would continually help States and CMS to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under section 1902(a)(30)(A) of the Act that payments be sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Transparency also helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties.

Comment: Several commenters expressed concern over low payment rates in Medicaid, particularly for HCBS, dental services, and behavioral health care, and the negative impact on access to care. Many commenters suggested that the primary causes of these low payment rates in Medicaid are stagnant and insufficient payment rates left unadjusted for rising costs, inflation,

new regulatory requirements, and increased service expectations over time, particularly for the HCBS direct care workforce.

A few of these commenters suggested CMS could address these issues directly by requiring States conduct regular rate reviews (for example, annual, biennial, triennial, or when a programmatic change occurs), publish the results, and update their payment rates, when necessary, based on criteria that CMS sets. One commenter suggested this could be achieved through regular SPA and waiver reviews where CMS could prevent stagnant and insufficient rates from being maintained. Particularly for HCBS, one commenter recommended setting a national standard base pay rate for direct care workers as determined by the States' cost of living index or requiring States have parity for all State payment rates, regardless of geographic location, but allow differences in payment rates for services provided to pediatric and adult populations.

Response: We appreciate the commenters' suggestions. However, we are limited in our authority to directly address the commenters' concerns regarding stagnant and insufficient payment rates. With limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute), we do not have the authority to require States update their payment rates to a particular level. Section 1902(a)(30)(A) of the Act requires that State plans assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Under the statutory authority at section 1902(a)(30)(A) of the Act and through this final rule, we are requiring States to develop and publish a payment rate transparency publication, comparative payment rate analysis of certain services, and payment rate disclosure for certain HCBS, which are directed at helping the

States and CMS ensure that State payment rates are consistent with the payment standards under section 1902(a)(30)(A) of the Act.

While we are not explicitly requiring that States update their payment rates to a particular level or regularly submit SPAs and/or waivers (except where desired by the State to implement a programmatic change, consistent with existing requirements) waivers in this rulemaking, we believe there are three requirements within our statutory authority and finalized by this rule that effectively address the concerns raised by commenters. First, this final rule requires States to review their payment rates during the development and publication of their payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Specifically, the payment rate transparency publication requires States to regularly review their rates in the course of publishing them and maintaining the current accuracy of the publication, including publishing the date the payment rate publication website was last updated, which will reveal any rates that may be stagnant and potentially insufficient. States must also ensure the data in the publication is kept current (that is, updates must be made within 1 month of a rate change). With this final rule, we focused on transparency to help ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public process available to interested parties. We acknowledge the provisions finalized in this rule do not specifically require rate reviews to ensure payment rates are adjusted for rising costs, inflation, new regulatory requirements, and increased service expectations that commenters suggested are factors contributing to a crisis in the HCBS direct care workforce. However, this provision creates a process to help validate that payment rates are compliant with section 1902(a)(30)(A) of the Act.

Second, this final rule requires States to establish an advisory group for interested parties to advise and consult on certain current and proposed Medicaid provider payment rates to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home

health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area. We strongly encourage States to use this group as part of a process to conduct rate reviews and encourage eligible participants (including direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State) to join their State's interested parties advisory group once established to bring their concerns directly to States that are setting the payment rates for HCBS.

Third, this final rule establishes a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. However, meeting the three criteria described in the first tier does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. The second tier of this approach, § 447.203(c)(2) requires the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. We believe this two-tiered approach, in combination with updated public process requirements in § 447.203(c)(4) (which this final rule relocates from § 447.203(b)(7)) will help us ensure that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(2) to (4) as proposed, apart from the following changes.

- Deleted the word “following” in two places in the following sentence in § 447.203(b)(2) “The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the **following** categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the **following** categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section.” The finalized language now states “The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section.” (bold added to emphasize the deleted word).

- Replaced “Medicaid payment rates” with “Medicaid fee-for-service fee schedule payment rates” in § 447.203(b)(2) with regard to the comparative payment rate analysis. The finalized language now states “...publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates...” for clarification and consistent terminology usage within § 447.203(b).

- Replaced “Medicaid payment rates” with “average hourly Medicaid fee-for-service fee schedule payment rates” in § 447.203(b)(2) with regard to the payment rate disclosure. The finalized language now states “...[publish]... payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates” for clarification and consistent terminology usage within § 447.203(b).

- Revised sentence structure organization and added clarifying language to the proposed language stating how the Medicaid FFS payment rates published in the comparative payment rate analysis and the payment rate disclosure need to be listed, if the rates vary. The proposed language in § 447.203(b)(2) stated “The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the following

categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the following categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.”

++ Added the following sentence to address payment rate variation for the comparative payment rate analysis: “If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.” in § 447.203(b)(2).

++ Revised the following sentence to add payment rate variation related to facility-related costs for the payment rate disclosure: “If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs**, as applicable.” (new language identified in bold)

The language is finalized as “The State agency is required to develop and publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section. **If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The State agency is further required to develop and publish** a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, **and whether the payment rate includes facility-related costs**, as applicable.” in paragraph (b)(2). (new language identified in bold)

- Updated “Outpatient behavioral health services” as a category of service in § 447.203(b)(2)(iii) to “Outpatient mental health and substance use disorder services.”

- Added “habilitation” as a category of service in the payment rate disclosure described in § 447.203(b)(2)(iv) and added a reference to § 440.180(b)(6). The finalized language now states “Personal care, home health aide, homemaker, **and habilitation** services, as specified in § 440.180(b)(2) through (4) **and (6)**, provided by individual providers and provider agencies (new language identified in bold).

- Clarified which publication requirements apply to the comparative payment rate analysis and payment rate disclosure in § 447.203(b)(3) and (b)(4) to align with a previously described update to the organizational structure of paragraph (b)(1) to add romanettes to specify the “publication requirements described in paragraph (b)(1) **through (b)(1)(ii)** of this section.” (new language identified in bold).

- Replaced “Medicaid base payment rates” with “base Medicaid fee-for-service fee schedule payment rates” in § 447.203(b)(3)(i)(B) through (E) for clarification and consistent terminology usage within § 447.203(b).

- Replaced “Medicare non-facility payment rate” with “Medicare non-facility payment rate as established in the annual Medicare Physician Fee Schedule final rule” in § 447.203(b)(3)(i)(C) and (D) for clarification.

- Added “and whether the payment rate includes facility-related costs” in § 447.203(b)(3)(ii) (B) to account for facility-related costs in habilitation settings, particularly residential habilitation or day habilitation. The finalized language now states, “[t]he disclosure must identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical

location, **and whether the payment rate includes facility-related costs**, as applicable in § 447.203(b)(3)(ii)(B) (new language identified in bold).

- Replaced “average hourly payment rate” with “average hourly Medicaid fee-for-service fee schedule payment rates” in § 447.203(b)(3)(ii) and (ii)(B) and (C) for clarification and consistent terminology usage within § 447.203(b).

- Replaced “to providers employed by an agency” with “provider agencies” in § 447.203(b)(2)(iv), (b)(3)(ii), and (b)(3)(ii)(B) for clarification.

- Replaced “Medicaid payment rates” with “Medicaid fee-for-service fee schedule payment rates” in § 447.203(b)(4) for clarification and consistent terminology usage within § 447.203(b).

- Updated the applicability date in § 447.203(b)(4) from January 1, 2026 and effective date of the Medicaid payment rates subject to the comparative payment rate analysis and payment rate disclosure from January 1, 2025 to read: “The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025, as required under paragraphs (b)(2) and (b)(3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update.”

c. Interested Parties Advisory Group § 447.203(b)(6)

In the proposed rule, we noted that a fundamental element of ensuring access to covered services is the sufficiency of a provider network.³³¹ As discussed elsewhere in this rule, the HCBS direct care workforce is currently experiencing notable worker shortages.³³² A robust workforce providing HCBS allows more beneficiaries to obtain necessary services in home and community-based settings. We proposed to use data-driven benchmarks in requiring

³³¹ 88 FR 27960 at 28023.

³³² <https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf>.

comparative payment rate analyses relative to Medicare non-facility payment rates as established in the annual Medicare PFS final rule for a calendar year for the categories of service specified in proposed § 447.203(b)(2)(i) through (iii), but Medicare non-facility payment rates are generally not relevant in the context of HCBS, as discussed earlier in this section. Furthermore, data alone cannot replace the lived experience of direct care workers and recipients of the services they provide.

Understanding how Medicaid payment rates compare in different geographic areas of a State and across State programs is also an important access to care data point for covered benefits where Medicaid is a predominant payer of services, as in the case of HCBS. In the absence of HCBS coverage and a lack of available payment rate and claims utilization data from other health payers, such as Medicare or private insurers, and with the significant burden and potential infeasibility associated with gathering payment data for individuals who pay out of pocket (that is, self-pay), we noted our belief that it would be a reasonable standard for States to compare their rates to geographically similar State Medicaid program payment rates as a basis for understanding compliance with section 1902(a)(30)(A) of the Act for those services. In addition, even for services where other payers establish payment rates, comparisons to rates paid by other geographically similar States could be important to understanding compliance with section 1902(a)(30)(A) of the Act since Medicaid beneficiaries may have unique health care needs that are not typical of the general population in particular geographic areas.

Section 2402(a) of the Affordable Care Act directs the Secretary to issue regulations ensuring that all States develop service systems that, among other things, improve coordination and regulation of providers of HCBS to oversee and monitor functions, including a complaint system, and ensure that there are an adequate number of qualified direct care workers to provide self-directed services. This statutory mandate, coupled with the workforce shortages exacerbated by the COVID-19 pandemic, necessitates action specific to direct care workers. As such, we proposed to require States to establish an interested parties advisory group to advise and consult

on FFS rates paid to direct care workers providing self-directed and agency-directed HCBS, at a minimum for personal care, home health aide, and homemaker services as described in § 440.180(b)(2) through (4), and States may choose to include other HCBS.

We proposed the definition of direct care workers under § 441.302(k)(1)(ii), which is being finalized under § 441.311(e)(1)(ii) in this final rule. We proposed to use that definition to consider a direct care worker a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving HCBS; a licensed nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; a direct support professional; a personal care attendant; a home health aide; or other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living directly to Medicaid-eligible individuals receiving HCBS available under part 441, subpart G. A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

We proposed that the group would consult on rates for service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to individual providers or providers employed by an agency for, at a minimum, the previously described types of services, including for personal care, home health aide, and homemaker services provided under sections 1905(a), 1915(i), 1915(j), and 1915(k) State plan authorities, and section 1915(c) waivers. These proposed requirements also would extend to rates for HCBS provided under section 1115 demonstrations, as is typical for rules pertaining to HCBS authorized using demonstration authority. We proposed that the interested parties advisory group may consult on other HCBS, at the State's discretion.

In this final rule, we are adding an additional service to the group's purview, habilitation services as found under § 440.180(b)(6). In the proposed rule, we proposed an alignment of

services subject to the requirements between the HCBS payment adequacy and access to care metrics requirements, and the payment rate disclosure and interested parties advisory group provisions. Within the payment adequacy and access to care metrics provisions of the proposed rule, we requested comment on whether to expand services subject to those requirements to include habilitation services from the proposed personal care, home health aide, and homemaker services. In this final rule, we are adding habilitation services to the reporting requirements for direct care worker compensation data under § 441.311(e) and access to care metrics under § 441.311(d)(2), and therefore are adding habilitation services to the interested parties' advisory group's purview (and, as previously discussed, to the payment rate disclosure requirements). This addition will create consistency between HCBS-related provisions of this final rule. It will also simplify the process for States to provide the relevant materials to members of the interested parties advisory group, and avoid any confusion on the scope of review. We also want to note the point made in earlier provisions of this final rule, that habilitation services can mean residential habilitation, day habilitation, or home-based habilitation services. All three types are included within the "habilitation services" we are adding to this provision.

In § 447.203(b)(6), we proposed that the State agency would be required to establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.311(e)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4). In this final rule, as noted, we are adding habilitation services as found at § 440.180(b)(6). The interested parties advisory group would be required to include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties. We explained that "authorized representatives" refers to individuals authorized to act on the behalf of the beneficiary, and other interested parties may include beneficiary family members and advocacy organizations. To the extent a State's MAC

established under proposed § 431.12, if finalized, meets these requirements of this regulation, we proposed that the State could use that committee for this purpose. However, we noted the roles of the MAC under proposed § 431.12 and the interested parties advisory group under proposed § 447.203(b)(6) would be distinct, and the existence or absence of one committee or group (for example, if one of these proposals is not finalized) would not affect the requirements with respect to the other as established in a final rule.

We further proposed in § 447.203(b)(6)(iii) that the interested parties advisory group would advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services. We want to clarify that the group would not be required to advise and consult on the HCBS payment adequacy data as required under § 441.311(e), and access to care metrics under § 441.311(d)(2), until such a time as those data are available under the newly established requirements. We also want to note again here that we are expanding the service categories to include habilitation services as found at § 440.180(b)(6).

In § 447.203(b)(6)(iv), we proposed that the interested parties' advisory group would meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency would be required to ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics for HCBS as described in § 441.311(d)(2) to produce these recommendations. These materials would be

required to be made be available with sufficient time for the advisory group to consider them, formulate recommendations, and transmit those recommendations to the State. If the State has asked the group to consider a proposed rate change, the State would need to provide the group with sufficient time to review and produce a recommendation within the State's intended rate adjustment schedule. We noted that this would be necessary because the group's recommendation would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze. The interested parties advisory group would make recommendations to the Medicaid agency on the sufficiency of the established and proposed State plan, section 1915(c) waiver and demonstration payment rates, as applicable. In other words, the group would provide information to the State regarding whether, based on the group's knowledge and experience, current payment rates are sufficient to enlist a sufficiently large work force to ensure beneficiary access to services, and whether a proposed rate change would be consistent with a sufficiently large work force or would disincentivize participation in the work force in a manner that might compromise beneficiary access. We clarify here, as well that the State would not be required to make available the HCBS provider payment adequacy minimum performance and reporting standards under § 441.311(e), and applicable access to care metrics for HCBS under § 441.311(d)(2), until such a time as those data are available per the applicable applicability dates of those respective provisions in this final rule.

We proposed to require States to convene this interested parties' advisory group every 2 years, at a minimum, to advise and consult on current and suggested payment rates and the sufficiency of these rates to ensure access to HCBS for beneficiaries consistent with section 1902(a)(30)(A) of the Act. This timing aligns with the comparative payment rate analysis and payment rate disclosure publication requirements proposed in § 447.203(b)(4), although we noted that this would be a minimum requirement and a State may find that more frequent meetings would be necessary or helpful for the advisory group to provide meaningful

and actionable feedback. We further proposed that the process by which the State selects its advisory group members and convenes meetings would be required to be made publicly available, but other matters, such as the tenure of members, would be left to the State's discretion. We want to note that the 2-year cadence could require the group to convene its first meeting and produce a recommendation before the HCBS payment adequacy data as required under § 441.311(e), and access to care metrics under § 441.311(d)(2), will be available. We do not expect the State to furnish information to the group that is not yet available or for the group to comment on those topics for which the State has not yet provided data. We nevertheless are maintaining the 2-year cadence that would require a recommendation 2 years from the effective date of this final rule, as we believe the benefits to the State and group in convening that initial time, even with a limited availability of data for the first meeting, will be beneficial for getting the group to be operational. States have the flexibility to convene the group within a shorter timeframe to adjust the future cadence to align with other publication schedules, if desired.

Finally, in § 447.203(b)(6)(v), we proposed that the Medicaid agency would be required to publish the recommendations of the interested parties' advisory group consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency. We intend that States would consider, but not be required to adopt, the recommendations of the advisory group. Under this proposal, the work of the advisory group would be regarded as an element of the State's overall rate-setting process. Additionally, the feedback of this advisory group would not be required for rate changes. That is to say, should a State need or want to adjust rates and it is not feasible to obtain a recommendation from the advisory group in a particular instance, the State would still be permitted to submit its rate change SPA to CMS. However, to the extent the group comments on proposed rate changes, its feedback would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze,

and submit such analysis to us, in connection with any SPA submission that proposes to reduce or restructure Medicaid service payment rates. In addition, by way of clarification, we noted our intent that the advisory group would be permitted to suggest alternate rates besides those proposed by the State for consideration.

We solicited comments on the proposed interested parties' advisory group and about whether other categories of services should be included in the requirement for States to consult with the interested parties advisory group. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing general support for the establishment of the interested parties advisory group. Commenters agreed that individuals with lived experience would provide invaluable insight into appropriate rates for direct care services, including both beneficiaries and direct care workers, which the proposed group would include. Commenters also pointed to a number of anticipated benefits, such as helping to increase pay for these valuable workers, giving beneficiaries a voice on decisions that impact them, providing additional insights into a unique area of the healthcare market, identifying what can attract workers, and addressing an area of critical concern for staffing, which is necessary for the stability of access to HCBS. Multiple commenters stated it was important to have payment rate decisions focus on community needs rather than be determined solely by a State's budget, and thus better meeting the needs of beneficiaries. One commenter stated this group would be valuable for staying abreast of the day-to-day provision of services as it relates to current pay rates, while another noted how it is important to focus on rates in a service area for which there is no Medicare comparison. Another stated this proposal should be used as the template for group feedback and reporting for all provider payment systems in a State.

Some commenters also chose to specifically highlight aspects of the proposals for this group they agreed with. These include having a group to advise on wages, the cadence of group meetings, the publication requirements, the composition of the group members, and allowing

States to set the tenure for members. One commenter also pointed out how this group will complement payment adequacy requirements by identifying rates that may meet a set threshold for direct compensation but remains low generally.

Response: We thank commenters for taking the time to express support for the provision and for highlighting many of the areas where we expect this group will add value. We are finalizing the provisions related to the interested parties' advisory group as proposed, with the addition of habilitation services. The shortage of direct care workers demands special attention, and we hope that finalizing these requirements will be one of several steps contained in this final rule toward addressing those concerns.

Comment: A very large proportion of commenters on these provisions had recommendations for changes or enhancements to the interested parties advisory group. A number of those comments related to the composition of the group, with commenters requesting certain proportions for types of members, or specific member positions be added generally or defined as an interested party. Specifically, various commenters recommended a required composition of 25 percent beneficiary representation, 25 percent direct care workers, and 25 percent provider employers, such as representatives from an agency providing HCBS and employing direct care workers. Some commenters expressed similar sentiments without precise numbers, instead recommending representation by various individuals: agency-based model providers; consumer-directed model providers; union representatives; patient advocates; program administrators; politicians; or members of the general public. Some commenters recommended that a majority of members be beneficiaries, unpaid beneficiary caregivers, and advocacy organizations. These commenters had concerns about the possibility that certain key voices could be silenced if not sufficiently represented within the overall composition of the group.

A number of commenters stated that the regulations should require other specific member types without defining in what proportion. There were multiple requests to require members from unions, worker advocacy organizations, consumer advocates, and representatives from

provider agencies and provider State associations. These commenters wanted to ensure certain technical expertise would be available amongst the group members. For example, a qualified consumer advocate may have knowledge of technical program aspects that other members may not.

One commenter requested nurses be included in the group, and another requested physician anesthesiologists, noting that they are subject to a uniquely structured payment system. Several commenters stated the group should bar employees of the State agency to ensure independence in developing the recommendations.

Finally, a few commenters requested members who were already among those included in the proposed regulation. Specifically, one commenter stated the group should include paid direct service workers, while another stated HCBS providers should be included.

Response: As stated, we are finalizing the interested party advisory group requirement as proposed apart from the addition of habilitation services, and that includes the provisions defining the membership of the group without specifying particular proportions of required membership. We agree generally that additional types of members such as those suggested by commenters could bring unique perspectives or expertise to the group. Nevertheless, we are finalizing as proposed the membership requirements, because we intentionally proposed a great deal of flexibility for States in recognition of the unique circumstances of State Medicaid programs. We also want to ensure States can meaningfully implement the requirements for this group, and every additional member or type of member presents additional considerations for recruitment needed to set up the group, as well as logistical considerations for coordinating meetings. We believe a limited but inclusive list, with considerable State flexibility in determining the composition of the group, will ensure that interested parties' voices are heard and not silenced, but as with any new policy, we will monitor implementation to identify if adjustments may be needed through future rulemaking.

As the proposed rule contained many changes to existing requirements and processes, we were mindful at every step of the burden this would place on States, and balanced potential State burden against the proposal's potential to help ensure and improve access. After careful consideration, we determined it was more important to implement a basic framework for the interested party advisory group and leave many details of its precise composition and operation to the States. Our access work is ongoing, and we will consider the recommendations provided on the proposed rule for any additional changes we may propose through future rulemaking.

We would encourage States, when recruiting members, to consider the composition of members that would best satisfy the goals of this group and identify where there is a need for technical expertise, sufficient representation, etc., and work to establish the group in a manner that promotes its efficient functioning and meaningful contribution to Medicaid policies in the State. The inclusion of "other interested parties" affords States the flexibility to do so. We believe the lived experiences of the members of this group when coupled with the requirements for States to provide relevant documents and reports for the group's consideration, will be adequate to provide the type of perspective on rates we are seeking through this group.

Finally, we want to clarify which members States are required to include as part of the interested parties advisory group. States are required to include direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the rates in question, as determined by the State, which may include beneficiary family members (other than those who may be authorized representatives for beneficiaries) and advocacy organizations. Representation from each type of individual specified on this list is required. As such, the group could not be solely beneficiaries, or solely direct care workers, or solely other individuals meeting neither of those criteria but whom a State would deem an interested party.

Comment: Another area where many commenters made suggestions was with respect to the scope of the group's work and the requirements related to consideration of the group's recommendations. Many commenters recommended that CMS require States to consult with the

group for any rate or payment methodology changes, highlighting the value of the group's input, and to require a written, public response to the recommendation of the group, with evidence and rationale, where the final rates differ from what the group recommended. One commenter also requested a public comment process for the group's recommendations. Some emphasized the importance of transparency of this process, and one suggested recommendations and responses be made public for a minimum of 30 days prior to the effective date of a new rate. Several commenters, noting the proposal made the group advisory in nature, recommended that States be required to justify when they choose to go against the recommendation of the group, with some of those commenters offering that at a minimum the State must engage again with the group when intending to finalize rates that differ from the group's recommendation, including meaningful negotiations with the providers represented on the group, perhaps with steps defined by CMS to reach consensus. One commenter wanted the public process regulations at § 447.204(a)(2) updated to explicitly include obtaining and considering the interested parties advisory group's input. The importance of the group's recommendation came up in multiple comments, with one stating it is not enough merely to require the State to receive, and provide a written response to, the advisory groups' input, but that we should ensure the group has authority to shape policy.

Some commenters had detailed recommendations for additional requirements related to the group's output. One suggested a structured and routine process for regular review and approval of new rates or changes, with meaningful input from beneficiaries. The commenter requested the structured process to be coupled with a requirement for States to explain the roles and responsibilities of a rate review advisory body. Another wanted CMS to require States to clearly delineate how a proposed rate change has factored in inflation and any unfunded mandates on providers. One commenter stated that the group's recommendations should go to the State Medicaid director, as well as to the governor, the State legislature, and HHS. Like other commenters, this commenter wanted the State to communicate acceptance or denial of

recommendations to the group, with explanations of the State's decisions in writing, but also stressed that CMS must monitor the State advisory committees as part of accountability and transparency and provide feedback to the State.

Some comments also contained other, related recommendations for the group's purview. Two commenters recommended the group be allowed to advise and comment on a broad range of HCBS provider rates, with one suggesting CMS consider leveraging the group for feedback on HCBS access issues more broadly. That commenter stressed the importance to the Medicaid program to evaluate rates and access for HCBS, especially considering the unique market power of Medicaid for HCBS infrastructure. A commenter requested the group's rate review consider the experience of individuals dually eligible for Medicare and Medicaid and factors related to Medicare coverage. One commenter stated the group should advocate for creating a sustainable wage program to attract and retain staff to benefit both recipients and providers of the specified services. Another commenter recommended that the group should review and comment on provider payment rates in managed care delivery systems. One commenter, in response for our request for comment on the services under review, stated the group should focus on direct care work across all waiver categories. Finally, a couple commenters sought clarity on how States must acknowledge or respond to the group's recommendations.

Response: We are finalizing as proposed the advisory nature of the interested parties advisory group. We agree that the group's input will be valuable in setting rates, assessing payment adequacy and applicable access to care metrics, and may provide a perspective on rates and access that could be lacking in existing processes. As one commenter noted, Medicaid has an important and large role in the market for HCBS. However, we believe the policies as we are finalizing them strike the right balance of accountability and flexibility for a wholly new rate advisory group process. The State will be required to publish the recommendations of the interested parties advisory group for transparency, under § 447.203(b)(6)(v). In addition, when the group has a recommendation on a proposed rate change, the State will be required to consider

and respond to that recommendation as it would be deemed part of the input of interested parties described in §§ 447.203(c)(4) and 447.204(b)(3). In light of the public notice and public input requirements already in place when a State proposes a rate change, and treatment of the recommendation as public input to which a State is required to consider and address under these requirements, we are not establishing any specific, new public notice or comment process requirements for the recommendations of the interested parties advisory group. The group could recommend a sustainable wage program, but we are not adding a requirement to develop one. We intend for the group to have broad discretion, within their remit, to make recommendations to the State, which could thereby result in such recommendations. We encourage the group to provide feedback to assist the State in implementing a sustainable HCBS program.

By keeping the group's recommendations recommendation advisory only (that is, non-binding on the State), we intend for the State to give serious consideration to the group's recommendations while avoiding the imposition of policy strictures on the State that could require sudden shifts in budget priorities or create conflicts, for example, with the State legislature. Fundamentally, the single State Medicaid agency must maintain ultimate responsibility to operate the State's Medicaid program. Also, because the group is advisory only, we are not including requirements for the State to negotiate with providers or the group on rate changes, or justify when a rate change is made that is not consistent with the recommendation of the group. However, we remind States that the group's recommendation, to the extent it has commented on rates included in a SPA, would be considered part of the public feedback to which the State must respond, under §§447.203(c)(4) and 447.204.

As part of the requirement to establish the interested parties' advisory group in this final rule, States will be responsible for giving appropriate guidance to the group so that it understands its role and responsibilities in producing recommendations. We defer to States on how to best communicate this information to the group. We also want to emphasize for States that the information they provide the group can be expected to shape the nature of the group's

recommendations. As such, although we are not requiring the State to explain if and how inflation has factored in to a proposed rate, for example, or provide information to the group on costs imposed on providers beyond what is required under the payment adequacy metrics required under 441.311(e), it would benefit a State to provide as much context as possible to the group so that it can produce the strongest, best-informed, most useful recommendations. Because the group's recommendations must be published publicly, interested parties such as State legislators and HHS will be able to see and review any recommendations.

In addition, with the meeting cadence we are finalizing (at least every 2 years), and with recent examples of when a rate change may be needed to be enacted quickly (for example, to address urgent programmatic needs in connection with the COVID-19 pandemic and public health emergency), it is not feasible to require consultation with the group for every possible rate change. We also note that the mandate of the group and the minimum required meeting cadence should not be viewed as limitations, and States have flexibility to rely on this group in ways that will best help to enhance HCBS or Medicaid more broadly. States may have the group review broader HCBS issues or rates if it so chooses; we merely focused the required scope on the most frequently used HCBS. They can also have the group advise on provider payment rates in managed care delivery systems even though that was not our prioritized focus in this new requirement, under the flexibility States have to direct the work of the group. We also note that although we are not requiring dually eligible beneficiaries specifically in the group to maximize the available pool for recruiting beneficiary members of the group, the majority of HCBS recipients are dually eligible. Finally, we appreciate the many recommendations and suggestions that we will consider if and when we examine the regulations for this group for potential changes through future rulemaking as part of our ongoing access work.

Comment: Several commenters had recommendations for the nature of materials, data, explanations, and information the group should have access to, to ensure the group's input could be fully informed by data, both public and internal to the agency, as to how any rates were

calculated. These comments included advice on what materials the group should have access to or suggestions of sources the group should be required to review and consider. Specifically, a couple of commenters wanted the group to be required to consult any analyses performed pursuant to the requirements we are finalizing in § 447.203(c), since those analyses would include valuable data on the number of home care claims, the number of enrollees receiving home care services, and the number of providers furnishing such services. Another commenter recommended the group to be required to consult wage data, such as data from the Bureau of Labor Statistics or from unions, to use as a basis of rate recommendations. Another commenter encouraged CMS to partner with the Department of Labor to provide States with data on competitive wages for other occupations with similar low entry level requirements, to avoid putting burden on States while providing the advisory group with State-level economic data to assess the competitiveness of direct care worker wages.

One commenter provided a detailed recommendation for data to provide the group, including explanations and supporting information on how any proposed rates were calculated, in addition to the metrics required under the payment adequacy and reporting requirements provisions of this final rule. Specifically, the commenter stated this information should include clear, consistent definitions of the cost elements that are considered in establishing a rate, noting that if the definitions of cost components such as employee travel or training are not clear and the bases for these calculations are not shared with sufficient granularity, then the advisory group will not be able to meaningfully comment. Similarly, a commenter urged CMS to ensure that the interested parties advisory group have access to both public-facing reports that States are required to produce and publish described in payment transparency provisions of this rule, and to the underlying data that States use to prepare these reports, which may allow the interested parties advisory group to identify trends or access issues that are not readily apparent in the public reports. One commenter recommended that States be required, through a phase-in, to both collect and provide to the group data on turnover and vacancy rates for direct care workers.

The commenter explained that tools currently used by States, such as the National Core Indicators-Intellectual and Developmental Disabilities Staff Stability Survey, or the National Core Indicators-Aging and Physical Disabilities tool currently being piloted, only provide data for agency-directed workers, and as such, more information was needed about independent providers in self-directed programs. The commenter noted these are important data elements to assess the adequacy of wages and compensation.

Finally, a few commenters stated that States should make compensation, including information on median wages and historic trends in compensation, available to all members of the public, for transparency and to assist current or future members of the group itself.

Response: We are finalizing as proposed, apart from the addition of habilitation services, the regulation requiring that the group will advise and consult on current and proposed payment rates, HCBS provider payment adequacy reporting information under § 441.311(e), and applicable access to care metrics under § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4) and (6). The responsibility for the group to advise and consult on these matters necessarily implies that the State must ensure that the group is provided access to current and proposed rate information, HCBS provider payment adequacy data, and applicable access to care metrics. We believe that these requirements, coupled with requirements we are finalizing for payment rate disclosures for HCBS at § 447.203(b)(2) through (3), will provide the group with sufficient data to develop and support their recommendations, and we also believe those additional finalized provisions will provide reassurance to commenters interested in more publicly available data. We further note that certain data, such as certain BLS wage data, are already publicly available and can be used by the group. We remind States that they are not limited to the requirements we are finalizing and are free to consider and provide as much data that the State considers relevant and reasonably available to support the group in its work.

We did not propose and are not finalizing any data collection requirements specifically with respect to the interested parties' advisory group to inform their consideration of Medicaid

payment rates for certain HCBS, although we understand that currently available tools and data may have some gaps. In view of the otherwise existing information sources just discussed, we do not believe the value of requiring States to identify or develop and make available additional data sources, such as reporting on independent providers in self-directed programs, would outweigh the added burden of a new data collection. We are similarly not taking on any additional data collection to support these efforts, again noting that we think the policies in this final rule will be sufficient, but as with any new or existing policy we will work with our State partners to assist them in establishing these groups and identifying where we can support State efforts that may extend beyond the requirements in this final rule.

Comment: We received a number of comments around various administrative aspects of § 447.203(b)(6), from member recruitment to the meeting cadence. Several commenters stated that the State should publicly recruit members and requested States to publicly disclose the process of how those members are recruited and the process to convene meetings. A few commenters recommended the members have term-limits, coupled with the protection to only be removed for cause during a term, in order to protect the individuals and the group from reprisal or disbandment.

Comments about the meeting cadence varied. A few recommended the group should meet for every rate change proposed by the State, one agreed with a biannual cadence, while another suggested to increase the cadence to annually in addition to meeting for every rate change. Another commenter supported annual meetings and noted that issues impacting the lives of beneficiaries and workers that should be addressed by rates can happen at a more frequent rate than biannual State budget cycles. One commenter stated the meeting cadence should be every 6 months.

A few commenters suggested a number of additional recommendations such as the regulation should include a requirement of recordkeeping, and the regulation should focus on the distinction between independent and agency-employed workers. Finally, one commenter

suggested a name change for the group, “direct care workforce payment advisory committee,” to clarify the role and importance of the group.

Response: We appreciate the feedback about the specifics of the administration of the interested parties advisory group. We are finalizing these aspects as proposed. The meeting cadence, as noted by the commenter, is intended to align with usual State budgetary cycles. While other factors may impact the needs of beneficiaries, providers and direct care workers, the State budget creates the framework in which decisions and recommendations can be made, and we believe aligning with that cycle appropriately balances the value gained from the interested parties advisory group’s recommendations with burden on States. Similarly, we are finalizing the ability of States to determine the tenure of members, as States are best situated to assess their beneficiaries’ and workers’ ability to participate in an advisory group and for what length of time. Term limits and removal for cause will be at the State’s discretion to ensure the effective operation of the group. We note that the regulation does specify that the process by which the State selects interested parties advisory group members and convenes its meetings must be made publicly available, which aligns with recommendations from some commenters.

States have requirements to maintain records of public input under § 447.203(c)(4)(iii), and as stated we would regard the recommendation of the group a form of public input to the extent the group comments on proposed rates.

With respect to individual and agency-employed providers, the payment rate disclosure requirements under § 447.203(b)(3)(ii2)(iv) require States to publish average hourly Medicaid FFS fee schedule payment rates for individual providers and provider agencies separately to the extent they differ, creating a new method through which the State, CMS, and the public can scrutinize any rate difference between individual providers and provider agencies. We are not adding additional requirements for the group to examine further distinctions between individual and provider agencies, but as the group will be reviewing current and proposed rates, they will have the opportunity to see where such rates differ and make recommendations accordingly.

Finally, we appreciate the suggestion to change the name of the group, but we want to remind that the purview of this group is not solely payments for HCBS, although that is the primary focus. The work includes access metrics, specifically HCBS payment adequacy data as required at § 441.311(e), and access to care metrics under § 441.311(d)(2). We understand the name is rather generic, and we will make every effort to ensure any materials or communications are clear about when an “interested parties advisory group” is in reference to § 447.203(b)(6).

Comment: We received some comments in opposition to an interested parties advisory group. A primary, recurring element of these comments was related to the burden of establishing this group relative to the value the commenters thought the group would add. One commenter stated this group would be duplicative of other State efforts, without adding value. Another was concerned that the group would establish a pattern for more, similar groups to be created, resulting in significant State burden. Another stated the group would create undue interference in a State’s ability to manage its Medicaid program. One commenter stated that limiting the group’s purview to three services would create disjointedness in discussions about HCBS or broader rates in general.

One commenter stated that their MCAC (or, following the effective date of this final rule, their MAC), already performs the same functions as the proposed interested parties advisory group. Another requested an exception to the requirement for States that already have a group established for similar topics. Two commenters in opposition to the requirement had recommendations for adjustments. One commenter stated that the group should not include members who have a conflict of interest because they stand to receive a financial benefit from the decisions of the group, or that the scope of the group’s recommendations should exclude payment rates if group members have financial conflicts of interest. Another commenter, who thought the group was unworkable and likely would not be productive, indicated it would be more productive to require States to establish a separate advisory group for each rate setting activity they undertake and to include both industry and consumer (beneficiary) representatives.

Response: We understand that there will be costs and work for States to set up a new advisory group. We do not take lightly the decision to finalize this policy. However, the circumstance of HCBS and the direct care workforce shortage described earlier in this section demand immediate action. We kept the required scope of the group's remit narrow to allow States that need to minimize the work of the group the ability to focus most acutely on certain services and certain topics around rates, access, and payment adequacy. However, we also wrote into these regulations a great deal of flexibility for States. We understand the burden our requirements put on States, which is why we take steps to create and highlight flexibility for States to minimize the burden of new requirements and help ensure that States are able to comply with new requirements in a manner likely to result in the greatest benefit given the particular circumstances of the State and its provider and beneficiary communities. We make these assessments with every rulemaking proposal. The creation of this group does not mean that we necessarily will propose to require the formation of additional similar, discrete groups in the future; we are mindful that any such proposal would be likely to involve additional burden on States, and analysis of that burden would inform any future proposal.

If a State believes the group, in the form which we are finalizing in this final rule, will not add value, there is room to expand and enhance the group to a point where that State realizes value to its program. The group's purview includes the requirement to examine rates for three services, but States can always have the group advise on more. In addition, the group will not be in a position to unduly influence the State's Medicaid program, as its role is only advisory in nature and the single State agency will maintain full responsibility to administer the State's Medicaid program. We also want to remind States what we included in the proposed rule, that to the extent a State's MAC established under § 431.12 meets the requirements of this regulation, the State could utilize that committee for this purpose, thereby eliminating duplication between these entities. Furthermore, while we are unaware of specific examples, if a State has another, extant group that meets the requirements of § 447.203(b)(6), then we expect the State could use

that group for this purpose as well, similar to what we indicated for MACs. Finally, we do not agree that having members in the group with a financial interest, such as the direct care workers whose wages may be impacted, and advising on rates creates a problematic conflict of interest. Rather, in the case of direct care workers, we believe their lived experience will supply a valuable perspective, and their input on rates specifically could be useful to the State agency that (although operating under a fiduciary obligation to administer the Medicaid program in the best interest of beneficiaries under section 1902(a)(19) of the Act) also has a fiscal interest in a proposed rate change. This final rule leaves States free to establish conflict of interest policies applicable to the members of the interested parties' advisory group, which we expect States will do in a manner that protects the integrity of the group while not unduly restricting input from individuals with perspectives the final rule is intended to ensure are heard.

Comment: Several commenters responded to language included in the proposed rule that, to the extent a State's MAC established under proposed § 431.12 also meets the requirements of this advisory group regulation, the State could utilize that committee for this purpose. The majority of those comments recommended keeping the MAC separate. These commenters explained that the work involved merits two groups and any overlap of membership between the groups would be acceptable and potentially beneficial. One of those commenters stated that the work of the interested parties' advisory group was much more specialized than that of the MAC. One suggested the interested parties' advisory group be a subgroup of the MAC, similar to the BAG. Finally, one commenter suggested that the MAC and interested parties' advisory group meetings be kept separate, or the MAC could have a dedicated subgroup responsible for HCBS, to ensure adequate attention to the topic. There were a few commenters who appreciated the flexibility to allow for the MAC to serve this dual purpose of meeting both the MAC requirements and the interested parties' advisory group requirements, and one expected some States may pursue this flexibility.

Response: When we were developing the proposed rule, which included proposals under § 431.12 to reconfigure the MCAC as the MAC and BAG (now BAC), we noted that the membership and scope of the MAC could potentially align with what we were proposing for the interested parties' advisory group. While we agree that the work of each is distinct and important, deserving of dedicated time and focus, we also seek to avoid duplication where possible. If a MAC has membership that includes direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services and rates of focus in the interested parties' advisory group, then we believe it would be unnecessarily duplicative to require a separate group and deny the State the ability to include the remit of the interested parties' advisory group in the work of the MAC under the flexibility given to States and their MACs under § 431.12(g)(8), which we are finalizing to include in the MAC's scope "[o]ther issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State." States potentially also could establish the interested parties' advisory group as a subgroup of the MAC, similar to the BAC, consistent with the requirements of this final rule. States will have the discretion to determine if the groups and/or their meetings need to be kept distinct in order best to fulfil the obligations of each.

However, we caution States that this flexibility is not creating any type of exception. The cadence of required meetings, focus, and work products of the interested parties advisory group are distinct, and States wishing to utilize their MAC will need to take adequate steps to ensure the MAC is meeting the regulatory requirements for both entities. Some States may find keeping the interested parties group distinct will allow for easier recruitment, retention, and focus on the relevant subject matter. We also want to highlight the concerns expressed by commenters requesting the groups be kept distinct and emphasizing the specialized work of this interested parties advisory group. Although we did not elect to add requirements to keep the groups or

meetings distinct, States should do so if combining the groups or their meetings would hinder the work of either the MAC or interested parties advisory group.

Comment: A few commenters requested additional clarity about what support would be available for States to establish the advisory group. A couple of commenters requested CMS confirm that States can claim FFP for activities related to establishing and running this group, similar to the confirmation provided in the MAC/BAG provisions explicitly saying FFP would be available.³³³ Others requested CMS make States aware of any available funding streams or opportunities for enhanced match.

Response: In the proposed rule, we specified that “FFP would be available for expenditures that might be necessary to implement the activities States would need to undertake to comply with the provisions of the proposed rule, if finalized.”³³⁴ As we are finalizing the requirements related to this advisory group, FFP will be available for States claiming qualifying expenditures for related activities. We note that generally, the applicable matching rate will be the general 50 percent administrative matching rate, but to the extent a State incurs expenditures it believes qualify for a higher match rate, higher statutory matching rates potentially could be available to the extent the expenditures meet applicable Federal requirements. There is not a separate, unique funding source for this provision of the final rule.

After consideration of public comments, we are finalizing all provisions under § 447.203(b)(6) with the following changes:

- Added a regulatory reference for habilitation services as a category of service in § 447.203(b)(6)(i). The finalized language now states “...for the self-directed or agency-directed services found at § 440.180(b)(2) through (4) **and (6).**” (new language identified in bold).
- Added a regulatory reference for habilitation services and “habilitation” as a category of service in § 447.203(b)(6)(iii). The finalized language now states “...associated with services

³³³ 88 FR 27960 at 27967.

³³⁴ 88 FR 27960 at 27962

found at § 440.180(b)(2) through (4) **and (6)**, to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, homemaker, and **habilitation services**” (new language identified in bold).

- Added language to clarify the “...publication requirements described in paragraph (b)(1) **through (b)(1)(ii)** of this section...” (new language identified in bold).

- Minor technical changes to wording.

3. State Analysis Procedures for Rate Reduction or Restructuring (§ 447.203(c))

As stated previously, the Supreme Court’s Armstrong decision underscored the importance of CMS’ administrative review of Medicaid payment rates to ensure compliance with section 1902(a)(30)(A) of the Act. CMS’ oversight role is particularly important when States propose to reduce provider payment rates or restructure provider payments, since provider payment rates can affect provider participation in Medicaid, and therefore, beneficiary access to care. In § 447.203(c), we proposed a process for State access analyses that would be required whenever a State submits a SPA proposing to reduce provider payment rates or restructure provider payments.

As noted previously, the 2015 final rule with comment period required that, for any SPA proposing to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, States must submit a detailed analysis of access to care under previous §§ 447.203(b)(1) and (b)(6) and 447.204(b)(1). This analysis includes, under previous § 447.203(b)(1), the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Previously, this

information was required for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, regardless of the provider payment rates or levels of access to care before the proposed reduction or restructuring.

Following the implementation of the 2015 final rule with comment period, as we worked with States to implement the previous AMRP requirements, many States expressed concerns that the requirements that accompany proposed rate reductions or restructurings are overly burdensome. Specifically, States pointed to instances where proposed reductions or restructurings are nominal, or where rate changes are made via the application of a previously approved rate methodology, such as when the State's approved rate methodology ties Medicaid payment rates to a Medicare fee schedule and the Medicare payment rate is reduced. We acknowledged these concerns through previous proposed rulemaking. In the 2018 proposed rule, we agreed that our experience implementing the previous AMRP process from the 2015 final rule with comment period raised questions about the benefit of the access analysis when proposed rate changes include nominal rate reductions or restructurings that are unlikely to result in diminished access to care.³³⁵

We did not finalize the 2018 proposed rule; instead, in response to feedback, we proposed a rescission of the previous AMRP process in the 2019 proposed rule.³³⁶ In that proposed rule, we indicated that future guidance would be forthcoming to provide information on the required data and analysis that States might submit with rate reduction or restructuring SPAs in place of the previous AMRP process to support compliance with section 1902(a)(30)(A) of the Act.³³⁷ We did not finalize the rescission proposed in the 2019 proposed rule. Although we were concerned that the previous AMRP process was overly burdensome for States and CMS in relation to the benefit obtained in helping ensure compliance with the access requirement in

³³⁵ 83 FR 12696 at 12697.

³³⁶ 84 FR 3372.2

³³⁷ Id at 33723.

section 1902(a)(30)(A) of the Act, our 2018 and 2019 proposed rules did not adequately consider our need for information and analysis from States seeking to reduce provider payment rates or restructure provider payments to enable us to determine that the statutory access requirement is met when making SPA approval decisions.

To improve the efficiency of our administrative procedures and better inform our SPA approval decisions, we proposed to establish standard information that States would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when the changes could result in diminished access, including a streamlined set of data when the reductions or restructurings are nominal, the State rates are above a certain percentage of Medicare payment rates, and there are no evident access concerns raised through public processes; and an additional set of data elements that would be required when States propose FFS provider payment rate reductions or restructurings in circumstances when the changes could result in diminished access and these criteria are not met. For both sets of required or potentially required elements, we proposed to standardize the data and information States would be required to submit with rate reduction or restructuring SPAs. Although the previous AMRP process has helped to improve our administrative reviews and helped us make informed SPA approval determinations, we explained that the proposed procedures would provide us with similar information in a manner that reduces State burden. Additionally, the proposed procedures would provide States increased flexibility to make program changes with submission of streamlined supporting data to us when current Medicaid rates and proposed changes fall within specified criteria that create a reasonable presumption that proposed reductions or restructuring would not reduce beneficiary access to care in a manner inconsistent with section 1902(a)(30)(A) of the Act.

This final rule seeks to achieve a more appropriate balance between reducing unnecessary burden for States and CMS and ensuring that we have the information necessary to make appropriate determinations for whether a rate reduction or restructuring SPA might result in

beneficiary access to covered services failing to meet the standard in section 1902(a)(30)(A) of the Act. In § 447.203(c), we proposed to establish analyses that States would be required to perform, document, and submit concurrently with the submission of rate reduction and rate restructuring SPAs, with additional analyses required in certain circumstances due to potentially increased access to care concerns.

We proposed a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, proposed at § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. The State agency would be required to provide written assurance and relevant supporting documentation that the three criteria specified in those paragraphs are met, as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act. As explained in more detail later in this section, these criteria proposed in § 447.203(c)(1) represent thresholds we believe would be strong indicators that Medicaid payment rates would continue to be sufficient following the change to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We noted that, in the course of our review of a payment SPA that meets these criteria, as with any SPA review, we may need to request additional information to ensure that all Federal SPA requirements are met. We also note that meeting the three criteria described in proposed § 447.203(c)(1) does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. Furthermore, if any criterion in the first tier is not met, we proposed a second tier in § 447.203(c)(2), which would require the State to conduct a more extensive access

analysis in addition to providing the results of the analysis in the first tier. A detailed discussion of the second tier follows the details of the first tier in this section.

Under proposed § 447.203(c)(1)(i), the State would be required to provide a supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that providers will participate in the Medicaid program, we proposed to use 80 percent as a threshold to help determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act. Establishing this threshold will allow CMS to focus its resources on reviewing payment proposals that are at highest risk for access to care concerns. Notably, there are other provisions of the proposal that would provide opportunities for the public to raise access to care concerns to State agencies and to CMS should the 80 percent prove insufficient to provide for adequate access to care for certain care and services.

In proposed § 447.203(c)(1)(i), we explained that we mean for “benefit category” to refer to all individual services under a category of services described in section 1905(a) of the Act for which the State is proposing a payment rate reduction or restructuring. Comparing the payment rates in the aggregate would involve first performing a comparison of the Medicaid to the Medicare payment rate on a code-by-code basis, meaning CPT, CDT, or HCPCS as applicable, to derive a ratio for individual constituent services, and then the ratios for all codes within the benefit category would be averaged by summing the individual ratios then dividing the sum by the number of ratios. For example, if the State is seeking to reduce payment rates for a subset of physician services, the State would review all current payment rates for all physician services and determine if the proposed reduction to the relevant subset of codes would result in an

average Medicaid payment rate for all physician services that is at or above 80 percent of the average corresponding Medicare payment rates. For supplemental payments, we are relying upon the definition of supplemental payments in section 1903(bb)(2) of the Act, which defines supplemental payments as “a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority . . . [b]ut such term does not include a disproportionate share hospital payment made under section 1923 [of the Act].” With the inclusion of supplemental payments, States would need to aggregate the supplemental payments paid to qualifying providers during the State fiscal year and divide by all providers’ total service volume (including service volume of providers that do not qualify for the supplemental payment) to establish an aggregate, per-service supplemental payment amount, then add that amount to the State’s fee schedule rate to compare the aggregate Medicaid payment rate to the corresponding Medicare payment rate. As this supported assurance in proposed § 447.203I(1)(i) is expected to be provided with an accompanying SPA, we noted that CMS may ask the State to explain how the analysis was conducted if additional information is needed as part of the analysis of the SPA. We solicited comments on the proposed § 447.203I(1)(i) supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services should include a weighted average of the payment rate analysis by service volume, number of beneficiaries receiving the service, and total amount paid by Medicaid for the code in a year using State’s Medicaid utilization data from the MMIS claims system rather than using a straight code-by-code analysis.

We explained that we understand this approach may have a smoothing effect on the demonstrated overall levels of Medicaid payment within a benefit category under the State plan. In many circumstances, only a subset of providers are recipients of Medicaid supplemental

payments with the rest of the providers within the benefit category simply receiving the State plan fee schedule amount. This could result in a demonstration showing the Medicaid payments being high relative to Medicare, but the actual payments to a large portion of the providers would be less than the overall demonstration would suggest. As an alternative, we considered whether to adopt separate comparisons for providers who do and who do not receive supplemental payments, where a State makes supplemental payments for a service to some but not all providers of that service. We solicited comments on the proposed approach and this alternative.

We selected FFS Medicare, as opposed to Medicare Advantage, as the proposed payer for comparison for a number of reasons. A threshold issue is payment rate data availability: private payer data may be proprietary or otherwise limited in its availability for use by States. In addition, Medicare sets its prices rather than negotiating them through contracts with providers, and is held to many similar statutory standards as Medicaid with respect to those prices, such as efficiency, access, and quality.³³⁸ For example, section 1848(g)(7) of the Act directs the Secretary of HHS to monitor utilization and access for Medicare beneficiaries provided through the Medicare fee schedule rates, and directs that the Medicare Payment Advisory Commission (MedPAC) shall comment on the Secretary's recommendations. In developing its comments, MedPAC convenes and consults a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care. In a March 2001 report, MedPAC summarized its evaluation of Medicare rates, stating "Medicare buys health care products and services from providers who compete for resources in private markets. To ensure beneficiaries' access to high-quality care, Medicare's payment systems therefore must set payment rates for health care products and services that are: high enough to stimulate adequate numbers of providers to offer services to beneficiaries, sufficient to enable efficient providers to supply high-quality services, given the trade-offs between cost and quality that exist with current

³³⁸ <https://www.healthcarevaluehub.org/advocate-resources/publications/medicare-rates-benchmark-too-much-too-little-or-just-right>.

technology and local supply conditions for labor and capital, and low enough to avoid imposing unnecessary burdens on taxpayers and beneficiaries through the taxes and premiums they pay to finance program spending.”³³⁹ Medicare’s programmatic focus on beneficiary access aligns with the requirements of section 1902(a)(30)(A) of the Act.

In addition, Medicare PFS fee schedule rates are stratified by geographic areas within the States, which we seek to consider as well to ensure that payment rates are consistent with section 1902(a)(30)(A) of the Act. The fee schedule amounts are established for each service, generally described by a particular procedure code (including HCPCS, CPT, and CDT,) using resource-based inputs to establish relative value units (RVUs) in three components of a procedure: work, practice expense, and malpractice. The three component RVUs for each service are adjusted using CMS-calculated geographic practice cost indexes (GPCIs) that reflect geographic cost differences in each fee schedule area as compared to the national average. The current Medicare PFS locality structure was implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (PAMA 2014). Under the current locality structure, there are 112 total PFS localities.³⁴⁰

When considering geography in their rate analyses, we noted that we expect States to conduct a code-by-code analysis of the ratios of Medicaid-to-Medicare provider payment rates for all applicable codes within the benefit category, either for each of the GPCIs within the State, or by calculating an average Medicare rate across the GPCIs within the State (such as in cases where a State does not vary its rates by region). In cases where a State does vary its Medicaid

³³⁹ MedPAC. Report to the Congress: Medicare Payment Policy, March 2001. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar01Ch1.pdf. Accessed December 20, 2022.

³⁴⁰ Section 220(b) of PAMA 204 added section 1848(e)(6) of the Act, which requires that, for services furnished on or after January 1, 2017, the locality definitions for California, which has the most unique locality structure, be based on the Metropolitan Statistical Area (MSA) delineations as defined by the Office of Management and Budget (OMB). The resulting modifications to California’s locality structure increased its number of localities from 9 under the previous structure to 27 under the MSA-based locality structure (operational note: for the purposes of payment the actual number of localities under the MSA-based locality structure is 32). Of the 112 total PFS localities, 34 localities are Statewide areas (that is, only one locality for the entire State). There are 75 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 112 localities. Medicare PFS Locality Configuration. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality>. Accessed December 21, 2022.

rates based on geography, but that variation does not align with the Medicare GPCI, we explained that the State should utilize the Medicare payment rates as published by Medicare for the same geographical location as the base Medicaid FFS fee schedule payment rate to achieve an equivalent comparison and align the Medicare GPCI to the locality of the Medicaid payment rates, using the county and locality information provided by Medicare for the GPCIs, for purposes of creating a reasonable comparison of the payment rates.³⁴¹ To conduct such an analysis that meets the requirements of proposed § 447.203(c)(1)(i), States may compare the Medicaid payment rates applicable to the same Medicare GPCI to each Medicare rate by GPCI individually, and then aggregate that comparison into an average rate comparison for the benefit category. To the extent that Medicaid payment rates do not vary by geographic locality within the State, the State may also calculate a Statewide average Medicare rate based upon all of the rates applicable to the GPCIs within that State and compare that average Medicare rate to the average Medicaid rate for the benefit category.

Once we decided to propose using Medicare payment rates as a point of comparison, we needed to decide what threshold ratio of proposed Medicaid to Medicare payment rates should trigger additional consideration and review for potential access issues. First, we considered how current levels of Medicaid payment compares to the Medicare payment for the same services. In a 2021 *Health Affairs* article, Zuckerman, et al, found that “Medicaid physician fees were 72 percent of Medicare physician fees for twenty-seven common procedures in 2019.”³⁴² This ratio varied by service type. For example, “the 2019 Medicaid-to-Medicare fee index was lower for primary care (0.67) than for obstetric care (0.80) or for other services (0.78).” The authors also found that “between 2008 and 2019 Medicare and Medicaid fees both increased (23.6 percent for Medicare fees and 19.9 percent for Medicaid fees), leaving the fee ratios similar.”³⁴³

³⁴¹ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality>.

³⁴² Zuckerman, S. et al. “Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,” *Health Affairs*, Volume 40, Number 2, February 2021. Available at <https://doi.org/10.1377/hlthaff.2020.00611> (accessed December 23, 2022).

³⁴³ *Id.*

Next, considering that Medicaid rates are generally lower than Medicare, we wanted to examine the relationship between these rates and a beneficiary's ability to access covered services. This led us to first look into a comparison of physician new patient acceptance rates based on a prospective new patient's payer. In a June 2021 fact sheet, MACPAC found "in 2017 (the most recent year available), physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent)."³⁴⁴ MACPAC found this to be true "regardless of physician demographic characteristics (age, sex, region of the country); and type and size of practice."³⁴⁵

We then wanted to confirm whether this was related to the rates themselves. In a 2019 *Health Affairs* article, the authors found that, "higher payment continues to be associated with higher rates of accepting new Medicaid patients...physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid."³⁴⁶ The study found that physicians in States that pay above the median Medicaid-to-Medicare fee ratio accepted new Medicaid patients at higher rates than those in States that pay below the median, with acceptance rates increasing by nearly 1 percentage point (0.78) for every percentage point increase in the fee ratio.³⁴⁷

Similarly, in a 2020 study published by the *National Bureau of Economic Research*, researchers found that there was a positive association between increasing Medicaid physician fees and increased likelihood of having a usual source of care, improved access to specialty doctor care, and large improvements in caregivers' satisfaction with the adequacy of health coverage, among children with special health care needs with a public source of health

³⁴⁴ MACPAC. "Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey." June. 2021. Available at <https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf> (accessed December 23, 2023).

³⁴⁵ Id.

³⁴⁶ Holgash, K. and Martha Heberlein, "Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't." *Health Affairs*, April 10, 2019. Available at <https://www.healthaffairs.org/doi/10.1377/forefront.20190401.678690/full/> (accessed February 22, 2023).

³⁴⁷ Id.

coverage.³⁴⁸ Further, Berman, et al, focused on pediatricians and looked at Medicaid-Medicare fee ratio quartiles, finding that the percent of pediatricians accepting all Medicaid patients and relative pediatrician participation in Medicaid increased at each quartile, but improvement was most significant up to the third quartile.³⁴⁹ According to the Kaiser Family Foundation, in 2016, following the expiration of section 1202 of the Affordable Care Act (Pub. L. 111-148), which amended section 1902(a)(13) of the Act to implement a temporary payment floor for certain Medicaid primary care physician services, the third quartile of States had Medicaid-Medicare fee ratios of between 79 and 86 percent for all services provided under all State Medicaid FFS programs.³⁵⁰ Importantly, considering the proposed requirements at paragraph (c) would pertain to proposed payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access, multiple recent studies have also shown that the association between Medicaid physician fees and measures of beneficiary access are consistent whether physician payments are increased or decreased to reach a particular level at which access is assessed.³⁵¹

The Kaiser Family Foundation found that 23 States have Medicaid-to-Medicare fee ratios of at least 80 percent for all services, 17 States have fee ratios of 80 percent for primary care services, 32 States have fee ratios of 80 percent for obstetric care, and 27 States have fee ratios of 80 percent for other services.³⁵² Additional studies support the Holgash and Heberlein findings that physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid, showing that States with a Medicaid to Medicare fee ratio at

³⁴⁸ Chatterji, P. et al. "Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs" National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2-54. Medicaid Physician Fees and Access to Care among Children with Special Health Care Needs | NBER. Accessed June 16, 2022.

³⁴⁹ Berman, S., et al. "Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients" *Pediatrics*.

³⁵⁰ <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index>.

³⁵¹ Candon, M., et al. "Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients" *JAMA Internal Medicine*, Volume 178, Number 1, January 2018, p. 145-146. Available at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2663253>. Accessed June 16, 2022.

³⁵² <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index>.

or above 80 percent show improved access for children to a regular source of care,³⁵³ and decreased use of hospital-based facilities, versus States with a lower Medicaid to Medicare fee ratio.

We noted our concern that higher rates of acceptance by some providers of new patients with payers other than Medicaid (specifically, Medicare and private coverage), and indications by some providers that low Medicaid payments are a primary reason for not accepting new Medicaid patients, may suggest that some beneficiaries could have a more difficult time accessing covered services than other individuals in the same geographic area. We are encouraged by findings that suggest that some increases in Medicaid payment rates may drive increases in provider acceptance of new Medicaid patients, with one study finding that new Medicaid patient acceptance rates increased by 0.78 percent for every percentage point increase in the Medicaid-to-Medicare fee ratio, for certain providers for certain States above the median Medicaid-to-Medicare fee ratio.³⁵⁴ ³⁵⁵ In line with the Berman study, which found that increases in the percentage of pediatricians participating in Medicaid and of pediatricians accepting new Medicaid patients occurred with Medicaid payment rate increases at each quartile of the Medicaid-to-Medicare fee ratio but were most significant up to the third quartile, we believe that beneficiaries in States that provide this level of Medicaid payment generally may be less likely to encounter access to care issues at rates higher than the general population.³⁵⁶ In line with the Kaiser Family Foundation reporting of the Medicaid-to-Medicare fee ratio third quartile as ranging from 79 to 86 percent in 2016, depending on the service, we stated our belief that a minimum 80 percent Medicaid-to-Medicare fee ratio is a reasonable threshold to propose in

³⁵³ Chatterji, P. et al. “Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs” National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2-54. Available at <https://www.nber.org/papers/w26769>. Accessed August 16, 2022.

³⁵⁴ MACPAC. “Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey.” June. 2021. Available at <https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf> (accessed December 23, 2023).

³⁵⁵ Holgash, K. and Martha Heberlein, “Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn’t.” *Health Affairs*, April 10, 2019. Available at <https://www.healthaffairs.org/doi/10.1377/forefront.20190401.678690/full/> (accessed February 22, 2023).

³⁵⁶ Berman, S., et al. “Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients” *Pediatrics*.

§ 447.203(c)(1)(i) as one of three criteria State proposals to reduce or restructure provider payments would be required to meet to qualify for the proposed streamlined documentation process.³⁵⁷ As documented by the Kaiser Family Foundation, many States currently satisfy this ratio for many Medicaid-covered services, and according to findings by Zuckerman, et al. in *Health Affairs*, in 2019, the average nationwide fee ratio for obstetric care met this proposed threshold.³⁵⁸ ³⁵⁹ We proposed that this percentage would hold across benefit categories, because we did not find any indication that a lower threshold would be adequate, or that a higher threshold would be strictly necessary, to support a level of access to covered services for Medicaid beneficiaries at least as great as for the general population in the geographic area. We noted that the disparities in provider participation for some provider types may be larger than this overview suggests, as such we proposed a uniform standard in the interest of administrative simplicity but cautioned that States must meet all three of the criteria in proposed paragraph (c)(1) to qualify for the streamlined analysis process; otherwise, the additional analysis specified in proposed paragraph (c)(2) would be required.

Given the results of this literature review, and by proposing this provision as only one part of a three-part assessment of the likely effect of a proposed payment rate reduction or payment restructuring on access to care, as further discussed in this section, we proposed 80 percent of the most recently published Medicare payment rates, as identified on the applicable Medicare fee schedule for the same or a comparable set of Medicare-covered services, as a benchmark for the level of Medicaid payment for benefit categories that are subject to proposed provider payment reductions or restructurings that is likely to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent as to the general population in the geographic area, where the additional tests in proposed § 447.203(c)(1) also are

³⁵⁷ <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index>.

³⁵⁸ Id.

³⁵⁹ Zuckerman, S. et al. “Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019,” *Health Affairs*, Volume 40, Number 2, February 2021. Available at <https://doi.org/10.1377/hlthaff.2020.00611> (accessed December 23, 2022).

met. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that providers will participate in the Medicaid program, we proposed to use 80 percent as a threshold to help determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act. Establishing this threshold will allow CMS to focus its resources on reviewing payment proposals that are at highest risk for access to care concerns. Notably, there are other provisions of the proposal that would provide opportunities for the public to raise access to care concerns to State agencies and to CMS should the 80 percent prove insufficient to provide for adequate access to care for certain care and services.

We explained that the published Medicare payment rates means the amount per applicable procedure code identified on the Medicare fee schedule. The established Medicare fee schedule rate includes the amount that Medicare pays for the claim and any applicable coinsurance and deductible amounts owed by the patient. Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries.

Section 447.15 defines payment-in-full as “the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual.” Therefore, State fee schedules should be inclusive of total base payments from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to include expected beneficiary cost sharing to align with Medicare’s fee schedule.

We noted that Medicaid benefits that do not have a reasonably comparable Medicare-covered analogue, and for which a State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access, would be subject to the expanded review criteria proposed in § 447.203(c)(2), because the State would be

unable to demonstrate its Medicaid payment rates are at or above 80 percent of Medicare payment rates for the same or a comparable set of Medicare-covered services after the payment rate reduction or payment restructuring. For identifying a comparable set of Medicare-covered services, we stated that we would expect to see services that bear a reasonable relationship to each other. For example, the clinic benefit in Medicaid does not have a directly analogous clinic benefit in Medicare. In Medicaid, clinic services generally are defined in § 440.90, as “preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.” This can include a number of primary care services otherwise available through physician practices and other primary care providers, such as nurse practitioners. Therefore, in seeking to construct a comparable set of Medicare-covered services to which the State could compare its proposed Medicaid payment rates, the State reasonably could include Medicare payment rates for practitioner services, such as physician and nurse practitioner services, or payments for facility-based services that bear a reasonable similarity to clinic services, potentially including those provided in Ambulatory Surgical Centers. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for constructing the Medicare rate to compare to Medicaid payment rates.

In § 447.203(c)(1)(ii), we proposed that the State would be required to provide a supported assurance that the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the State fiscal year, would result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a single State fiscal year. We explained that the documentation will need to show the change stated as a percentage reduction in aggregate FFS Medicaid expenditures for each affected benefit category. We recognized that the

effects of payment rate reductions and payment restructurings on beneficiary access generally cannot be determined through any single measure, and applying a 4 percent threshold without sufficient additional safeguards would not be prudent. Therefore, we proposed to limit the 4 percent threshold as the cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. We proposed the cumulative application of the threshold to State plan actions taken within a State fiscal year as opposed to a SPA-specific application to avoid circumstances where a State may propose rate reductions or restructurings that cumulatively exceed the 4 percent threshold across multiple SPAs without providing additional analysis.

For example, if a State proposed to reduce payment rates for a broad set of obstetric services by 3 percent in State fiscal year 2023 and had not proposed any other payment changes affecting the benefit category of obstetric care during the same State fiscal year, that payment change would meet the criterion proposed in § 447.203(c)(1)(ii) because it would be expected to result in no more than a 3 percent reduction in aggregate Medicaid expenditures for obstetric care within a State fiscal year. However, if the State had received approval earlier in the State fiscal year to revise its obstetric care payment methodology to include value-based arrangements expected to reduce overall Medicaid expenditures for obstetric care by 2 percent per State fiscal year, then it is likely that the cumulative effect of the proposal to reduce payment rates for a broad set of obstetric services by 3 percent and the Medicaid obstetric care expenditure reductions under the earlier-approved payment restructuring would result in an aggregate reduction to FFS Medicaid expenditures for obstetric services of more than 4 percent in a State fiscal year. If so, the State's proposal would not meet the criterion proposed in § 447.203(c)(1)(ii), and the proposal would be subject to the additional review criteria proposed in § 447.203(c)(2). The State would need to document for our review whether the three percent payment rate reduction proposal for the particular subset of obstetric services would be likely to

result in a greater than 2 percent further reduction in aggregate FFS Medicaid expenditures for obstetric care as compared to the expected expenditures for such services for the State fiscal year before any payment rate reduction or payment restructuring; if this expected aggregate reduction is demonstrated to be 2 percent or less, then the proposal still could meet the criterion proposed in § 447.203(c)(1)(ii).

We proposed to codify a 4 percent reduction threshold for aggregate FFS Medicaid expenditures in each benefit category affected by a proposed payment rate reduction or payment restructuring within a State fiscal year. This threshold is consistent with one we proposed in the 2018 proposed rule, which proposed to require the States to submit an AMRP with any SPA that proposed to reduce provider payments by greater than 4 percent in overall service category spending in a State fiscal year or greater than 6 percent across 2 consecutive State fiscal years, or restructure provider payments in circumstances when the changes could result in diminished access.³⁶⁰ The proposed rule received positive feedback from States regarding its potential for mitigating administrative burden, and providing States with flexibility to administer their programs and make provider payment rate changes. Some States and national organizations requested that we increase the rate reduction threshold to 5 percent and increase the consecutive year threshold to 8 percent.^{361, 362} Non-State commenters cautioned CMS against providing too much administrative flexibility and to not abandon the Medicaid access analysis the previous AMRP regulations required. Commenters also raised that 4 and 6 percent may seem nominal for larger medical practices and health care settings, but for certain physician practices or direct care workers a 6 percent reduction in payment could be considerable.³⁶³ This feedback has been essential in considering how we proceed with this rulemaking, in which we emphasize that the

³⁶⁰ 83 FR 12696 at 12698.

³⁶¹ Connecticut Department of Social Services. Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf.

³⁶² National Association of Medicaid Directors. Comment Letter on 2018 Proposed rule (June 1, 2018), https://downloads.regulations.gov/CMS-2018-0031-0115/attachment_1.pdf.

³⁶³ American Academy of Family Physicians, Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0017/attachment_1.pdf.

size of the rate reduction threshold proposed in § 447.203(c)(1)(ii) would operate in conjunction with the two other proposed elements in § 447.203(c)(1)(i) and (iii) to qualify the State for a streamlined analysis process and would not exempt the proposal from scrutiny for compliance with section 1902(a)(30)(A) of the Act.

We proposed a 4 percent threshold on cumulative provider payment rate reductions throughout a single State fiscal year as one of the criteria of the streamlined process in proposed paragraph (c)(1), and therefore, emphasizing that while we believe this payment threshold to be nominal and unlikely to diminish access to care, we proposed to include paragraph (c)(1)(i) to require States to review current levels of provider payment in relation to Medicare and proposed to include paragraph (c)(1)(iii) to require that States rely on the public process to inform the determination on the sufficiency of the proposed payment rates after reduction or restructuring, with consideration for providers and practice types that may be disproportionately impacted by the State's proposed rate reductions or restructurings.

As previously noted, we would not consider any payment rate reduction or payment rate restructuring proposal to qualify for the streamlined analysis process in the proposed paragraph (c)(1) unless all three of the proposed paragraph (c)(1) criteria are met. Using information from the Kaiser Family Foundation's Medicaid-to-Medicare fee index³⁶⁴ as an example, only 15 States could have reduced primary care service provider payment rates by up to 4 percent in 2019 and continued to meet the 80 percent of Medicare threshold in proposed paragraph (c)(1). Even those 15 States with rates above the 80 percent of Medicare threshold would be subject to proposed paragraph (c)(2) requirements if the State received significant public feedback that the proposed payment reduction or restructuring would result in an access to care concern, if the State were unable to reasonably respond to or mitigate such concerns. All States with primary care service payment rates below the 80 percent of Medicare threshold, no matter the size of the payment rate reduction or restructuring and no matter whether interested parties expressed access

³⁶⁴ <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/>.

concerns through available public processes, would have to conduct an additional access analysis required under proposed paragraph (c)(2).

We issued SMDL #17-004 to provide States with guidance on complying with regulatory requirements to help States avoid unnecessary burden when seeking approval of and implementing payment changes, because States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17-004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17-004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule.³⁶⁵

In instances where States submitted payment rate reduction SPAs after the publication of SMDL #17-004, we routinely have asked the State for an explanation of the purpose of the proposed change, whether the FFS Medicaid expenditure impact for the service category would be within a 4 percent reduction threshold, and for an analysis of public comments received on the proposed change, and approved those SPAs to the extent that the State was able to resolve any potential access to care issues and determined that access would remain consistent for the

³⁶⁵ See, for example: Indiana Family and Social Services Administration. Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0055/attachment_1.pdf; Colorado Department of Health Care Policy and Financing. Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0087/attachment_1.pdf; The Commonwealth of Massachusetts Executive Office of Health and Human Services Office of Medicaid. Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0020/attachment_1.pdf.

Medicaid population. For example, in the proposed rule, we stated that, of the 849 SPAs approved in 2019, there were 557 State payment rate changes. Of those, 39 were classified as payment rate reductions or methodology changes that resulted in a reduction in overall provider payment. Within those 39, there were 18 SPAs that sought to reduce payments by less than 4 percent of overall spending within the benefit category, most of which were decreases related to changes in Medicare payment formulas. Sixteen of the remaining 21 SPAs fell into an area discussed in SMDL #17-004 as being unlikely to result in diminished access to covered services, where with the State's analytical support, we were able to determine that the payment rates would continue to comply with section 1902(a)(30)(A) of the Act without the State submitting an AMRP with the SPA. Six of these SPAs represented rate freezes meant to continue forward a prior year's rates or eliminate an inflation adjustment. Six SPAs reduced a payment rate to comply with Federal requirements, such as the Medicaid UPLs in §§ 447.272 and 447.321, the Medicaid DME FFP limit in section 1903(i)(27) of the Act, or the Medicaid hospice rate, per section 1902(a)(13)(B) of the Act. Four SPAs contained reductions that resulted from programmatic changes such as the elimination of a Medicaid benefit or shifting the delivery system for a benefit to coverage by a pre-paid ambulatory health plan. Finally, we identified five SPAs for which States were required to submit AMRPs. In each instance, the SPAs were approved by CMS, with three of the SPAs being submitted to us in 2017 and updated for 2019 with the appropriate AMRP data submission required by the 2015 final rule with comment period. Overall, our review of SPAs revealed that smaller reductions may often be a result of elements or other requirements that may be outside of the State's control, such as Federal payment limits or changes in the Medicare payment rate that might be included in a State's proposed payment methodology (such as where some Medicare payment rates for certain services increased and others decreased as a result of the Medicare payment formulas, which may disproportionately impact one benefit category), or coding changes that might affect the amount of payment related to the unit of service. We determined, using this information, that it

is necessary to provide States with some degree of flexibility in making changes, even if that change is a reduction in provider payment. For example, if a State submits a SPA to reduce or restructure inpatient hospital base or supplemental payments, where inaction on the State's part would result in the State exceeding the applicable UPL, the State will need to reduce inpatient hospital payments or risk a compliance action against the State for violating Medicaid UPL requirements authorized under section 1902(a)(30)(A) of the Act and implementing regulations in 42 CFR 447 subparts C and F. We recognized that this flexibility does not eliminate the need to monitor or consider access to care when making payment rate decisions, but also recognized the need to provide some relief in circumstances where the State must take a rate action to address an issue of compliance with another statutory or regulatory requirement.

Accordingly, we proposed that, where a State has provided the information required under proposed paragraphs (c)(1)(i) through (iii), we would consider that the proposed reduction would result in a nominal payment adjustment unlikely to diminish access below the level consistent with section 1902(a)(30)(A) of the Act and would approve the SPA, provided all other criteria for approval also are met, without requiring the additional analysis that otherwise would be required under proposed § 447.203(c)(2).

Finally, in § 447.203(c)(1)(iii), we proposed that the State would be required to provide a supported assurance that the public processes described in § 447.203(c)(4) yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate, as documented in the analysis provided by the State under § 447.204(b)(3). The State's response to any access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us.

We noted that the proposed requirement in § 447.203(c)(4) would not duplicate the requirements in previous § 447.204(a)(2), as the previous § 447.204(a)(2) required States to consider provider and beneficiary input as part of the information that States are required to

consider prior to the submission of any SPA that proposes to reduce or restructure Medicaid service payment rates. The proposed § 447.203(c)(4) describes material that States would be required to include with any SPA submission that proposes to reduce or restructure provider payment rates. As discussed in the CMCS informational bulletin dated June 24, 2016,³⁶⁶ before submitting SPAs to us, States were required under previous § 447.204(a)(2) to make information available so that beneficiaries, providers, and other interested parties may provide input on beneficiary access to the affected services and the impact that the proposed payment change would have, if any, on continued service access. We explained that States are expected to obtain input from beneficiaries, providers, and other interested parties, and analyze the input to identify and address access to care concerns. States must obtain this information prior to submitting a SPA to us and maintain a record of the public input and how the agency responded to the input. When a State submits the SPA to us, § 447.204(b)(3) requires the State to also submit a specific analysis of the information and concerns expressed in input from affected interested parties. We would rely on this and other documentation submitted by the State, including under proposed § 447.203(c)(1)(iii), (c)(2)(vi), and (c)(4), to inform our SPA approval decisions.

In addition, we noted that States are required to use the applicable public process required under section 1902(a)(13) of the Act, as applicable, and follow the public notice requirement in § 447.205, as well as any other public processes required by State law (for example, State-specified budgetary process requirements), in setting payment rates and methodologies in view of potential access to care concerns. States have an important role in identifying access to care concerns, including through ongoing and collaborative efforts with beneficiaries, providers, and other interested parties. We acknowledged that not every concern would be easily resolvable, but we anticipate that States would be meaningfully engaged with their beneficiary, provider, and other interested party communities to identify and mitigate issues as they arise.

³⁶⁶ CMCS Informational Bulletin, “Federal public notice and public process requirements for changes to Medicaid payment rates.” Published June 24, 2016. <https://www.medicaid.gov/federal-policy-guidance/downloads/cib062416.pdf>. Accessed November 3, 2022.

We explained that we would consider information about access concerns raised by beneficiaries, providers, and other interested parties when States propose SPAs to reduce Medicaid payment rates or restructure Medicaid payments and would not approve proposals that do not comport with all applicable requirements, including the access standard in section 1902(a)(30)(A) of the Act.

In feedback received regarding implementation of the previous AMRP requirements in the 2015 final rule with comment period, States expressed concern about burdensome requirements to draft, solicit public input on, and update their AMRPs after receiving beneficiary or provider complaints that were later resolved by the State's engagement with beneficiaries and the provider community. we explained that our proposal to require access review procedures specific to State proposals to reduce payment rates or restructure payments would provide an opportunity for the State meaningfully to address and respond to interested parties' input, and seeks to balance State burden concerns with the clear need to understand the perspectives of the interested parties most likely to be affected by a Medicaid payment rate reduction or payment restructuring. Previously, § 447.203(b)(7) requires States to have ongoing mechanisms for beneficiary and provider input on access to care through various mechanisms, and to maintain a record of data on public input and how the State responded to such input, which must be made available to us upon request. We proposed to retain this important mechanism and to relocate it to § 447.203(c)(4). Through the cross reference to proposed § 447.203(c)(4) in proposed § 447.203(c)(1)(iii), we would require States to use the ongoing beneficiary and provider feedback mechanisms to aid in identifying and assessing any access to care issues in cooperation with their interested parties' communities, as a component of the streamlined access analysis criteria in proposed § 447.203(c)(1).

Together, we stated our belief that the proposed criteria of § 447.203(c)(1)(i) through (iii), where all are met, would establish that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the

Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access. Importantly, as noted above, proposed § 447.203(c)(4) (proposed to be relocated from previous § 447.203(b)(7)) would ensure that States have ongoing procedures for compliance monitoring independent of any approved Medicaid payment changes.

We previously outlined in SMDL #17-004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. We did not propose to codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. However, as a possible addition to the proposed streamlined access analysis criteria in proposed § 447.203(c)(1), we solicited comments on whether this list of circumstances discussed in SMDL #17-004 should be included in a new paragraph under proposed § 447.203(c)(1) and, if one or more of these circumstances were applicable, the State's proposal would be considered to qualify for the streamlined analysis process under proposed § 447.203(c)(1) notwithstanding the other criteria in proposed paragraph(c)(1).

In proposed paragraph (c)(1), we specified the full set of written assurances and relevant supporting documentation that States would be required to submit with a proposed payment rate reduction or payment restructuring SPA in circumstances when the changes could result in diminished access, where the requirements in proposed paragraphs (c)(1)(i) through (c)(1)(iii) are met. The inclusion of documentation that confirms all criteria proposed in paragraph (c)(1) are met would exempt the State from the requirements in proposed § 447.203(c)(2), discussed

later in this section; however, it would not guarantee SPA approval. Proposed payment rate reduction SPAs and payment rate restructuring SPAs meeting the requirements in proposed § 447.203(c)(1) would still be subject to CMS' standard review requirements for all proposed SPAs to ensure compliance with section 1902(a) of the Act, including implementing regulations in part 430. Specifically, and without limitation, we noted that this includes compliance with section 1902(a)(2) of the Act, requiring financial participation by the State in payments authorized under section 1903 of the Act. We review SPAs involving payments to ensure that the State has identified an adequate source of non-Federal share financing for payments under the SPA so that section 1902(a)(2) of the Act is satisfied; in particular, section 1903(w) of the Act and its implementing regulations establish requirements for certain non-Federal share financing sources that CMS must ensure are met. We further noted that a proposed SPA's failure to meet the criteria in proposed paragraph (c)(1) would not result in automatic SPA disapproval; rather, such proposals would be subject to additional documentation and review requirements, as specified in proposed § 447.203(c)(2).

In paragraph (c)(2), we proposed the additional, more rigorous State access analysis that States would be required to submit where the State proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) are not met. We explained our belief that this more rigorous access analysis should be required where the State is unable to demonstrate that the proposed paragraph (c)(1) criteria are met, because more scrutiny then is needed to ensure that the proposed payment rates and structure would be sufficient to enlist enough providers so that covered services would be available to beneficiaries at least to the same extent as to the general population in the geographic area. Accordingly, we proposed in § 447.203(c)(2) to have States document current and recent historical levels of access to care, including a demonstration of counts and trends of actively participating providers, counts and trends of FFS Medicaid beneficiaries who receive the services subject to the proposed payment

rate reduction or payment restructuring; and service utilization trends, all for the 3-year period immediately preceding the submission date of the proposed rate reduction or payment restructuring SPA, as a condition for approval. As with the previous AMRP process, the information provided by the State would serve as a baseline of understanding current access to care within the State's program, from which the State's payment rate reduction or payment restructuring proposal would be scrutinized.

The 2015 final rule with comment period included requirements that the previous AMRP process include data on the following topics, in previous § 447.203(b)(1)(i) through (v): the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The usefulness of the previous ongoing AMRP data was directly related to the quality of particular data measures that States selected to use in their AMRPs, and one of the biggest concerns we heard about the process was that States were not always certain that they were providing us with the relevant data that we needed to make informed decisions about Medicaid access to care because the 2015 final rule provided States with a considerable amount of flexibility in determining the type of data that may be provided in support of the State's access analysis included in their AMRP. In addition, States were required to consult with the State's medical advisory committees and publish the draft AMRP for no less than 30 days for public review and comment, per § 447.203(b). Therefore, the final AMRP, so long as the base data elements were met and supported the State's conclusion that access to care in the Medicaid program met the requirements of section 1902(a)(30)(A) of the Act, then the AMRP was accepted by us. As a result, the previous AMRPs were often very long and complex

documents that sometimes included data that was not necessarily useful for understanding the extent of beneficiary access to services in the State or for making administrative decisions about SPAs. In an effort to promote standardization of data measures and limit State submissions to materials likely to assist in ensuring consistency of payment rates with the requirements of section 1902(a)(30)(A) of the Act, we proposed to maintain a number of the previously required data elements from the previous AMRP process but to be more precise about the type of information that would be required.

In § 447.203(c)(2), we proposed that, for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, where the requirements in paragraphs (c)(1)(i) through (iii) are not met, the State would be required to also provide specified information to us as part of the SPA submission as a condition of approval, in addition to the information required under paragraph (c)(1), in a format prescribed by us. Specifically, in § 447.203(c)(2)(i), we proposed to require States to provide a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year. We proposed to collect this information for SPAs that require a § 447.203(c)(2) analysis, but for those that meet the criteria proposed under § 447.203(c)(1), we did not proposed to require a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change beyond that which is already provided as part of a normal State plan submission or as may be requested by CMS through the normal State plan review process; we solicited comments whether these elements should apply to both proposed § 447.203(c)(1) and (c)(2) equally.

In § 447.203(c)(2)(ii), we proposed to require the State to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We noted that this proposed element is similar to the previous § 447.203(b)(1)(v) rate comparison requirement, which required the previous AMRPs to include “[a]ctual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service.” However, the proposed analysis specifically would require an aggregate comparison including Medicaid base and supplemental payments, as applicable, before and after the proposed reduction or restructuring are implemented, compared to the most recently published Medicare payment rates for the same or comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We found that, first, States struggled with obtaining and providing private payer data as contemplated by the 2015 final rule with comment period, and second, States were confused about how to compare Medicaid rates to Medicare rates where there were no comparable services between Medicare and Medicaid. We wanted to acknowledge the feedback we received from States during the previous AMRP process and modify the requirements in the final rule by focusing on the more readily available Medicare payment data as the most relevant payment comparison for Medicaid, as discussed in detail above. We explained that the E/M CPT/HCPCS code comparison methodology included in the proposed § 447.203(b)(3)(i) and the payment rate disclosure in proposed § 447.203(b)(3)(ii) could serve, at a minimum, as frameworks for States that struggled to compare

Medicaid rates to Medicare where there may be no other comparable services between the two programs. Otherwise, where comparable services exist, States would be required to compare all applicable Medicaid payment rates within the benefit category to the Medicare rates for the same or comparable services under proposed § 447.203(c)(2)(ii). For reasons mentioned previously in this section, Medicare through MedPAC engages in substantial analysis of access to care as it reviews payment rates for services, so we noted our belief that this is a sufficient benchmark for the Medicaid payment rate analysis.

In § 447.203(c)(2)(iii), we proposed to require States to provide information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, we stated that an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State would be required to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of actively participating providers in each geographic area over this period. The State could provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area. This data element is similar to previous § 447.203(b)(1)(ii), under which States must analyze the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service, in the previous AMRP process; however, the proposal would require specific quantitative information describing the number of providers, by geographic area, provider type, and site of service available to furnish services to Medicaid beneficiaries and would leave less discretion to the States on specific data measures. With all of the data elements included in proposed paragraph (c)(2), we proposed that the data come from

the 3 years immediately preceding the State plan amendment submission date, as this would provide us with the most recent data and would allow for considerations for data anomalies that might otherwise distort a demonstration of access to care if only 1 year of data was used.

In § 447.203(c)(2)(iv), we proposed to require States to provide information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish). The State would be required to document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State would be required to provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. We explained that this proposed provision is a combination of previous § 447.203(b)(1)(i) and (iv), which require States to provide an analysis of the extent to which beneficiary needs are met, and the characteristics of the beneficiary population (including considerations for care, service, and payment variations for pediatric and adult populations and for individuals with disabilities). Even though we did not propose to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we proposed to require current information on the number of beneficiaries currently receiving services through the FFS delivery system in each benefit category affected by

the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this beneficiary data is relevant because it provides information about the recipients of Medicaid services and where, geographically, these populations reside to ensure that the statutory access standard is met.

In § 447.203(c)(2)(v), we proposed to require information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State would be required to provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. We noted that this proposed data element was similar to that previously required in § 447.203(b)(1)(iii), which required an analysis of changes in beneficiary utilization of covered services in each geographic area. However, as stated earlier, the difference here is that this proposed analysis would be limited to the beneficiary populations impacted by the rate reduction or restructuring, for a narrower set of data points, rather than requiring the State to conduct a full review of the Medicaid beneficiary population every 3 years on an ongoing basis. Even though we did not propose to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we

proposed to require current information on the number and types of Medicaid services being delivered to Medicaid beneficiaries through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this data is relevant because it provides information about the actual distribution of care received by Medicaid beneficiaries and where, geographically, these services are provided to ensure that the statutory access standard is met.

Finally, in § 447.203(c)(2)(vi), we proposed to require a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). We noted that this proposed requirement mirrors the requirement in § 447.204(b)(3), which requires that for any SPA submission that proposes to reduce or restructure Medicaid service payment rates, a specific analysis of the information and concerns expressed in input from affected interested parties must be provided at the time of the SPA submission. The new proposed § 447.203(c)(2)(vi) would require the same analysis while providing more detail as to what we expect the State to provide. Proposed § 447.203(c)(2)(vi) would require information about concerns and complaints from beneficiaries and providers specifically, as well as from other interested parties, and would underscore that the required analysis would be required to include the State's responses.

Where any of the previously discussed proposed data elements requires an analysis of data over a 3-year period, we proposed this time span to smooth statistical anomalies, and so that data variations can be understood. For example, any 3-year period look-back that includes portions of time during a public health emergency, such as that for the COVID-19 pandemic, might include much more variation in the access to care measures than periods before or after the public health emergency. By using a 3-year period, it is more likely that the State, CMS, and other interested parties would be able to identify and appropriately account for short term

disruptions in access-related measures, for example, when the number of services performed dropped precipitously in 2020 as elective visits and procedures were postponed or canceled due to the public health emergency.³⁶⁷ If the proposed rule only included a 12-month period, for example, it might not be clear that the data represent an accurate reflection of access to care at the time of the proposed reduction or restructuring. For example, a State may see variation in service utilization if there have been programmatic changes that are introduced over time, such as a move to increase care provided through a managed care delivery system in the State through which the FFS utilization declines steadily until managed care enrollment targets are achieved, but a one-time review of that FFS utilization capturing just a 12-month period might not capture data most reflective of the current FFS utilization demonstrating access to care consistent with section 1902(a)(30)(A) of the Act. We solicited comments on the proposed use of a 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2). We also solicited comments on the data elements required in § 447.203(c)(2) as additional State rate analysis.

Proposed paragraph (c)(2) would require that States conduct and provide to us a rigorous analysis of a proposed payment rate reduction's or payment restructuring's potential to affect beneficiary access to care. However, by limiting these analyses to only those proposed payment rate reductions and payment restructurings in circumstances when the changes could result in diminished access that do not meet the criteria in proposed paragraph (c)(1), we believe that the requirements proposed in paragraph (c)(2) would help to enable us to determine whether the proposed State Medicaid payment rates and payment methodologies are consistent with section 1902(a)(30)(A) of the Act while minimizing State and Federal administrative burden, to the extent possible. We would use this State-provided information and analysis to help us understand the current levels of access to care in the State's program, and determine, considering

³⁶⁷ Stuart, B. "How The COVID-19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead." *Health Affairs*, October 8, 2020. Available at <https://www.healthaffairs.org/doi/10.1377/forefront.20201006.263687> (accessed February 27, 2023).

the provider, beneficiary, and other interested party input collected through proposed § 447.203(c)(4), whether the proposed payment rate reduction or payment restructuring likely would maintain access to care for the particular service(s) consistent with the statutory standard in section 1902(a)(30)(A) of the Act. If we approve the State's proposal, the data provided would serve as a baseline for prospective monitoring of access to care within the State.

We explained that the proposed analysis and documentation requirements in paragraph (c)(2) draw, in part, from the requirements of the previous AMRP process in the previous § 447.203(b)(1) and reflect the diverse methods and measures that are and can be used to monitor access to care. We also drew on some of the comments received on the 2011 proposed rule, as discussed in the 2015 final rule with comment period, where several commenters recommended that CMS consider identifying a set of uniform measures that States must collect data on or that CMS weighs more heavily in its analysis.³⁶⁸ We proposed to provide more specificity on the types of uniform data elements in § 447.203(c) than is provided under previous § 447.203(b)(1). States have shown that they have access to the data listed in the proposed § 447.203(c)(2) when we have requested it during SPA reviews and through the previous AMRP process, and through this proposed rule, we proposed to specify the type of data that we would expect States to provide with rate reduction or restructuring SPAs that do not meet the proposed criteria for streamlined analysis under § 447.203(c)(1). As noted elsewhere in the preamble, the ongoing AMRP requirements previously presented an administratively burdensome process for States to follow every 3 years, particularly where we did not provide States with the specific direction on the types of data elements we preferred for States to include. However, the data elements involved in the previous AMRP process in § 447.203(b)(1) can provide useful information about beneficiary access to care in previous § 447.203(b)(1)(i), (iii), and (iv); Medicaid provider availability in previous § 447.203(b)(1)(ii); and about payment rates available from other payers, which may affect Medicaid beneficiaries' relative ability to access care, in previous

³⁶⁸ 80 FR 67576 at 67590

§ 447.203(b)(1)(v). We found that the previous AMRPs were most relevant when updated to accompany a submission of rate reduction or restructuring SPAs as specified in the previous § 447.203(b)(6); accordingly, to better balance ongoing State and Federal administrative burden with our need to obtain access-related information to inform our approval decisions for payment rate reduction or restructuring SPAs, we proposed to end the ongoing AMRP requirement but maintain a requirement that States include similar data elements when submitting such SPAs to us that do not qualify for the proposed streamlined analysis process under § 447.203(c)(1).

We explained that the proposed analyses in paragraph (c)(2) would enable us to focus our review of Medicaid access to care on proposals that are at highest risk to result in diminished access to care, enabling us to more substantively review a proposed rate reduction's or restructuring's potential impact on access (for example, counts of participating providers), realized access (for example, service utilization trends), and the beneficiary experience of care (for example, characteristics of the beneficiary population, beneficiary utilization data, and information related to feedback from beneficiaries and other interested parties collected during the public process and through ongoing beneficiary feedback mechanisms, along with the State's responses to that feedback), while also being able to more quickly work through a review of nominal rate reduction SPAs for which States have demonstrated certain levels of payment and for which the public process did not generate access to care concerns. By including information on provider type and site of service, we believe States would be able to demonstrate access to the services provided under a specific benefit category within a number of different settings across the Medicaid program, such as the availability of physician services delivered in a physician practice, clinic setting, FQHC or RHC, or even in a hospital-based office setting. We noted our belief that defining specific data elements that must be provided to support a payment rate reduction SPA would create a more predictable process for States and for CMS in conducting the SPA review than under the previous AMRP process in § 447.203(b)(6).

Furthermore, data elements proposed to be required under proposed § 447.203(c)(2) would be based on State-specified geographic stratifications, to help ensure we can perform access review consistent with the requirements of section 1902(a)(30)(A) of the Act. We expect that States would have readily available access to geographically differential beneficiary and provider data. We observed that some of this information is available through CMS-maintained resources, such as the Transformed Medicaid Statistical Information System (T-MSIS), and other data is available through the National Plan and Provider Enumeration System (NPPES), but States should have their own data systems that would allow them to generate the most up-to-date beneficiary utilization and provider enrollment data, stratified by geographic areas within the State. States should use the most recent complete data available for each of the proposed data elements, and each would be required to be demonstrated to CMS by State-specified geographic area. We noted our belief that the geographic stratification would enable CMS to establish a baseline for Medicaid access to care within the geographic areas so that we can determine if current levels of access to care are consistent with section 1902(a)(30)(A) of the Act and can make future determinations if access is diminished subsequently within the geographic area. For all of the data elements in proposed § 447.203(c)(2), we stated that the more geographic differentiation that can be provided (that is, the smaller and more numerous the distinct geographic areas of the State that are selected for separate analysis), the more we believe that the State can meaningfully demonstrate that the proposed rate changes are consistent with the access standard in section 1902(a)(30)(A) of the Act, which requires that States assure that payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

If finalized, we stated that we would anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the *Comparative Payment Rate Analysis*

Timeframe proposed in § 447.203(b)(4). In the intervening period, we would anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act.

In § 447.203(c)(3), we proposed mechanisms for ensuring compliance with requirements for State analysis for rate reduction or restructuring, as specified in proposed paragraphs (c)(1) and (c)(2), as applicable. We proposed that a State that submits a SPA that proposes to reduce provider payments or restructure provider payments that fails to provide the required information and analysis to support approval as specified in proposed paragraphs (c)(1) and (2), as applicable, may be subject to SPA disapproval under § 430.15(c). Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed SPA, including any raised by CMS in our review of the proposal and any raised through the public process as specified in proposed paragraph (c)(4) of this section, or under § 447.204(a)(2), may be subject to SPA disapproval under § 430.15(c). Disapproving a SPA means that the State would not have authority to implement the proposed rate reduction or restructuring and would be required to continue to pay providers according to the rate methodology described in the approved State plan. Proposed paragraph (c)(3) would further provide that if, after approval of a proposed rate reduction or restructuring, State monitoring of beneficiary access shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in the number of beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, we may take a compliance action. As described in § 447.204(d), compliance actions would be carried out using the procedures described in § 430.35.

As discussed in the prior section, we proposed to move previous § 447.203(b)(7) to § 447.203(c)(4) as finalized in this rule. We did not propose any changes to the public process described in paragraph (b)(7). We proposed that if the other provisions of the proposed rule are

finalized, we would redesignate paragraph (b)(7) as paragraph (c)(4). The ability for providers and beneficiaries to provide ongoing feedback to the State regarding access to care and a beneficiary's ability to access Medicaid services is essential to the Medicaid program in that it provides the primary interested parties the opportunity to communicate with the State and for the State to track and take account of those interactions in a meaningful way. We stated that the ongoing mechanisms for provider and beneficiary feedback must be retained, as this process serves an important role in determining whether or not the public has raised concerns regarding access to Medicaid-covered services, which would inform the State's approach to ongoing Medicaid provider payment rates and methodologies, and whether related proposals would be approvable.

We proposed to move previous § 447.203(b)(8) to § 447.203(c)(5), as finalized in this rule, to better organize § 447.203 to reflect the policies in the proposed rule. We did not propose any changes to the methods for addressing access questions and remediation of inadequate access to care, as described in paragraph (b)(8). We proposed that if the other provisions of the proposed rule are finalized, we would redesignate paragraph (b)(8) as paragraph (c)(5). We stated that it is important to retain this provision because we acknowledge that there may be access issues that come about apart from a specific State payment rate action, and there must be mechanisms through which those issues can be identified, and corrective action taken.

Finally, we proposed to move previous § 447.204(d) to proposed § 447.203(c)(6). We noted our belief that the subject matter, of compliance actions for an access deficiency, is better aligned to the proposed changes in § 447.203. We did not propose any changes to the remedy for the identification of an unresolved access deficiency, as described in § 447.204(d). We proposed that if the other provisions of this proposed rule are finalized, we would redesignate § 447.204(d) as paragraph (c)(6).

We solicited public comment on our proposed procedures and requirements for State analysis when submitting payment rate reduction or payment restructuring SPAs. We received

public comments on these proposals. The following is a summary of the comments we received and our responses, organized by regulatory section.

a. General Comments

Comment: Many commenters supported the approaches to reviewing rate changes. Specifically, a number of commenters noted support for the two-tiered process to provide specific levels of information and data with a request to reduce or restructure payment rates in circumstances where such changes could result in diminished access to care, with some commenters specifically supporting the inclusion of concerns raised during the public comment process. Other commenters noted general support for requiring State justification for rate reductions and restructurings as it would provide greater transparency and accountability into State justifications for potentially harmful rate reductions. A couple commenters noted support for CMS' administrative review of rate changes to ensure continued access. One commenter was encouraged that CMS proposed to include protections to mitigate the risk that payment reductions will translate into reduced access. Another commenter agreed with CMS that additional scrutiny is warranted when a rate reduction is more than nominal, and when public concerns are raised regarding the rate. Finally, one commenter expressed appreciation for CMS' detailed review and summary of the literature on the impact of payment rates for providers on access to care for beneficiaries.

Response: We appreciate the support of the commenters on both our overall approach and for certain specific aspects of our proposed policies, which we are finalizing as proposed. We agree that the public process is an important component of Medicaid program changes.

Comment: One commenter supported requiring States to demonstrate that a reduction in payment rates will not adversely impact access to care. The commenter stated that the effort required for States to make such a showing will guard against rate reductions that would be detrimental to Medicaid recipients' ability to access care.

Response: We appreciate the support of the commenter. We believe there will be States,

in certain circumstances, that will be able to meet the requirements of the streamlined access process under § 447.203(c)(1). The intention of the § 447.203(c) provisions is to balance the requirement that State's ensure compliance with section 1902(a)(30)(A) of the Act with reducing unnecessary burden in the State's administration of their Medicaid programs. We believe that the streamlined process under § 447.203(c)(1) is itself consistent with the statutory access standard, because the policies in this final rule ensure that only rate reductions or restructurings that are likely to be consistent with that standard will be approvable under this streamlined process.

Comment: One commenter stated that in some States, there is high potential for interruption in access due to delays created by the SPA process. The commenter was concerned that long delays caused by the SPA process can interrupt access to the latest standard of care. They stated that clarification on CMS regulations for SPAs for changes that increase access to the standard of care could reduce the risk of care interruptions.

Similarly, another commenter recommended that CMS give States the flexibility to increase rates to 100 percent of the equivalent Medicare rate without a SPA, and to make midyear adjustments to rates without a SPA. The commenter also indicated SPAs should only be required beyond specified thresholds.

Response: We appreciate the concern of the commenter related to any delays in the approval of SPAs. We are interested in approving approvable SPAs as expeditiously as possible, which is one of the reasons for issuing this final rule with an included template. SPAs generally may be effective no earlier than the first day of the quarter in which they are submitted per 42 C.F.R. § 430.20. The policies in this final rule and the template process provide States with clear documentation requirements for SPAs proposing to reduce or restructure provider payment rates. Without exception, our policy, as set forth in § 447.201(b), is that States must receive approval through the SPA process to modify Medicaid payment methodologies. CMS approval ensures that the changes in service payment methodologies comply with all applicable regulatory and

statutory requirements and that resulting State expenditures are eligible for FFP. Changes to these requirements are beyond the scope of this rulemaking. In addition, regardless of this final rule, all SPAs are reviewed using the criteria and timeframes outlined in 42 CFR part 430 subpart B.

Comment: One commenter requested that CMS clarify how the § 447.203(c) provisions would apply to performance-based incentives, withholds, and alternative payment models, indicating that States should not be penalized for moving away from a FFS model that is not tied to performance.

Response: Performance-based incentives, innovative care models, and alternative payment models are often designed to improve quality of care, promote better patient outcomes, and reward providers for improvements to quality of care and patient outcomes, while lowering the cost of care. In the 2015 final rule with comment period, we signaled our interest in working with States in promoting innovative patient care models and delivery system changes that seek to reward the provision of quality patient care that also lowered cost to the Medicaid program.³⁶⁹

The provisions of the final rule in § 447.203(c) provide processes for rate reductions or restructurings, with the goal of determining when those changes could result in diminished access. In most instances, a performance-based incentive, innovative care models, or alternative payment models that restructure provider payments do so in a manner that would not result in diminished access and that we would not regard as a restructuring subject to § 447.203(c). For example, a State may propose an episode of care arrangement that bundles all of the care related to a defined medical event, including the care for the event itself, any precursors to the event and follow-up care. As a component of this methodology, the State would make one payment for the whole episode that is meant to encompass the medical event including the precursors and follow-up care, with up-side and down-side incentives paid or collected based on the providers' performance against the mean. Providers must volunteer to enroll in this program, and any other

³⁶⁹ 80 FR 67578 and 67579.

provider would continue to be paid as they normally would under the State plan. Such a restructuring proposal does not diminish access because the providers are electing to participate and understand the risk, but since care must be provided for the performance incentives to be determined and non-participating providers would not experience a change in payment, Medicaid beneficiaries will not experience diminished access to services. We also note that other simple add-on payments for achievement of specified quality targets where there is no possibility of a reduction to any provider's payment would not be considered a restructuring subject to the requirements of § 447.203(c).

However, to the extent that a State implements a performance-based incentive, withhold, or alternative payment model would reduce payment rates, such as models that involve downside risk arrangements where provider payments could decrease from current levels in certain circumstances, these changes likely would have the potential to result in diminished access to care and therefore would be a restructuring that would fall under the requirements of § 447.203(c). For example, if a State proposed to implement a quality improvement payment arrangement involving downside risk, meaning that providers could their payment rates reduced the State's quality improvement proposal, for which providers were required to participate then CMS could view this arrangement as being a payment reduction or restructuring that could affect access to care. The State in this instance would be expected to conduct the appropriate level(s) of analysis required under § 447.203(c).

We want to note that the requirement to perform an initial or initial and additional analysis under § 447.203(c) does not mean the State will be unable to enact the proposed payment arrangement; it simply means CMS wants to verify that access will not be negatively impacted with additional documentation to demonstrate this fact. As such, this final rule does not limit a State's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. We do not view this as a

penalty, as the commenter suggested, but rather a documentation of consistency with the statute. Under the Act, rates must be both economic and efficient, and they also must ensure that individuals have sufficient access to covered services. We interpret section 1902(a)(30)(A) of the Act as requiring a balanced approach to Medicaid rate-setting and we encourage States to use appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect States to document that Medicaid rates are economic and efficient when the State submits changes to payment methodologies through a SPA. If a State is unsure whether its proposed performance-based incentive, innovative care model, or alternative payment models contains a restructuring subject to § 447.203(c), they can engage with CMS prior to submission of a SPA. CMS can and may request § 447.203(c) analyses upon receipt of a proposal as well.

Comment: A few commenters expressed concern that the provisions of § 447.203(c) appear to be operating under the assumption that current payment rates are adequate, with some commenters focusing on HCBS service payment, and concern that there is no express requirement to regularly review the payment methodology to account for inflationary updates. For example, one commenter indicated that there would be no analysis required by a State that today pays less than the cost of delivering care and does not increase rates for the next 5 years, but also does not propose any rate reductions. Another indicated that the new rate review process requires no accountability from a State that may currently have rates below the cost of care or where rates remain static for several years. These commenters strongly encouraged CMS to include provisions that would require States to review current payment rates for adequacy and update payment rates immediately and on an ongoing basis either annually or up to every 2 years to account for inflation, new regulatory requirements that impose costs on providers, and other changes that may impact the cost of doing business.

Response: We agree with the commenter on the importance of States having adequate rates, even when they are not proposing to reduce or restructure those provider payment rates. We direct the commenter to the other provisions of this final rule, including the payment rate

transparency publication in § 447.203(b)(1), comparative rate analysis in § 447.203(b)(2), and payment rate disclosure in § 447.203(b)(3), which are intended to make available readily accessible information relevant to whether the rates States currently are paying (beginning with the initial publications on or before July 1, 2026) are adequate. We also note that beneficiaries and providers have opportunities to raise access to care concerns to the State through the State's mechanisms for ongoing beneficiary and provider input described in § 447.203(c)(4). This final rule addresses how States can demonstrate sufficient access to care as required by section 1902(a)(30)(A) of the Act when submitting SPAs that propose to reduce or restructure provider payment rates. Neither provider cost nor inflation is a required review element in meeting the requirements of the final rule. States may certainly consider these elements when engaging in rate setting or conducting rate reviews, but it is not a required component of this final rule.

Comment: Two commenters supported the proposal to revamp previous requirements in effect for SPAs that propose to reduce rate or restructure payments and strongly urged CMS to consider changes to the final rule to ensure the new proposed structure does not permit States to alter rates in ways that negatively impact beneficiary access.

Response: We appreciate the commenters' support. We are finalizing the provisions as proposed. The final rule provides CMS with an administrative process through which States can demonstrate that they have considered access to care and responded to public concerns in the implementation of payment rate reduction or restructuring SPAs. We are confident these steps will ensure rate changes do not impact access in a manner inconsistent with section 1902(a)(30)(A) of the Act.

Comment: Some commenters supported efforts to bring more transparency to the rate-setting process but did not support CMS' proposed change to replace the current rate reduction review process for one that examines proposed rate reductions on a State fiscal year basis. One commenter expressed concern that the proposal to establish an across-the-board threshold for provider payment rate reductions subject to the access review process fails to recognize the need

for variable rate assumptions consistent with the characteristics of different Medicaid eligibility groups. The commenters expressed concern that it is not always appropriate to use the same assumptions for all populations or providers serving these eligibility groups, especially for complex populations, and noted that this proposal fails to recognize the impact individual provider rate reductions may have on a class of providers, noting that it is not appropriate to aggregate the impact of provider rate reductions, particularly for services provided to complex populations served under the Temporary Aid for Needy Families; Aged, Blind, and Disabled; and LTSS eligibility groups.

Response: We understand the commenters' concerns. States, under the finalized § 447.203(c)(1) and (2), as applicable, will be required to analyze the impact on provider payments based on the affected benefit category, but we acknowledge that particular services within a benefit category may be provided across different provider classes or settings. For example, physicians may provide services in an office setting, a hospital setting, or a clinic setting. The provider may receive a different payment rate for physician services depending upon the setting where services are performed as a result of differences between facility and non-facility payment rate types, which account for the difference in provider overhead cost assumptions based on the setting where the services occur.

We also note, as the commenter specifically raised concerns regarding complex populations and eligibility groups, that CMS policy has long established policy, consistent with statutory requirements for comparability in amount, duration, or scope of medical assistance, that States may not establish differential rates based upon an individual's eligibility category. States are able to set rates based on a patient's acuity, service complexity, or other service-related consideration, but to set different rates for different eligibility categories could promote inequity across the Medicaid program if providers were offered greater financial incentives to furnish services to beneficiaries in some eligibility groups than others. Such differentiation of payment rates would also not be considered economic and efficient in a manner consistent with section

1902(a)(30)(A) of the Act because some payment rates would be higher than necessary considering relevant service-related factors, for example, if rates were higher for certain eligibility groups than others in relation to the Federal matching rate available for expenditures for the respective groups.

Comment: One commenter recommended CMS clarify that FQHC services are included in protections for payment rate reductions in § 477.203(c).

Response: The requirements in § 447.203(c) are applicable to all Medicaid FFS services under the Medicaid State plan, including services furnished by FQHCs.

Comment: One of the commenters recommended that CMS consider proposals to address stagnant and insufficient Medicaid payment rates that are not high enough to support paying competitive wages. One commenter recommended that CMS require States to perform a one-time rate review analysis (requiring States to submit the data described in paragraph (c)(1) and, if not all three of the requirements are met, (c)(2)) upon implementation of this rule to ensure payment adequacy necessary to support access to quality care.

Response: We understand the commenters' concerns regarding stagnant provider payment rates and rates that may not support competitive wages. We encourage providers to engage with their State Medicaid programs through forums available to them, such as the interested parties advisory group and the mechanisms for ongoing beneficiary and provider input, described in § 447.203(c)(4). In addition, we direct the commenter to the other provisions of this final rule, including the payment rate transparency publication in § 447.203(b)(1), comparative rate analysis in § 447.203(b)(2), and payment rate disclosure in § 447.203(b)(3), which are intended to make available readily accessible information relevant to whether the rates States currently are paying (beginning with the initial publications on or before 7/1/26) are adequate.

We explained in the proposed rule that our primary objective was to replace the previous AMRP process with something that could better assess access while decreasing burden on States.

Requiring the analysis described by the commenters would represent an enormous one-time burden on States. We note that we are finalizing the rate transparency and analysis requirements proposed under § 447.203(b), which we expect will provide greater insight into rates relative to access issues, while maintaining a scope that seeks to minimize unnecessary burden on States.

Comment: A few commenters noted how CMS indicated in the preamble of the proposed rule that the term “benefit category” under § 447.203(c) would refer to services under a category of services as described in section 1905(a) of the Act. One commenter stated that CMS has declined to define “benefit category” in a meaningful way and requested clarification. The commenter was concerned that extremely large swaths of services can be grouped together for the purposes of conducting the analysis, which could circumvent the analysis of real-world impact of payment cuts on specific provider types. Another commenter requested that CMS clarify that the required analyses apply to both home care services (that is, personal care and home health services) provided under section 1905(a) of the Act and to services provided under 1915 authorities. However, rather than treating (for example) personal care services as a single benefit category across all authorities for the purpose of the required analysis, the commenter suggested that CMS view 1905(a) PCS as one benefit and treat the set of HCBS coverable under 1915 and other authorities as a separate single benefit.

Response: Reiterating the definition in the preamble, we mean for “benefit category” to refer to all individual services under a category of services described in the Medicaid State plan for which the State is proposing a payment rate reduction or restructuring. Just as with our review of Medicaid payment rates, we do not review the inclusion of individual services within a benefit category unless the intention of a SPA is to specifically add or remove coverage for a particular service from the State plan. Further, we have concerns about the usefulness of information that would inform our SPA review as the relevant unit of analysis becomes smaller (from benefit category to individual service level). For example, it is unclear that a reduction in the number of group occupational therapy services furnished by therapy providers during a given

time frame would indicate that there is an issue with provider payment rates being insufficient to support adequate beneficiary access, or if the reduction merely represented a data anomaly that is unrelated to the rate of payment. We believe that the higher level of review of payment rate sufficiency at the benefit category level is consistent with the requirement in section 1902(a)(30)(A) of the Act that rates be sufficient to ensure that “care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.”

That being said, if a State proposes to group together services together that are not reasonably considered to be within the same benefit category (including where the grouping is not consistent with how the State covers and/or pays for the services under the State plan) to attempt to meet the paragraph (c)(1) thresholds and avoid the need to submit additional analysis under paragraph (c)(2), we will request additional information from the State including demonstrations that the paragraph (c)(1) criteria are met using a reasonable benefit category definition, or the additional analysis required under paragraph (c)(2), to support SPA approval.

Finally, in response to the commenter that requested that CMS clarify that the required analyses apply to home care services (including personal care and home health services) under section 1905(a) of the Act and to those covered under section 1915 authorities, we affirm that the analyses apply to both types of home care services under State plan, section 1915(c) waiver and demonstration payment rates, as applicable. To the extent that it is applicable, the 1905(a) PCS is one benefit category and the set of HCBS coverable PCS under 1915 and other authorities are considered as individual benefits as the payment methodologies for these services of often distinct methodologies across the different State plan or waiver authorities.

Comment: One commenter suggested CMS provide a template for the code-by-code analysis level to support the State analysis procedures for rate reductions or restructurings.

Response: We produced and are finalizing a template for States to ease the administration of the requirements of this final rule, including a code-by-code analysis to the

support the payment analysis. The template will assist the States with meeting the § 447.203(c)(1)(i) and (c)(2)(ii) requirements for an aggregate analysis of Medicaid base and supplemental payments relative to Medicare, but it is important for us to clarify that these provisions do not necessarily require submission to CMS of a code-by-code analysis as suggested by the commenter. Section 447.203(c)(1)(i) requires States to provide written assurance and relevant supporting documentation that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. Section 447.203(c)(2)(ii) requires States to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. In each case, the analysis performed would be an aggregate comparison of the State's proposed Medicaid rates to Medicare; however, CMS may request that the State provide supporting documentation, for example, where CMS has concerns with the accuracy of the analysis performed.

Comment: One commenter stated that, while imperfect as a point of comparison, Medicare is at least a reliable source of data that utilizes cost studies and other factors in its own rate setting processes. The commenter stated that if Medicare is retained as the benchmark, they would endorse use of an aggregate, as opposed to code-by-code, comparison with Medicaid rates. They explained that a code-by-code analysis would be extremely difficult, as CMS would need to define a methodology to determine if there is a one-to-one match between service

descriptions and procedural codes in Medicare and Medicaid; Medicaid agencies report significant variation in codes and service descriptions.

Response: We agree with the commenter and note that the final rule in § 447.203(c)(1)(i), and the similar provision in § 447.203(c)(2)(ii), require that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring be compared to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services. For this purpose, the Medicare services selected for comparison should align reasonably with the Medicaid services covered by the State within the affected Medicaid benefit category. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for constructing the comparison of Medicaid to Medicare payment rates.

Comment: A few commenters opposed the two-tiered approach, believing that this approach is insufficient to ensure access. Those commenters urged CMS to only use the tier two (§ 447.203(c)(2)) analysis on any SPA that proposes to reduce or restructure provider payment rates. One of the commenters opposed the two-tiered system on the basis that it would result in States implementing significant cuts to Medicaid rates without scrutiny for prolonged periods of time as long as they are exempt from second-tier analysis.

Response: We appreciate the commenters' viewpoints, but we are finalizing the two-tiered analysis as proposed. We do not agree that the two-tiered system would result in States implementing significant cuts to Medicaid without scrutiny for prolonged periods of time. We are finalizing § 447.203(c)(1) to require that all three provisions of § 447.203(c)(1) must be met in order for the SPA to qualify for the streamlined analysis provision of the final rule. In our view, the streamlined review for qualifying SPAs under § 447.203(c)(1) is sufficient because the State's payment rates would remain at or above 80 percent of the Medicare rate; the proposed

reduction or restructuring would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public process yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate. Taken together, the streamlined State analysis provides safeguards to mitigate the impact of State rate reductions while also providing protection for compounding reductions that could occur over a prolonged period of time. We anticipate that compounding rate reductions or restructurings would lower the possibility that a State's payment rates remain at or above 80 percent of Medicare and the public input process would generate significant provider and beneficiary feedback in the event that such reductions are taken at 4 percent per State fiscal year which would disqualify a State Plan rate reduction or restructuring proposal from meeting the requirements for the streamlined § 447.203(c)(1) process. We included this aspect of the analysis, in part, to protect against a large reduction spread over time through smaller reductions that pass initial scrutiny having an unacceptable negative impact on beneficiary access. As noted above, we anticipate that any State that is making significant cuts to provider payment rates over time will have a significant challenge in meeting the requirements for the initial State analysis in § 447.203(c)(1).

Comment: One commenter noted that the proposed rule would require States to provide additional information to justify their requests for reduced or restructured payment rates in SPAs, but the commenter noted that CMS does not commit to denying the requests where the State proposes payment rates below 80 percent of Medicare and did not agree with CMS's lack of commitment to disapprove such requested rate actions. The commenter did not believe this would sufficiently dissuade rate reductions, and that the language indicating CMS might not approve such proposed payment rate reduction or restructuring SPAs would just generate

confusion, as well as attempts by States to “game the system” to try to figure out what language they should submit to win approval of their applications.

Response: Much like the previous AMRP process from the 2015 final rule with comment period, the access provisions contained in § 447.203(c) are intended to create a baseline measurement from which the State rate reduction or restructuring proposals may be evaluated. CMS has not taken the position that State payment rate proposals that set provider payment rates below 80 percent of Medicare are to be automatically disapproved, but instead we are committing States to a process by which they demonstrate that access is sufficient in their State so the agency can properly evaluate these State proposals under the section 1902(a)(30)(A) of the Act requirements. SPAs that fail to include the information required under the applicable provisions of § 447.203(c) will be disapproved by CMS. For proposals that do not meet the streamlined State analysis requirements under § 447.203(c)(1), States are required to provide the following with all payment rate reduction or restructuring SPAs: a summary of the proposed change, including the State’s reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services; information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring; information about the number of Medicaid beneficiaries receiving services through

the FFS delivery system in each benefit category affected by the proposed reduction or restructuring; information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring; and a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed, as required under § 447.204(a)(2). In addition to being used to establish a baseline, as mentioned above, CMS will use the information in determining whether access is sufficient based on the State's submission of the required data and analysis, including of Medicaid provider enrollment, service utilization, and number of beneficiaries receiving affected services (including observed trends). We expect State proposals to be accompanied by documentation of meaningful engagement with providers, beneficiaries, and potentially other interested parties, to ensure that the proposed payment rate reductions or restructurings will not reduce access to care for Medicaid beneficiaries below the standard set in section 1902(a)(30)(A) of the Act. However, we acknowledge that the individual circumstances of the SPA proposal will inform the precise information required to be submitted under this final rule. We are confident that the provisions of the final rule are clear and outline a process which States will be required to follow when reducing or restructuring provider payment rates which CMS will review on a case-by-case basis, but we are confident that the documentation requirements will not allow States to game the system, as the commenter contends.

Comment: One commenter urged CMS to take an approach that is more straightforward than the two-tiered proposal to better monitor provider payment adequacy. For example, the commenter stated that payment reductions in excess of 5 percent for any given service or CPT code should be reviewed by CMS to determine if beneficiary access is at risk. Another commenter was concerned that CMS' proposed "aggregate" standard, reviewing rates across a benefit category rather than at the service-specific level, could mean that some Medicaid services may be paid well below the percentage threshold even if the overall benefit category achieves the

threshold. They recommended setting the threshold on a disaggregated basis to protect access to key services and avoid permitting States to obscure low payment rates.

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, provided that the State is using a consistent payment rate methodology for the entirety of the fee schedule, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan. For example, if the State uses the Medicare fee schedule for items of DME under the Medicaid State plan but decides to alter the payment rate for the oxygen codes (E0441, for example) to set Medicaid-specific rates, we will review those individual payment rate changes as they fall outside of the State's payment rate setting methodology under the State plan. Further, the payment rate transparency publication in § 447.203(b)(1) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

b. Initial State analysis for rate reduction or restructuring (§ 447.203(c)(1))

Comment: One commenter stated their general support for the streamlined initial review process, noting it provides States with clear safe harbor guidelines.

Response: We appreciate the support of the commenter. However, we note that section 447.203(c)(1) does not necessarily provide a "safe harbor" guaranteeing approval of a SPA. All applicable Federal requirements must be met for SPA approval. And even where paragraph

(c)(1)(i) and (ii) are met because the aggregate Medicaid payment rates for the benefit category after reduction or restructuring would be at or above 80 percent of the most recently published Medicare rates for the same or a comparable set of Medicare-covered services, and the cumulative effect of all reductions or restructurings throughout the current State fiscal year would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for the benefit category, paragraph (c)(1)(iii) still must be met. That is to say, even when the quantitative standards of the first two prongs of the (c)(1) test are satisfied, we will carefully review the information the State provides to us under section 447.204(b)(3) specifically analyzing any information and concerns expressed in input from affected interested parties in connection with the proposed SPA. As specified in section 447.203(c)(1)(iii), there must be no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if public processes did yield such concerns, the State must be able to reasonably respond to or mitigate them, as appropriate.

Comment: One commenter noted their support of CMS' first-tier proposal for handling rate reductions. However, they recommended that CMS establish a process for granting States flexibility from the requirements under unique circumstances. For example, a reduction may occur as the result of a decrease in CMS' RVUs or Medicare payment schedules. Some State fee schedules are indirectly tied to CMS RVUs or other Medicare payment schedules, and decreases occurring there are likely to also occur on the State's fee schedule. The commenter stated that an exemption from rate reduction requirements would be justified in this circumstance.

Response: For States that have set their approved State plan payment methodology at the current Medicare RVU prices, CMS would interpret such a methodology as accounting for changes that Medicare makes to components of their RVU-based methodology without the need for additional SPA action on the State's part. This would only include scenarios where the State has specifically indicated that the payment rates for Medicaid services are set at the current

Medicare price for the State plan services and would not apply to circumstances where the State creates a static fee schedule that simply relies on a particular snapshot of Medicare prices to inform a State fee schedule, or for methodologies that rely upon a prior iteration of the Medicare prices for the current Medicaid payment rates.

Comment: One commenter suggested that provider associations and participant representatives be part of reviewing and analyzing the impacts on rate reductions and access that would be required under § 447.203(c)(1) and (2).

Response: Section 447.203(c)(4) as finalized in this final rule provides that States must have ongoing mechanisms for beneficiary and provider input (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), through which interested parties can raise concerns about access, including payment sufficiency. Provider associations and participant representatives, which we understand to be representatives of beneficiaries that may be under the age of 21, are able to participate in public engagement through these mechanisms, related to State actions that could result in a reduction or restructuring of State plan payment rates. To be clear, the public process in § 447.203(c)(4) serves as a means for the State to receive feedback on real-time access to care issues that may be addressed on an ad hoc basis; interested parties do not need to wait for the State to develop a payment SPA to raise access to care issues through mechanisms under § 447.203(c)(4). This input, as well as input collected through the public input process under § 447.204, will be considered under § 447.203(c)(1)(iii) and used to determine whether or not the proposed reduction or restructuring SPA is consistent with section 1902(a)(30)(A) of the Act.

Comment: A few commenters suggested CMS use its authority to encourage States toward a national floor for rates, with some stating the Medicaid-to-Medicare fee ratio threshold proposed in § 447.203(c)(1)(i) should become a Federal floor for all SPA and waiver approvals. For example, they recommended that CMS could phase-in an explicit regulatory floor or implement standards tying improvements in Medicaid rates to approvals of related Medicaid

flexibilities, such as section 1115 approvals, SDPs, etc. One commenter pointed out that some States have rates well below Medicare levels and change rates infrequently. This means that, assuming a State does nothing, currently inadequate rates could simply persist for decades more under CMS' approach, and in fact regress relative to inflation. Another commenter specifically recommended that CMS require both an initial in-depth analysis of access metrics as well as an analysis over time for any State that implements payment rates lower than Medicare.

Response: Unless explicitly authorized by statute, CMS does not have the authority to establish a national floor for Medicaid payment rates. Refusing to approve any payment rate reductions or restructurings that do not specifically meet the thresholds in § 447.203(c)(1)(i) could be construed as setting a national floor for rates. We understand that some States may infrequently update their payment rates, but section 1902(a)(30)(A) of the Act provides States with flexibility to establish payment rates in a manner that balances consideration of State budgetary needs and restrictions with the obligation to provide medical assistance under the State plan in accordance with Federal requirements. With the policies finalized throughout this final rule, we hope that both States and the public will more closely examine existing rates. Our policies around rate transparency and adequacy will enhance opportunities to determine where an existing rate may negatively impact access to care and identify for States where a need should be addressed by providing beneficiaries, providers, other and interested parties with easier access to State plan payment rates through payment rate transparency publications, comparative payment rate analyses, and payment rate disclosures. Our policies around the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) and addressing access questions and remediation of inadequate access to care in § 447.203(c)(5) will further provide beneficiaries and providers opportunities to engage with States where existing payment rates may have an impact on beneficiaries' access to care.

The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process under the 2015 final rule with comment

period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1), and note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. This final rule provides CMS and States with an administrative process through which rate reductions or restructurings can be reviewed and approved, so long as the proposed SPA satisfactorily includes the information required under this final rule and meets all applicable Federal requirements.

We note that the policies finalized in § 447.203(c)(2) do include an analysis of data that looks back at a 3-year period of time to help ascertain whether access to care for the relevant services is consistent with the statutory access standard. Further, the rule includes a requirement for ongoing access monitoring to the extent that access issues are identified that require State intervention, as provided in § 447.203(c)(5), which requires the State to take corrective action resulting in measurable and sustainable access improvements.

Comment: One commenter recommended that CMS amend § 447.203(c)(1) and (2) to require States to demonstrate compliance with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), as applicable, for any proposed rate reduction or restructuring and provide technical assistance to States on compliance with this provision that would include guidance on the required comparative analysis both for the standard as written and in operation.

Response: CMS works closely with State Medicaid agencies to ensure compliance with MHPAEA in Medicaid managed care arrangements, Medicaid alternative benefit plans (managed care and FFS), and CHIP benefits (managed care and FFS) whenever changes to coverage of mental health or SUD benefits are proposed by States. We did not specifically

require that States demonstrate compliance with the MHPAEA as part of this final rule, as the final rule focuses on payment rates established by the State Medicaid agencies to pay for allowable Medicaid services under the Medicaid State plan through FFS. Congress has not extended MHPAEA requirements to Medicaid benefits provided solely through FFS delivery systems. Nonetheless, we encourage our State Medicaid and CHIP agency partners to ensure their FFS benefits comply with MHPAEA. Moreover, CMS reviews State proposals regarding rate reductions or restructuring to ensure compliance with the requirements of section 1902(a)(30)(A) of the Social Security Act “to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan, at least to the extent that such care and services are available to the general population in the geographic area.” This review thus includes the fundamental objective of MHPAEA – to ensure access to mental health and substance use disorder treatment.

Comment: One commenter requested further information on what circumstances CMS would expect to result in diminished access for a SPA that would restructure, but not reduce, rates.

Response: We acknowledge that there may be any number of payment methodology changes that could harm access to care even when there is a restructuring but not reduction in rates, and unfortunately, we are unable to identify all such circumstances in advance. However, as discussed previously, one common type of restructuring is a change in the targeting of supplemental payments. States may alter payments, including in ways that are budget neutral for a benefit category as a whole (that is, they do not decrease overall Medicaid spending for the benefit category), but the changes would reduce payments for some providers, potentially harming beneficiary access.

Comment: One commenter requested that CMS clarify what is meant by “restructure” and confirm that this would not include any type of rate increase.

Response: A rate restructuring is a payment action where a State amends its methodology for an interrelated set of rates whereby individual rates may increase, decrease, or remain the same, which the State typically undertakes to achieve some programmatic purpose, such as achieving more efficient payment for services that frequently are furnished together. While a rate restructuring potentially could include rate increases, if increasing rates is the only effect of the rate restructuring, then we generally would not expect these to be circumstances when the changes could result in diminished access, and the requirements of § 447.203(c)(1) through (3) would not have to be met. Although we cannot set forth an exhaustive list of rate restructurings, one common type of restructuring is a change in the targeting of supplemental payments, under which the set of providers qualifying for a supplemental payment might change and/or the amounts received by each provider might increase or decrease. States may use a methodology to identify amounts that a provider would receive, which would not require a SPA to initiate a change in the amounts providers receive. For example, a State sets up supplemental payment pools of \$10 million for trauma care centers in the State and that payment pool is distributed based upon a provider's pro rata share of Medicaid services. The amounts paid to providers eligible for that pool may vary from year to year based upon each providers' relative Medicaid utilization within the State, but the total amount of available funds remains the same. If that State submits a SPA to change the distribution methodology or to add more qualifying providers to the payment methodology, but not change the \$10 million pool, then this change would be considered a payment restructuring. If the State were to reduce the total pool from \$10 million to \$8 million, then that would be considered a reduction. A change in supplemental payments that reduces the total amounts that providers receive or shifts funds from one provider to another could result in access to care issues and is one example of a potential payment restructuring that could negatively impact access to care. Where there is uncertainty, we will work with States to help identify situations where a rate restructuring could diminish access to care such that the processes under § 447.203(c)(1) through (3) will apply.

Comment: One commenter suggested streamlined approval should apply to any rate reduction that meets any one of the three criteria listed in the proposed rule. The commenter specifically recommended providing streamlined approval for rate reductions that result in the rates being 100 percent or higher of the comparable Medicare rate regardless of the reduction in overall expenditures for the benefit category (otherwise stated, without the application of § 447.203(c)(1)(ii)). Another commenter recommended that CMS' primary goal should be to encourage increasing rates to Medicare levels and generating feedback through processes with interested parties.

Response: To the extent a State proposes a payment rate reduction or restructuring which results in payment rates at or above 100 percent of Medicare, it would certainly meet one of the three criteria in § 447.203(c)(1) for the initial State analysis for rate reduction or restructuring, but would still require that the other two criteria in § 447.203(c)(1) be met. We are requiring all three criteria in § 447.203(c)(1) be satisfied for the State to qualify for the streamlined process, to protect access across varied circumstances. For example, a proposed rate may be 100 percent of Medicare, but if the currently approved Medicaid payment rate is higher such that the change represents a payment reduction, then the proposed rate reduction still could harm beneficiary access to the relevant services and potentially reduce access to below the statutory standard.

Although we generally believe that setting rate thresholds at a level recommended by the commenter (100 percent of the corresponding Medicare rate, or higher) could help support adequate access to care for Medicaid beneficiaries, we believe there are circumstances where balancing State budgetary considerations, and the willingness of providers to accept a given level of payment for services provided to the Medicaid population, will suggest a Medicaid payment rate that diverges from a corresponding Medicare rate but is still consistent with the access requirement under section 1902(a)(30)(A) of the Act.

Comment: One commenter requested that CMS provide additional guidance about how to conduct the Medicaid to Medicare comparison required under § 447.203(c)(1) and (2).

Response: As part of the proposed rule PRA process, we proposed a template for States to use to complete the analyses under § 447.203(c). The template includes detailed instructions for how States should complete each tier and component of the analysis, as applicable. We are finalizing that template as proposed.

Comment: Several commenters inquired about whether the guidance provided in SMDL #17-004³⁷⁰ would remain applicable under the new proposals, wherein CMS determined that there were circumstances unlikely to diminish access, and as such, would not invoke the requirements of § 447.203(b)(6) of the 2015 final rule with comment period: reductions necessary to implement CMS Federal Medicaid payment requirements (for example, Federal upper payment limits and financial participation limits), but only in circumstances under which the State is not exercising discretion as to how the requirement is implemented in rates; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology (For example, modifications to diagnostic related groups and the resource based relative value scale, adoption of new Medicare payment systems, consistency with value-based purchasing initiatives, etc.). One commenter specifically inquired about circumstances where payment rates would be below the threshold of 100 percent of the most recently published Medicare rates for the same or comparable services in the impacted benefit area before and after the proposed restructuring. A few other commenters encouraged CMS to allow a tier 1 review for rate reductions in circumstances where rate reductions: (1) are necessary to implement CMS Medicaid payment requirements (for example, UPL); (2) result in payment rates that remain at or above Medicare or average commercial rate amounts; or (3) are prompted

³⁷⁰ SMDL #17-004. November 16, 2017. <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd17004.pdf>.

by a change in Medicare payment rates when the State's rate methodology adheres to Medicare methodology. One commenter specifically recommended that the exemptions provided under SMDL #17-004 be included in the exemptions under § 447.203(c)(1), specifically citing circumstances in the SMDL where Medicaid payment rate reductions generally would not be expected to diminish access, such as: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology.

Response: We did specifically request comment on whether and how the policies discussed in SMDL #17-004 should be included in the final rule, and we thank the commenters for their helpful suggestions. As stated, we are finalizing § 447.203(c)(1) as proposed, and we are not finalizing any exceptions to the tier 1 (or tier 2) analysis. We believe the analysis is warranted under any rate reduction or restructuring. The three circumstances described by commenters from SMDL #17-004 are either inapplicable to this final rule or already accounted for. Specifically, in the first circumstance, where Federal Medicaid payment requirements are otherwise established in statute or regulation, we recognize that States often have multiple ways of complying with multiple Federal requirements that may bear upon payment rates, and the review required in this final rule in § 447.203(c) is necessary to ensure that the State's programmatic decisions are consistent with all applicable Federal requirements including that they ensure sufficient beneficiary access to care. In the third circumstance, reductions that result from changes implemented through the Medicare program, where such a change does not require a SPA to implement would also fall outside of § 447.203(c)(1) through (3), which are only applicable when a State must submit a SPA. The final rule provisions only apply to the extent that a SPA is needed to implement the proposed reduction or restructuring.

The second circumstance is the only one subject to the provisions of this final rule, for reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates. These reductions or restructurings would need to meet all of the requirements of § 447.203(c)(1) in order to be eligible for the streamlined access review criteria. We decided not to include this criterion from SMDL #17-004 in this final rule because we received a number of comments on this final rule that suggested that providers and beneficiaries should have input where non-nominal rate reductions or restructurings may occur, regardless of the current or proposed payment level. Including this particular provision could provide a State with a means to significantly reduce provider payment rates without needing to engage with the provider and beneficiary community on the impact such a reduction might have on access to care.

Comment: One commenter expressed concern that CMS' proposals would slow or in some cases prevent altogether the adoption of VBP arrangements or other alternative payment models. Under these models, the commenter stated that it is common for some providers to experience increases in payment reflective of outcomes attributable to those providers, and it is also common for some providers to experience decreases in payment, including when aggregate levels of payment are increasing for a relevant service or services. Given that any SPA proposing to implement or substantially modify a VBP payment arrangement could reasonably be considered a proposal to "restructure" payments, the commenter was concerned that the proposed rule essentially would treat all VBP payment arrangements as inherently suspect and as requiring additional scrutiny and administrative burden. The commenter encouraged CMS to continue to identify ways to support and encourage the adoption of VBP models in Medicaid, noting that CMS should not adopt rules that create additional obstacles for States seeking to implement VBP models. A few other commenters suggested that streamlined review should be available in situations where rate reductions are used to implement VBPs through a withhold

payment rate restructuring that does not reduce the total payments within the overall service category, because the withheld amounts subsequently are paid out based on performance.

Response: We agree with the commenter that VBP arrangements can be useful tools to promote high-quality services for Medicaid beneficiaries while promoting efficient and economic care delivery, fully consistent with beneficiary access to covered services that meets the statutory standard. Although a proposed SPA seeking to implement or significantly modify a VBP arrangement likely may be considered a payment rate restructuring, nothing in the final rule would prohibit or is intended to discourage States from adopting such structures. Performance-based incentives, innovative care models, and alternative payment models are often designed to improve quality of care, promote better patient outcomes, and reward providers for improvements to quality of care and patient outcomes, while lowering the cost of care. In the 2015 final rule with comment period, we signaled our interest in working with States in promoting innovative patient care models and delivery system changes that seek to reward the provision of quality patient care that also lowered cost to the Medicaid program.³⁷¹

The provisions of the final rule in § 447.203(c) provide processes for rate reductions or restructurings, with the goal of determining when those changes could result in diminished access. In most instances, a performance-based incentive, innovative care models, or alternative payment models that restructure provider payments do so in a manner that would not result in diminished access and that we would not regard as a restructuring subject to § 447.203(c). For example, a State may propose an episode of care arrangement that bundles all of the care related to a defined medical event, including the care for the event itself, any precursors to the event and follow-up care. As a component of this methodology, the State would make one payment for the whole episode that is meant to encompass the medical event including the precursors and follow-up care, with up-side and down-side incentives paid or collected based on the providers' performance against the mean. Providers must volunteer to enroll in this program, and any other

³⁷¹ 80 FR 67578-67579.

provider would continue to be paid as they normally would under the State plan. Such a restructuring proposal does not diminish access because the providers are electing to participate and understand the risk, but since care must be provided for the performance incentives to be determined and non-participating providers would not experience a change in payment, Medicaid beneficiaries will not experience diminished access to services. We also note that other simple add-on payments for achievement of specified quality targets where there is no possibility of a reduction to any provider's payment would not be considered a restructuring subject to the requirements of § 447.203(c).

However, to the extent that a State implements a performance-based incentive, withhold, or alternative payment model would reduce payment rates, such as models that involve downside risk arrangements where provider payments could decrease from current levels in certain circumstances, these changes likely would have the potential to result in diminished access to care and therefore would be a restructuring that would fall under the requirements of § 447.203(c). For example, if a State proposed to implement a quality improvement payment arrangement involving downside risk, meaning that providers could their payment rates reduced the State's quality improvement proposal, for which providers were required to participate then CMS could view this arrangement as being a payment reduction or restructuring that could affect access to care. The State in this instance would be expected to conduct the appropriate level(s) of analysis required under § 447.203(c).

We want to note that the requirement to perform an initial or initial and additional analysis under § 447.203(c) does not mean the State will be unable to enact the proposed payment arrangement; it simply means CMS wants to verify that access will not be negatively impacted with additional documentation to demonstrate this fact. As such, this final rule does not limit a State's ability to reduce or restructure rates based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. We do not view this as a

penalty, as the commenter suggested, but rather a documentation of consistency with the statute. Under the Act, rates must be both economic and efficient, and they also must ensure that individuals have sufficient access to covered services. We interpret section 1902(a)(30)(A) of the Act as requiring a balanced approach to Medicaid rate-setting and we encourage States to use appropriate information and program experience to develop rates to meet all of its requirements. Further, we expect States to document that Medicaid rates are economic and efficient when the State submits changes to payment methodologies through a SPA. If a State is unsure whether its proposed performance-based incentive, innovative care model, or alternative payment models contains a restructuring subject to § 447.203(c), they can engage with CMS prior to submission of a SPA. CMS can and may request § 447.203(c) analyses upon receipt of a proposal as well.

Comment: One commenter strongly suggested that the State rate analysis be required on an annual basis, not only upon rate reductions or restructuring, and further suggested that any rate examinations by CMS should also include rates paid in managed care, noting the volume of HCBS provided under managed care, and as such, focusing only on FFS rates is a disservice to much of the industry.

Response: We intend for the payment rate transparency provisions in § 447.203(b) to provide interested parties with insight into State plan payment rates relative to the Medicare payment rates for the same services. While these payment analyses will be updated every other year, as opposed to annually as mentioned by the commenter, the § 447.203(b) analysis will be available for CMS and for interested parties to review, while the § 447.203(c) analysis will apply only to SPA submissions that propose to reduce or restructure provider payment rates. The § 447.203(c) provisions of this final rule concern SPAs proposing to reduce or restructure payment rates in Medicaid FFS. Other components of this final rule address payment rate adequacy and transparency for HCBS specifically, and access to care in managed care is being addressed through the Managed Care final rule (as published elsewhere in this **Federal Register**).

Comment: One commenter stated that SPAs that would result in Medicaid payments that

are at or above 80 percent of Medicare rates for the same or comparable services should be approvable without resorting to the larger access analysis described in proposed § 447.203(c)(2). The commenter noted that it is common for Medicaid to pay a percentage of Medicare rates (for example, 85 percent of Medicare) and stated that a proposed payment methodology should not have to result in Medicaid payments that are exactly the same as Medicare rates to avoid access concerns.

Response: This final rule does not require that the proposed payment methodology result in payments that are exactly the same as Medicare rates, or any specific percentage of the Medicare rates for the same or a comparable set of services. States that have rates at or above 80 percent of Medicare in the aggregate, including base and supplemental payments, can qualify for the streamlined initial State analysis for rate reduction or restructuring in § 447.203(c)(1) of the final rule, provided that the other criteria of § 447.203(c)(1) are met. As discussed in an earlier response to comment in this final rule; however, we do not agree that State payment proposals that meet the 80 percent of Medicare threshold should be exempt from the other qualification criteria specified in § 447.203(c)(1)(ii) and (iii), nor the additional analysis elements in § 447.203(c)(2) if all the criteria for the streamlined process are not met.

Comment: One commenter commended CMS for moving towards more clear and transparent processes for rate analyses associated with State-proposed payment changes. However, the commenter indicated that the first tier's streamlined requirements are unlikely to ever be met, as the commenter noted that there are rarely any changes in rates that are proposed that do not elicit complaints and/or concerns about impacts to access from the public and/or interested parties, even in such circumstances as rate increases. The commenter suggested that CMS reconsider the tier guidelines to make it more feasible for a State to meet the requirements of the initial, streamlined tier.

Response: We disagree that the streamlined requirements are unlikely to ever be met. We discussed a State's ability to meet the streamlined criteria in the preamble, and direct the

commenter to sections II.C.3 and III.C.11.d.i. of the final rule, which discusses the overall impact of this policy on State proposals to reduce or restructure provider payment rates. Similar to our experience after the issuance of SMDL #17-004, as discussed in the above referenced sections of the final rule, we anticipate that there will be States that propose rate reductions or restructurings that will be able to demonstrate compliance with § 447.203(c)(1). The final rule provides that significant access concerns can be raised, and the proposal can still meet the (c)(1) threshold, provided that the State can reasonably respond to or mitigate the concerns, as appropriate. States should be working with their provider and beneficiary communities and engaging with constructive criticism and complaints, and provide justification to those interested parties as to why the reductions are necessary, and discuss alternatives considered. An important purpose of § 447.203(c)(1)(iii) is to encourage meaningful engagement between States and s interested parties.

Comment: Multiple commenters recommended that CMS increase the proposed threshold to qualify for the streamlined payment SPA analysis proposed at § 447.203(c)(1)(i) from 80 percent of Medicare, with some commenters suggesting that the threshold be changed to 100 percent of Medicare to make the streamlined process more meaningful. These commenters noted that, although Medicare FFS pays physicians considerably more, on average, than Medicaid, it is not competitive in markets with a large percent of commercial payers and Medicare Advantage plans, which typically pay more than traditional Medicare. Therefore, these commenters stated that setting a benchmark at 80 percent of a rate that is not competitive in many parts of the country would undermine efforts to ensure Medicaid payments comply with section 1902(a)(30)(A) of the Act. Another commenter stated that many people cannot access Medicaid acute-care services of the types that Medicare pays for because States do not pay providers adequate rates to induce them to accept Medicaid as payment, and the commenter noted that this problem has existed for a very long time, and it is not related to whether a State wants to reduce or restructure rates from their current levels. One commenter noted that many

providers are already paid at 80 percent of Medicare and thus recommended that it seems appropriate to select a higher standard by which to assess whether a reduction would diminish access. Further, a couple of commenters suggested that if access problems persist after a State has achieved the 80 percent threshold for a suitable period of time, and those problems can be traced to inadequate rates, then the State should be required to raise those rates to 85 percent, then 90 percent and so on until the rates reach 100 percent of the Medicare rate. One commenter suggested that such a graduated approach to the § 447.203(c)(1)(i) threshold should be included regardless of whether there are persistent documented access to care issues. Some commenters had similar recommendations to increase the threshold without recommending a specific number, noting that Medicare payments are often low relative to provider costs, and one of these commenters also recommended a phase-in approach.

Some commenters suggested that CMS take a different approach for different services where the commenters suggested that Medicare may undervalue a service, such as mental health, or where certain service providers do not take insurance, which leads to higher charges in the private market. One specifically suggested a 100 percent threshold for behavioral health, for these reasons.

Response: We appreciate the viewpoints and suggestions of the commenters. First, where the commenters suggested raising the 80 percent threshold to a higher level, such as a 100 percent threshold, to make the streamlined process more protective of beneficiary access, we believe the 80 percent threshold continues to present a meaningful threshold, particularly as it is coupled with the other standards in § 447.203(c)(1). As we discussed in the preamble, after careful review of the literature, we determined that 80 percent of Medicare would be a reasonable payment rate threshold to aid States' and our assessment of compliance with section 1902(a)(30)(A) of the Act. Based on a review of evidence discuss elsewhere in the proposed rule and preamble of this final rule, we do not currently have evidence that a ratio higher than 80

percent is necessary to ensure compliance with the statutory access standard.³⁷² However, we are committed to monitoring implementation and would consider proposing a sliding percentage threshold for the Streamlined analysis required under § 447.203(c)(1) through future rulemaking, if it is determined that such a change would be appropriate. The threshold is not a level set for approval (or disapproval) of a SPA, but merely to inform the level of analysis would be required. Additionally, the other commenter's assertion that many providers are already paid at 80 percent of Medicare does not, in our view, indicate a need for stricter thresholds, but rather provides that some States may simply be able to meet the § 447.203(c)(1)(i) threshold. If these providers, the beneficiaries they serve, and/or other interested parties have access-related concerns about current or proposed payment rates in their State, they may raise those concerns to the State through the various available forms of public process, which the State would need to address consistent with § 447.203(c)(1)(iii) to qualify for the streamlined analysis process in the event of a payment SPA that would reduce or restructure rates in circumstances that could result in diminished access. We note that, in general, there is no requirement that payment rates for Medicaid services include explicit consideration of a provider's cost of care. The level of payment rates in relation to provider costs is not necessarily the only or the decisive factor in ensuring access to care consistent with the statutory standard, and we do not require that States establish that rates are sufficient to ensure access by reviewing the relationship of payment rates to provider costs.

Second, we agree that Medicare payment rates are typically higher than Medicaid, but do not agree the fact that some private payer rates and Medicare Advantage rates are higher than Medicare FFS rates requires that we select a threshold rate of higher than 80 percent of the Medicare FFS rate to achieve a meaningful comparison that helps ensure that Medicaid rates are adequate to meet the statutory access standard. In addition, regarding the comment that certain providers that do not take insurance, which leads to higher charges, we do not consider a charged

³⁷² 88 FR 28027 through 28029.

amount to be comparable to a payment rate unless the provider actually receives the charged amount as payment amount from a payer (including self-pay individuals). Some providers bill patients on a sliding fee scale, dependent on factors like the individual's income level, even if the provider does not take insurance. This does not mean that using a provider's customary charge is a reasonable proxy for an economic and efficient payment rate or for a payment level that is necessary to support adequate access to care, because not all providers receive payment at their charge rate, even if they bill the patient directly.

We are finalizing the § 447.203(c)(1)(i) threshold at 80 percent of Medicare FFS because we wanted to balance an achievable threshold for States while also establishing a threshold that we believe would be strongly indicative that Medicaid payment rates would be likely to comply with section 1902(a)(30)(A) of the Act. While we acknowledge that 80 percent of Medicare rates may not provide absolute assurance that a given provider, or a sufficient number of providers, will participate in the Medicaid program, we are using 80 percent as a threshold to determine the level of analysis and information a State must provide to CMS to support consistency of payment rates with section 1902(a)(30)(A) of the Act. Notably, there are other provisions of the final rule that provide opportunities for the public to raise access to care concerns to State agencies and to CMS should Medicaid payment rates be insufficient to ensure adequate provider participation so that the statutory access standard is met, as provided in §§ 447.203(c)(4) and 447.204.

Finally, we acknowledge the commenter that suggested that 80 percent of Medicare does not take into account circumstances in which Medicare may undervalue a service, such as mental health. In the 2024 Medicare PFS final rule, Medicare did finalize an adjustment to the payment for certain timed behavioral health services paid under the PFS.³⁷³ In the same rule, we acknowledged the systemic valuation problem and finalized an adjustment to help mitigate the impact which is scheduled to be phased-in over 4 years. While there are certainly going to be

³⁷³ 88 FR 79006.

issues within any selected rate comparison approach, do not believe that Medicare payment rates for certain services or in general are insufficient in a manner that would suggest a need to use a threshold higher than 80 percent of the Medicare PFS rate. We acknowledge that the reluctance of some provider types to accept payment from various payers, including public and private payers, is concerning, as this can have a negative effect on access to needed care for Medicaid and Medicare beneficiaries, as well as the public at large, including those who are privately insured. However, to the extent the broader public has difficulty accessing a particular service due to high levels of refusal among providers of that service to accept payment offered by public and private payers, then it is possible that the access standard under section 1902(a)(30)(A) of the Act could be met even if Medicaid beneficiaries are experiencing significant difficulty obtaining services from these providers. Although CMS would encourage States in such circumstances to explore all available options to encourage greater provider participation in Medicaid, we have not seen evidence that leads us to believe this circumstance warrants a different approach to evaluating the sufficiency of payment rates for behavioral health services that is different than the approach for physical health services.

Comment: One commenter recommended that CMS establish a minimum payment threshold that States must adhere to if there are significant, demonstrated access problems, noting that States where the 80 percent threshold has been met or exceeded have significantly fewer problems with access to Medicaid services than States where that has not happened. Therefore, the commenter recommended that CMS require States to set all rates under the Medicaid State plan to at least 80 percent of the comparable Medicare rate, unless the State can demonstrate that it does not have a significant access problem with the services for which Medicaid payment rates are below that threshold.

Response: We appreciate the recommendations of the commenters, but the statute does not provide CMS with the authority to establish a floor for Medicaid payment rates as recommended by the commenter, with limited statutory exceptions (such as for hospice services

under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute). We are finalizing the § 447.203(c)(1) and (2) provisions as proposed. Payment rates are not the sole indicators of access to care, and States should pursue any means to improve access to care to the extent that they are able. To the extent that there are significant access issues where the provider payment rates are at least 80 percent of Medicare, the other components of § 447.203(c)(1) would also be reviewed to determine if the payment rate reductions or restructurings meet the § 447.203(c)(1) thresholds. If there are access to care issues, then in following the process described in this final rule, we anticipate that the public processes in paragraph (c)(4) and § 447.204 may yield significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed. We would only consider approving a payment SPA in such circumstances under the streamlined process under § 447.203(c)(1) if the State were able to reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

Comment: One commenter encouraged CMS to conduct enhanced reviews, consistent with § 447.203(c)(2), of payment rates for States that are already below the 80 percent threshold, even if the State has not submitted a triggering rate reduction SPA.

Response: We appreciate the suggestion of the commenter. The payment rate transparency publication, comparative payment rate analysis, and payment rate disclosure requirements we are finalizing in § 447.203(b) will allow States, CMS, and the public a better insight into rates regardless of whether a SPA is submitted. However, we are not requesting a § 447.203(c)(2) analysis where the State has not submitted a SPA because we are moving away from the previous AMRP process from the 2015 final rule with comment period and replacing that process with the new § 447.203 provisions of this final rule. We will continue in our

oversight role of the Medicaid program and note that we can initiate a State plan compliance action if we have evidence that the State's Medicaid payment rates do not meet the access standards in section 1902(a)(30)(A) of the Act, regardless of whether the State is seeking to change them with a SPA.

Comment: For the 80 percent of Medicare analysis, two commenters recommended weighting codes in the analysis by service volume to reflect payment levels more meaningfully across the benefit category. These commenters were concerned that CMS' proposed "aggregate" standard, reviewing rates across a benefit category rather than at the service-specific level, will mean that some Medicaid services are paid below 80 percent (including frequently provided services) even if the overall benefit category (including equally weighted but infrequently provided services) achieves the 80 percent threshold. They recommended that CMS set the threshold on a disaggregated basis to avoid permitting States to obscure low payment rates for key services.

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan, or to the extent that we have reason to believe that common billing codes most frequently used by providers within the State are disproportionately impacted, as determined by the State's public input process, by the payment rate reduction or restructuring proposal. Further, the payment rate

transparency publication in § 447.203(b)(1) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

Comment: One commenter recommended that, for services for which the State does not use a cost-based payment methodology, CMS should require States to transition to a cost-based methodology. Alternatively, they recommended that CMS require Medicaid rates be no less than 80 percent of Medicare, private insurance, private payment (which we interpret to mean self-pay), or rates for State-furnished or paid services or other comparable service rates.

Response: We appreciate the recommendations of the commenter, but with limited statutory exceptions (such as for hospice services under section 1902(a)(13)(B) of the Act and FQHC/RHC services under section 1902(bb) of the Act, which each establish a floor for provider payment rates which prohibits States from implementing rate reductions below the amount calculated through the methodology provided in the statute), the statute does not provide CMS with the authority to establish a floor or a particular payment methodology for Medicaid payment rates as recommended by the commenter. There is also no statutory requirement to pay providers at the cost of providing services or rates that are equivalent to cost. Prior to 1997, the Omnibus Reconciliation Act of 1980 included the “Boren Amendment” which required under then section 1902(a)(13) of the Act that some institutional providers, in particular nursing facilities and intermediate care facilities, receive payments were reasonable and adequate to meet the costs which much be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards. In 1997, through the Balance Budget Act of 1997, the Boren Amendment was repealed and replaced with the current section 1902(a)(13) of Act to instead require States to use a public process to set institutional provider payment rates. Since these statutory changes have occurred, States are not required to consider the cost of care in the development of provider payment rates, but instead rely on input from those providers in their

rate setting, which input also is important under the requirements set forth in this final rule. We are finalizing the § 447.203(c)(1) and (2) provisions as proposed.

Comment: A couple of commenters questioned the use of Medicare rates as the basis for comparison in § 447.203(c), as it is not a significant payor of certain Medicaid-covered services and serves a significantly different population. These commenters suggested that services such as substance-use disorder services, facility-based treatment, dental services, and certain LTSS lack a comparable set of Medicare-covered services that would “bear a reasonable similarity” to the Medicaid-covered services. One commenter expressed concern about whether States may compare against Medicare rates that are perhaps similar in concept but not in practice. Specifically, the commenter noted that Medicare Home Health Aides and Medicare in-home skilled nursing services seem like they might be comparable to certain Medicaid HCBS and LTSS, but in practice serve different populations in vastly different volumes and as such are not appropriate comparisons. Commenters urged CMS to issue guidance to States on service categories that would require the submission of additional data under this circumstance. One commenter acknowledged that the aggregate comparison, rather than a rate-by-rate comparison, alleviated some of the challenges of finding a Medicare equivalent for certain services.

Further, one commenter suggested a more nuanced approach to examining payment rates as they relate to access, such as benchmarking against rates for a subset of the highest performing States in terms of access to care for these service categories. That commenter cited recent research from the American Dental Association’s Health Policy Institute, which does not suggest a strong relationship between the ratio of Medicaid-to-private payer rates and dental provider participation in Medicaid, meaning that a comparison to private payer rates is not necessarily instructive for all services in the absence of Medicare comparator rates.

Response: We are finalizing § 447.203(c)(1) and (2) as proposed. The regulations account for circumstances where Medicare does not cover comparable services, by requiring States to compare, “as reasonably feasible, to the most recently available payment rates of other

health care payers in the State or the geographic area for the same or a comparable set of covered services, “which comparison is required even if it is impossible to compare” to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services because no such set of Medicare-covered services exists. We also agree with the commenter who pointed out that the aggregate comparison at the level of the benefit category makes it more feasible to find a reasonable Medicare comparison. While the regulations allow States some flexibility in determining how to perform the required comparison in developing and submitting their SPA analysis, all State-submitted information will be reviewed by CMS through the SPA process, and we reserve the right to request any additional information necessary to further understand the SPA or the accompanying analysis, which may include a request for additional rate comparison information.

Although we appreciate the concern of the commenter about circumstances where neither Medicare nor private payer rates provide a reasonable analog to assess access to care, we have to balance our requirements against the feasibility of obtaining data for comparison. Although the rate transparency requirements we are finalizing in this rule will increase the availability of State rate data, determining the highest performing States for use as the commenter suggested would require additional burden on both States and the Federal Government to determine which States would be benchmark States for which services. In addition, it is not necessarily clear that this approach would be appropriate to ensure compliance with the statutory access standard, which looks to whether beneficiaries have access to covered services at least as great as that enjoyed by the general population in the same geographic area. We believe the policies we are finalizing strike an appropriate balance that reasonably considers availability of data and State burden, as well as the need to ensure sufficient beneficiary access.

We acknowledge the commenters’ concern that services such as substance-use disorder services, facility-based treatment, dental services, and certain LTSS lack a comparable set of Medicare-covered services that would “bear a reasonable similarity” to the Medicaid-covered

services, and the concern about whether States may compare against Medicare rates that are perhaps similar in concept but not in practice. Particularly for facility-based services, we recognize that Medicare and Medicaid provider types may not be identical in certain cases. However, often, facility-based services furnished by a provider type enrolled in one program are covered when furnished in a different setting or by a provider with a different enrollment type in the other program. In such cases, States should look to the nature of the service rather than, for example, the enrollment type of the provider, to identify a reasonably similar set of Medicare-covered services for comparison. We acknowledge that Medicare also establishes payment rates for certain services for which Medicare seldom pays; however, States still should consider these rates when constructing their comparisons to Medicare in accordance with the provisions of this final rule.

Comment: Some commenters requested that CMS remove the 4 percent threshold under 447.203(c)(1), noting that a 4 percent, or even lower, standard would in most cases be reducing a rate which is already far below Medicare levels. One commenter suggested that if a 1 or 2 percent threshold is not feasible for every State, then CMS should use this standard (that is, 1 or 2 percent, instead of 4 percent) for States whose aggregate Medicaid FFS payments average less than the national average of 72 percent for the most common E/M services.

One of these commenters supported CMS' proposal to assess such rate reductions on a cumulative basis over the course of a State fiscal year. Another commenter urged CMS to consider designing a limit to ensure that States could not implement a large cut (for example, 20 percent) to payments for a particular service, which the commenter perceived as a risk due to our proposal to analyze changes at the benefit category level, where we proposed to examine whether aggregate payment rate changes for the benefit category as a whole would exceed the 4 percent threshold. The commenter also suggested that CMS could also consider disaggregating service analysis in future rulemaking.

Response: We are finalizing § 447.203(c)(1) and (2) as proposed. As discussed

previously, the 4 percent threshold is one of three criteria identified in § 447.203(c)(1), which, if not met, will require the State to submit additional information required under § 447.203(c)(2). Where a State's payment rates are already below 80 percent of the Medicare FFS payment rate for the same or a comparable set of services, then any rate reductions from that State would be subject to the requirements of § 447.203(c)(2). This feature will ensure States with rates already below 80 percent of comparable Medicare FFS rate levels will have to take additional steps to establish that the rate change will not result in access below the level required under section 1902(a)(30)(A) of the Act. We declined to include a lower threshold because we believe that the 4 percent is sufficient based upon our experience with State proposals received after the publication of SMDL #17-004. State proposals that included a reduction less than or equal to 4 percent of the aggregate FFS Medicaid expenditures for each benefit category impacted by the reduction or restructuring generally did not result in access to care issues for affected services.

Comment: Multiple commenters were concerned that the 4 percent reduction criterion is not nominal, as CMS had described it. These commenters urged CMS to re-assess the appropriateness of the 4 percent threshold.

Response: As discussed in the proposed rule, States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly.³⁷⁴ We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17-004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17-004 six years ago, the 4 percent

³⁷⁴ 88 FR 28030

threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule, as well as in response to the proposed rule in this rulemaking. The provisions of the final rule in § 447.203(c)(1) are not intended to be individually applicable, as they were under the SMDL #17-004, and are instead intended for each element of § 447.203(c)(1) to be met in order for the rate reduction or restructuring SPA to be considered consistent with section 1902(a)(30)(A) of the Act under the streamlined analysis process. In each instance, the State's proposal would need to demonstrate that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services; the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public processes described in paragraph (c)(4) and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

Comment: One commenter noted that the 4 percent reduction threshold is consistent with the 2018 proposed rule, but suggested that CMS assess any rate reduction compared to broader trends in the economy, particularly when considering rising medical cost and adjusting for inflation, a 4 percent payment cut should not be considered nominal, especially in States where Medicaid payments are already low. Furthermore, the accumulating effect of yearly cuts to

provider payments, which could still meet the thresholds of the rule, would be extremely detrimental to access for beneficiaries in the Medicaid program. For example, the Medicare Economic Index (MEI) measures the impact of inflation faced by physicians with respect to practice costs and general wage levels, and as such show the year-over-year change in cost of providing the same basket of services. The commenter stated that rate reductions should be compared against this type of measure rather than against an arbitrary percentage. The commenter also noted that the 4 percent rate reduction threshold would operate in conjunction with the other criteria in § 447.203(c)(1), and therefore not exempt a State proposal from compliance with the broader access framework in the rule, but expressed concern about the disproportionate impact a 4 percent reduction can have on certain practice types, such as pediatric.

Response: We appreciate the suggestion of the commenter. We are finalizing § 447.203(c)(1)(ii) as proposed. We did not want to rely upon the MEI to supply an inflation factor that must be considered in examining the approvability of payment rate changes or restructurings because we wanted to provide flexibility for States within their budgetary constraints. We also note that the comparison of State payment rates to Medicare would accomplish a similar goal to that stated by the commenter. By requiring State rate actions be compared to the most recently published Medicare rate, which are trended forward annually, the (c)(1)(i) threshold does take into account inflation that may occur in the health care industry.

We reiterate the statement of the commenter that the provisions of the final rule in § 447.203(c)(1) are not intended to be individually applicable, as they were under the SMDL #17-004, and are instead intended for each element of § 447.203(c)(1) to be met in order for the rate reduction or restructuring SPA to be considered consistent with section 1902(a)(30)(A) of the Act under the streamlined analysis process. In each instance, the State's proposal would need to demonstrate that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected

by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services; the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year; and the public processes described in paragraph (c)(4) and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

We disagree that 4 percent is an arbitrary threshold. As noted in a prior response, States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction threshold with respect to a particular service category in SMDL #17–004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17–004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule and the proposed rule in this rulemaking. In addition, we did not receive comments indicating that specific State rate reductions that were less than 4 percent had an impact on beneficiary access to care in their State

Medicaid programs. In addition, the 4 percent threshold is then a measure to ensure that payment rates are not reduced by too significant of an amount over a single State fiscal year. The two quantitative thresholds in paragraphs (c)(1)(i) and (ii), taken together with the public input requirements in paragraph (c)(1)(iii), work in conjunction to ensure that State payment rates are consistent with section 1902(a)(30)(A) of the Act.

Comment: One commenter suggested where States make changes to a cost-related payment methodology that may result in diminished access (for example, by placing a new cap on administrative costs, requiring a “rebase,” or otherwise altering cost-reporting procedures), it may be challenging to determine whether the change would result in a 4 percent or more decrease in payment.

Response: We understand the commenter’s concern and note that the 4 percent threshold is a cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. During the SPA process, States are required to estimate the amount of the financial impact on their CMS form 179 and in their public notice as required by § 447.205(c)(2), which states that the public notice must “give an estimate of any expected increase or decrease in annual aggregate expenditures.” Where States are unsure how they should demonstrate whether the proposed change meets the 4 percent threshold in § 447.203(c)(1)(ii), they should look to existing criteria and methodologies used to estimate financial impacts for the CMS form 179 and public notice under § 447.205.

Comment: One commenter noted that § 447.203(c)(1)(iii) requires an assessment of “significant concerns” from providers and others, and requested additional detail regarding the definition of “significant concern,” and what the State’s response to significant concerns must entail. A couple of commenters stated that requiring States to demonstrate that no concerns were raised or to “address” concerns raised in public comment would be a difficult requirement to meet, noting that any proposed rate reduction is likely to result in significant public comment.

One of these commenters stated it is unclear what level of concern or complaint would shift a State from one tier (that is, the streamlined process under § 447.203(c)(1)) to the next (that is, to requiring the additional analysis under § 447.203(c)(2)). The other of these commenters added that, as CMS does not define the term “address” in the rule, it is concerning that a State must meet all of the criteria in § 447.203(c)(1) to qualify for the streamlined analysis.

Response: The term “significant” can be dependent upon the circumstances, but we generally consider “significant concerns” to mean those that are not easily resolvable through engagement with beneficiaries, providers, and other interested parties. We also note that the regulation does not actually use the word “address” but rather requires that, to the extent that States received public input on their proposed SPA to reduce or restructure payment rates that “yielded . . . significant access to care concerns from beneficiaries, providers, or other interested parties,” the State must demonstrate that it is able to “respond to or mitigate the concerns, as appropriate.” For example, a State may receive a large number of public comments on a proposed rate change, but if all the comments merely seek to clarify an aspect of the change, this situation, despite the high volume of comments, would not be a significant concern, because no concern has been raised other than a request for clarification of the proposal. As an alternative example, where providers are raising concerns about the level of payment they would receive under a State’s new payment rate proposal, the State could discuss with interested parties other legislative initiatives underway or programmatic goals that might be considered as offsetting any decrease in provider payments that might be expected from the proposed rate action. This is common with value-based purchasing initiatives in States. Section 447.203(c)(4), where we are recodifying § 447.203(b)(7) as finalized in the 2015 final rule with comment period, continues to require that “States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.” Furthermore, § 447.203(c)(4)(ii) provides that “States should promptly respond to

public input through these mechanisms . . . with an appropriate investigation, analysis, and response,” and “States must maintain a record of data on public input and how the State responded to this input,” which record the State must make available to us upon request. If the State is not able to demonstrate that its proposal will not decrease access below the statutory standard, including by credibly refuting any reasonable, supported concern raised in public comments that it will harm access excessively, then the proposed rate reduction or restructuring will not meet the requirements for the streamlined (c)(1) process and will be subject to the tier 2 process in paragraph (c)(2), where additional data and analysis will be required to be submitted. In all cases, we will review to ensure that statutory access standard and all other applicable Federal requirements are met.

Comment: A few commenters commended CMS for including the third criterion, which centers the importance of public concerns about rate reductions or restructuring, but these commenters opposed CMS implementing any threshold for rate reduction or restructuring SPAs under § 447.203(c)(1).

Response: We appreciate the support of the commenters. With respect to the inclusion of this criterion as one of three requirements needed to qualify for a streamlined access analysis and in response to the commenters’ opposition to implementing any threshold for rate reductions or restructuring SPAs under § 447.203(c)(1), we note that the intention of this final rule is to balance the administrative burden on the States associated with rate reduction or restructuring SPAs with the need to have sufficient information to make an administrative decision on State payment rate proposals, and whether they satisfy the access standard in section 1902(a)(30)(A) of the Act, while also providing providers, beneficiaries, and interested parties to raise concerns directly to the State through the mechanisms for ongoing beneficiary and provider feedback in § 447.203(c)(4) of the final rule.

Comment: A few commenters strongly supported the public input process provision in § 447.203(c), particularly in § 447.203(c)(1)(iii), since developing robust mechanisms for States to

hear feedback from providers and interested parties about access concerns will be critical to assuring that access analysis in connection with payment SPAs has its intended effect. One commenter suggested that CMS should further consider formalizing a specific role for the MAC/BAG in this process.

Response: We appreciate the support of the commenters and note that the public input processes defined in § 447.203(c)(4), where we are recodifying requirements previously located in § 447.203(b)(7), requires that States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204. We did not specifically provide a defined role for the MAC or BAC in the regulatory rate reduction or restructuring process, but States are not prohibited from including such entities in their public input process to the extent that they believe it would be valuable. However, if the MAC/BAC under § 431.12 of this final rule, or the interested parties' advisory group under § 447.203(b)(6) produces a comment on a State proposal to reduce or restructure payment rates, then the State would be required to consider and respond to it as public input under § 447.204.

Comment: A few commenters stated that providers that receive Medicaid payments always raise concerns about any proposed rate reduction or restructuring. These concerns are typically framed as concerns about access. While one commenter reiterated the value of the input of providers and other interested parties in the rate-setting process, a requirement to conduct an access analysis any time a provider voices concerns during the public input process is a de facto requirement to conduct an access analysis for all SPAs. The commenter stated that this will increase the administrative burden for States and CMS and undermine the two-tiered level of analysis envisioned by CMS.

Response: We understand the viewpoint of the commenter and can affirm that the mere existence of one or more comments is not in and of itself a measure of whether the comments

have raised a significant access to care concern or whether the State is able to respond to and mitigate any significant concern, as appropriate. If comments received do not raise any significant access to care concern, or if they do but the State documents a reasonable response to all significant concerns that demonstrates that the proposal will not reduce access below the statutory standard notwithstanding the concerns, or that mitigations identified by the State will prevent such a degradation of access, then the proposed reduction or restructuring will qualify for the streamlined initial State analysis under § 447.203(c)(1). We also point out that the requirement that States provide adequate notice and consider public comment for payment rate changes is a long-standing requirement of the Medicaid program in 42 CFR part 447, Subpart B.

Comment: One commenter expressed concern that § 447.203(c)(1)(iii), which states as a criterion that “public feedback yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate,” presents a dangerous loophole through which States can drastically cut payment for services, including, for example, specialist office visits, without triggering additional regulatory scrutiny. The commenter expressed doubt that the subjective inquiry on whether State efforts might be reasonable coupled with the non-specific activity the State would undertake (“respond” or “mitigate”) would provide an actual hurdle to payment cuts, including cuts that could constrict access for beneficiaries with rare and ultra-rare conditions.

Response: We disagree that this provision provides States with a loophole enact drastic cuts for services. First and foremost, the provision in question is just one of three criteria a State must meet in order to perform only a streamlined access analysis under § 447.203(c)(1). Second, qualification for the streamlined analysis does not result in automatic approval of the SPA. We will still review both the SPA itself and the streamlined analysis as submitted by the State to determine accuracy and whether the State has met all applicable Federal requirements. We fully expect that some States may submit documentation for the streamlined analysis, and CMS will determine that a more extensive analysis under § 447.203(c)(2) is necessary. For example, if we

disagreed that a State's streamlined access analysis submission adequately documented that the State had reasonably responded to or mitigated all significant access concerns raised through public processes in connection with a SPA to reduce or restructure payment rates, we would require the State to submit the additional access analysis provided for in this final rule to enable us to verify that the SPA satisfies the access standard in section 1902(a)(30)(A) of the Act.

To be clear, the State's response to any significant access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us. In addition, § 447.203(c)(4), where we are recodifying § 447.203(b)(7), continues to require that "States have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204." Furthermore, § 447.203(c)(4)(ii) provides that "States should promptly respond to public input through these mechanisms . . . with an appropriate investigation, analysis, and response," and "States must maintain a record of data on public input and how the State responded to this input," which record the State must make available to us upon request. A major benefit and intent of this repeated emphasis on public process is to protect against the situation the commenter describes. Our regulations ensure other parties besides the State have visibility into a proposed rate reduction or restructuring, and are able to voice related concerns, so we do not need to rely solely on a State's assertion that there are no access-related concerns or that all such concerns have been addressed.

c. Additional State rate analysis (§ 447.203(c)(2))

Comment: One commenter expressed support for the proposed changes to strengthen and clarify requirements for the analysis required for reductions in rates or restructuring of provider payments under § 447.203(c)(2); however, the commenter raised concerns about comparing Medicaid rates solely to Medicare rates, as Medicare does not have comparable services for every benefit category in Medicaid. As such, the commenter suggested using private pay where

no Medicare payment rates are available.

Response: We appreciate the support of the commenter and point out that a comparison to Medicare payment rates is not the sole means of assessing access to care in this final rule. This final rule requires that, for States submitting a proposed rate reduction or restructuring, the proposed reduction or restructuring must meet all three criteria set out in § 447.203(c)(1), which include the 80 percent of Medicare comparison, or else the additional analysis under § 447.203(c)(2) would be required. We also finalized in § 447.203(c)(2)(ii) to require a comparison of Medicaid payment rates to Medicare “and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services” but note that the availability of private payer rate information that has proven difficult for States to obtain due to its often proprietary nature. Similarly, under § 447.203(c)(2), a comparison to Medicare rates is just one part of the full, required analysis for States that must complete the tier 2 analysis. The full tier 2 analysis, which we are finalizing as proposed, requires the following in addition to the full tier 1 analysis: a summary of the proposed payment change including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring; an analysis of the Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring and a comparison of each to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or geographic area; information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend information; information about the number of Medicaid beneficiaries receiving services through the FFS

delivery system in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend and beneficiary population information and anticipated effects; information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring for each of the immediately preceding 3 years including trend and service-recipient beneficiary population information and anticipated effects; and a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). For services for which a Medicare comparator is not available, the § 447.203(c)(2) analysis is required to be submitted by the State along with the SPA proposing to reduce or restructure provider payment rates as the State is unable to demonstrate compliance with § 447.203(c)(1). The regulations being finalized in § 447.203(c)(2)(ii) account for circumstances where Medicare does not cover comparable services, by requiring States to compare, "as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services because no such set of Medicare-covered services exists.

Comment: One commenter expressed concern that, while CMS understandably seeks to clarify which SPAs are subject to heightened scrutiny under the tier 2 analysis requirements in § 447.203(c)(2), the criteria are skewed toward services that are paid for off a fee schedule, and which correspond to Medicare-covered services.

Response: We acknowledge that there is an administrative ease associated with meeting the requirements of § 447.203(c) where States pay according to a fee schedule. However, it is also possible to compare payment amounts where no such fee schedule exists. State UPL demonstrations are a valuable resource in determining level of payment of both base and

supplemental payments compared to a reasonable estimate of the amount that Medicare would pay for the same services, and our experience has shown that States are able to make these comparisons on both a provider-specific level and in the aggregate. The methodology States use for required UPL demonstrations would support the analysis required under § 447.203(c) of this final rule, even where the payment methodology is not based on a fee schedule.

Comment: One commenter noted that the proposed first-tier analysis requires States to compare proposed Medicaid rates to Medicare rates, but as CMS acknowledges in the preamble, the absence of a comparable Medicare service for some services would mean the State would need to perform the full two-step access analysis, since they would not be able to meet all three criteria in § 447.203(c)(1). The commenter stated that this expectation is not clearly reflected in proposed § 447.203(c) and suggested that CMS add language clarifying that when there is no comparable set of Medicare services, the State must perform the second tier of analysis under § 447.203(c)(2). Another commenter expressed support for CMS's preamble provision that, for services in which a reasonably comparable Medicare-covered analogue is not available, the State would be obligated to support its rate reduction or restructuring proposal through the submission of additional information under § 447.203(c)(2).

Response: We reiterate that we are finalizing § 447.203(c)(1) and (2) as proposed. In addition, we are finalizing our statement in preamble that for any service for which the State has proposed to reduce or restructure the Medicaid payments in circumstances when the changes could result in diminished access, for which there are no comparable Medicare services that would enable the State to make the showing required under § 447.203(c)(1)(i), the State is required to conduct the secondary analysis required under § 447.203(c)(2). For example, where Medicare does not cover routine dental care, payment rate reductions or restructurings of such services would be subject to § 447.203(c)(2) since comparable Medicare payment information required under § 447.203(c)(1)(i) of the final rule would be unavailable.

Comment: One commenter stated that the information States are required to collect and

examine, especially the number of providers, beneficiaries, and services, will be particularly valuable in assessing the impact of rate changes on access to home care services. One commenter specifically expressed support for the § 447.203(c)(2)(iii) proposal to require States to provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area, provider type, and site of service. That commenter acknowledged that this would be valuable information to be made publicly available. Another agreed, saying CMS should require States to publicly post the enhanced analysis, including data submissions, to ensure full transparency.

Response: We appreciate the support of the commenters. At this time, there is no plan for CMS to make the information States provide in these analyses publicly available. Approved SPAs are public facing documents and are posted on Medicaid.gov after they are approved by CMS. Payment rates used to provide the § 447.203(b) and (c) of the final rule should come from these approved SPAs, and these SPAs should help to clarify questions about the State's particular rate model. We further note that the requirements we are finalizing at §§ 447.203(c)(1)(iii), (c)(4), and 447.204 regarding public process and mechanisms for ongoing beneficiary and provider input should provide interested parties opportunity for meaningful input on State rate actions. Otherwise, information may be available upon request from either States or CMS, and we note that some of this information may be subject to Freedom of Information Act (FOIA) disclosure requirements.

Comment: Several commenters expressed that States should be required to provide detailed information described in § 447.203(c)(2)(i) through (vi) about proposed rate reductions or restructuring any time it proposes to reduce rates or restructure rates in a way that could result in diminished access, and not only when the proposed rate fails to meet certain criteria such as those specified in § 447.203(c)(1). These commenters stated concern that the proposed two-tier structure would still permit States to alter rates in ways that harm beneficiary access.

Response: The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process outlined in the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1). The commenters' recommendation seems to suggest something closer to a continuation of the previous AMRP process, whereas we believe this final rule strikes a more appropriate balance of easing State burden where SPAs meet the § 447.203(c)(1) criteria (making them unlikely to result in reducing beneficiary access to care to a level inconsistent with section 1902(a)(30)(A) of the Act), and requiring more rigorous data and analysis requirements for SPAs that do not meet the § 447.203(c)(1) criteria and may present more cause for concern related to beneficiary access to care.

Comment: A commenter recommended that, in addition to requiring States to provide summary information about proposed changes, and information about the rates in aggregate in § 447.203(c), CMS should require States to provide the specific range of rates, including any variation in rates (for example, regional differences, or differences based on provider specialty).

Response: We approve States' rate methodologies for compliance with regulation and statute, but may not approve individual service rates unless a State presents a final rate, or a fee schedule, as the output of a rate methodology. This final rule does not change that policy or imply that CMS will review individual rates for sufficiency in all cases. Reviewing individual rates within a fee schedule would not necessarily provide a better determination of whether the rates are adequate to enlist sufficient providers into the Medicaid program or not, provided that the State is using a consistent payment rate methodology for the entirety of the fee schedule, since we do not believe that providers generally make decisions about whether to participate with a payer (and accept the payer's rates) based on the rate for a single service. However, we will review individual payment rate codes to the extent that the rate changes fall outside of the typical methodology used by the State in their payment rate setting methodology under the State plan, or

to the extent that we have reason to believe that common billing codes most frequently used by providers within the State are disproportionately impacted by the payment rate reduction or restructuring proposal. Further, the payment rate transparency publication in § 447.203(b) will require States to publish their fee schedule rates for services specified in that section of the final rule, which will include individual fee schedule payment rates for services for CMS and public review.

Comment: Several commenters noted appreciation that the additional information that would be required from States that seek to reduce payment rates or restructure payments in a manner that could result in decreased access noting their belief that the § 447.203(c)(2) provision will create important safeguards to prevent decisions that are solely based on State budgetary concerns rather than an actual analysis of the cost of providing services in the Medicaid program. A few commenters noted that they were glad to see that, because of the nature of HCBS, the majority of rate reductions for home care services and supports would always be subject to the provisions mandating greater scrutiny under § 447.203(c)(2), because Medicare rates for the same or a reasonably similar set of services generally will not be available to make such SPAs eligible for the streamlined access review process under § 447.203(c)(1).

Response: We appreciate the support of the commenters, but note for clarity, as discussed earlier in this preamble, there is no requirement in the Medicaid program that payment rates be based on provider cost.

Comment: A few commenters recommended that, at a minimum, CMS should require all States to complete the more extensive access analysis under § 447.203(c)(2) shortly after publication of the final rule to establish a baseline assessment of access to care for Medicaid beneficiaries. Such analysis should include FFS as well as managed care, enabling comparison of payment and access within and across delivery systems. These commenters urged that this baseline analysis should serve as a comparison point for future access monitoring. Other commenters suggested that the requirement for the analysis in § 447.203(c) should be decoupled

from a State's intention to reduce or restructure rates, suggesting instead that all States should be required to conduct this analysis annually, every 2 years, or at least every 3 years across all rates for all Medicaid FFS and managed care programs for which a Medicare comparison is possible.

Response: We appreciate the suggestion of the commenters. The purpose of this final rule is to create a process that is less administratively burdensome than the previous, ongoing AMRP process outlined in the 2015 final rule with comment period, while also maintaining a data submission process for payment rate reduction and restructuring SPAs that do not meet the thresholds set out in § 447.203(c)(1), and note that the FFS provisions, including the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements (§ 447.203(b)(1) through (5)), interested parties' advisory group requirements (§ 447.203(b)(6)), and State analysis procedures for payment rate reductions or payment restructuring (§ 447.203(c)), finalized in this rule are expected to result in a net burden reduction on States compared to the previous AMRP requirements, as discussed in the proposed rule and in section III. of this final rule. This final rule provides CMS and States with an administrative process through which rate reductions or restructurings can be reviewed and approved, so long as the proposed SPA satisfactorily includes the information required under this final rule and meets all applicable Federal requirements. CMS is discontinuing the previous AMRP process in this final rule, and did not propose and is not finalizing a substantially similar process, as we believe doing so would impose a great deal of burden on States and CMS without commensurate programmatic value, as discussed in the proposed rule and in this final rule (88 FR 27965). We note that the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider input provide impacted parties opportunities to raise access concerns or issues to the State at any point through State-provided input processes.

Comment: One commenter requested that CMS clarify the criteria in both tiers which CMS will use to determine the appropriate level of access on which to provide analyses and documentation of adequate access, claiming there are no details available on the criteria. The

commenter requested that CMS define a measurable methodology with which to determine and demonstrate adequacy of access to care in relation to the criteria of the analysis required in the applicable provisions of § 447.203(c).

Response: We are finalizing § 447.203(c)(1) and (2) as proposed, and are providing a template which will assist States with the data demonstrations which will be used to comply with the provisions of the final rule. We produced a template that was submitted to OMB for public review under control number 0938–1134 (CMS–10391) and will be submitted for approval with this final rule and a final template will be available shortly thereafter. Between the regulation text, the preamble of this final rule, and the components of the analysis template, we believe that the criteria we will use to evaluate SPA proposals are clear. We are electing not to otherwise define adequate levels of access to care under § 447.203(c) because section 1902(a)(30)(A) of the Act establishes that a measure for access is that payment rates are “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area,” which level of access (based on whatever metric might be selected) will vary based on geographic area and the level of access available to the general population for a given service. Although CMS reserves the right to request additional information, we have developed the template to ensure that a State has a mechanism through which all of the data elements in § 447.203(c) can be gathered and presented in a straightforward format. Completing the applicable fields of the template will ensure that the State provides all required data elements of under § 447.203(c), and we will review the materials provided by the State to determine that the State has demonstrated current and anticipated levels of access under the SPA in a manner demonstrates compliance with section 1902(a)(30)(A) of the Act. CMS will review each proposal and the State-provided supporting information to ensure compliance with section 1902(a)(30)(A) of the Act and all other applicable Federal requirements before approving any SPA.

Comment: One commenter urged CMS to require States to identify the unique number of

Medicaid-paid claims for beneficiaries (in addition to the full number of services required in the regulations as proposed) and the unique number of beneficiaries who received services. The commenter also stated that measuring providers' capacity to provide Medicaid services, by including an estimated number of beneficiaries who could have received the respective services, would allow States to fully assess the gaps in service and number of providers required to meet the need, noting that this assessment would be needed to assess proposed rate reductions or restructuring under proposed § 447.203(c).

Response: We are finalizing § 447.203(c)(2)(v) as proposed. The measures mentioned by the commenter are often associated with health care system capacity by looking at enrolled providers with open panels, which is very useful in addressing individual beneficiary requests for services, or finding care for individuals within a geographic area, which are the type of request we would expect to be made through the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider input, and States should be using any information they can to address beneficiary needs in this way. We encourage any interested parties to engage with their State partners to ensure that real-time access to care concerns are able to be addressed by the State as applicable. Further, the provisions of § 447.203(c)(2) are designed to present an overall picture of access to care for each affected benefit category in the State's program. States are welcome to use any additional measures the State believes would be helpful to assess access to care within each affected benefit category, above and beyond the requirements of this final rule.

Comment: One commenter, citing the 3-year period where the proposed rule would require data about trends over time in the data elements proposed to be required under § 447.203(c)(2), supported the use of statistical methods that provide an accurate picture of utilization trends, but recommended that CMS use its discretion in analyzing the information States provide to meet the required data elements. The commenter stated use of a 3-year analysis as a blanket approach may not be required in periods of stable utilization.

Response: The requirements in § 447.203(c)(2)(iii), (iv), and (v) to use 3-year periods

are being finalized as proposed. The purpose of the 3-year analysis is to help identify and appropriately account for statistical anomalies that might appear in the data demonstration. Further, we wanted to provide a clear expectation for what States would be required to provide and thereby remove ambiguity, which we believe existed in the previous AMRP process from the 2015 final rule with comment period. In the 2015 final rule with comment period, the previous AMRP data elements were limited to those specified in § 447.203(b)(1)(i) through 447.203(b)(1)(v), which stated that the AMRP and monitoring analysis will consider: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Within the final rule with comment period, there was discussion regarding the types of data States might use to provide the required information, but much of the final rule with comment period left the specifics of the particular data elements up to the States. In this rulemaking, we proposed and are finalizing considerably more detail in § 447.203(c)(2) than was present in the previous AMRP requirements in the former 447.203(b)(1).

We are also finalizing the 3-year time frame for data analysis in this final rule in § 447.203(c)(2) because we determined that a 3-year look back on provider enrollment, beneficiary enrollment, and beneficiary utilization provides sufficient data to show trends in the data while also helping to identify data anomalies. Where the commenter stated that the use of a 3-year analysis as a blanket approach may not be required in periods of stable utilization, we disagree. The commenter's statement implies that a determination would still need to be made that utilization was stable, therefore by requiring 3 years' worth of data, CMS and the State will be able to document that utilization was stable during the prior 3 years.

Comment: One commenter opposed the requirement to provide an additional summary of the proposed payment change, as described in § 447.203(c)(2)(i), to both § 447.203(c)(1) and (2) equally. The commenter was concerned about the administrative burden these requirements place on States, which could delay SPA submission and in turn affect access to services. The commenter also specifically pointed out that SPAs for services without comparable Medicare rates would, by default, need to complete the additional analysis under § 447.203(c)(2), adding administrative burden. The commenter further recommended CMS implement a form similar to the Standard Funding Questions submitted for Medicaid payment SPAs, in which the State would be able to answer a specific set of questions that would capture the analysis that is being sought. Another commenter noted that the § 447.203(c)(2) data submission requirements may impact significant portions of Medicaid services, such as LTSS, and creates administrative burdens, disincentivizing States from modernizing rate methodologies for these services. This commenter recommended that for services without comparable Medicare rates, the initial analysis be sufficient if all other criteria of the initial review (that is, § 447.203(c)(1)(ii) and (iii)) are satisfied.

Response: States are responsible to ensure that their proposed reduction or restructuring SPA submission includes all of the information required under § 447.203(c)(1) prior to submission. If the proposed reduction or restructuring SPA does not meet all of the paragraph (c)(1) requirements, then the State would need to provide the additional analysis required under § 447.203(c)(2).

We understand that there is burden associated with these new requirements. However, as discussed in the proposed rule in section III.C.11.d, this new process will be less burdensome on States than the previous AMRP process. We also do not believe a State could adequately demonstrate access by answering a standard set of questions as suggested by the commenter, as we would be concerned that static questions may not be well suited to solicit the full scope of data elements that could be necessary to evaluate a particular proposal and therefore prefer to

keep data submission requirements open-ended so that States are able to provide the most complete and appropriate information possible to establish that their proposal satisfies section 1902(a)(30)(A) of the Act as implemented in this final rule. We anticipate providing a considerable amount of technical assistance and templates to assist States with the preparation and submission of data and analysis required under § 447.203(c)(1) and (2).

The rule does not limit a State's ability to reduce or restructure rates where the State believes it appropriate to do so, for example, based on information that the rates are not economic and efficient; rather, it ensures that States take appropriate measures to document access to care consistent with section 1902(a)(30)(A) of the Act. This includes efforts to modernize rates, as noted by the commenter, including by implementing or adjusting VBP arrangements. While we appreciate that the analysis creates a burden for States, we note that we are replacing a process that was more burdensome. For services for which a Medicare comparator is not available, the § 447.203(c)(2) analysis is required to be submitted by the State along with the SPA proposing to reduce or restructure provider payment rates. As the § 447.203(c)(2) elements are based upon and similar to the elements included in the former § 447.203(b)(1) of the 2015 final rule with comment period, we do not believe the new requirements are more burdensome than the 2015 final rule with comment period which created the previous AMRP process. Therefore, we do not believe this final rule disincentivizes States from modernizing payment rates or methodologies as compared to the previous requirements under the 2015 final rule with comment period. For some services, particularly for those for which the State can demonstrate that the § 447.203(c)(1) requirements are met, the final rule considerably reduces burden on States.

Comment: A few commenters urged caution not to impose overly rigid restrictions on States' and CMS' ability to adjust provider payment rates, noting that State Medicaid programs are constrained by the same factors that constrain all State spending, including general economic conditions, State balanced budget requirements, and State general fund revenue. One commenter

noted that requiring a significant analysis for proposed reductions in Medicaid FFS payment rates will create administrative burden for States that have been mandated by their legislatures to reduce certain rates or Medicaid spending in general. The commenter noted that in such circumstances, States have a limited number of “levers” at their disposal—(1) they can reduce the number of individuals enrolled in Medicaid, (2) they can impose reductions on the covered services that Medicaid beneficiaries receive, or (3) they can adjust provider payment rates. If CMS makes it impossible (or inordinately difficult) to restructure provider payment rates, then States may be forced to make other undesirable reductions to coverage and/or eligibility in order to cope with difficult economic conditions.

Response: We understand the concerns of the commenters. States are required to operate their Medicaid programs within their budgetary constraints, and we agree with the commenter that, of the options available for States facing budgetary issues, none of the available approaches typically is ideal. However, we also note that States are also obligated to comply with section 1902(a)(30)(A) of the Act, which requires States to “assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” The requirement specifically references payment rates for “care and services available under the plan” such that the services that are covered under the State plan as both mandatory and optional benefits, must be supported by adequate payment rates for those services. We anticipate providing a considerable amount of technical assistance to ease the administrative burden on States that both need to reduce rates and need to satisfy the requirements of § 447.203(c) to ensure that the statutory access standard is met. We are also finalizing the template we proposed to accompany these requirements and assist States with supplying the necessary data to fulfil these requirements.

Comment: One commenter recommended that CMS build into the review and approval of all SPAs, waiver amendments, and waiver renewals a process for the review of payment rates.

The commenter further suggested that CMS require adequate payment rates prior to approving these amendments and renewals. The commenter indicated that this would allow CMS to review rates more often and prevent years or decades passing without rates being reviewed or adjusted.

Response: CMS reviews all SPAs affecting Medicaid payment for compliance with section 1902(a)(30)(A) of the Act. Outside of the SPA process, the corrective action plan process under § 447.203(c)(5) (which we are recodifying from § 447.203(b)(8)) is available to address access issues that may arise even when the State has not submitted a payment SPA. Further, to the extent that a State submits a SPA that updates coverage of a Medicaid service but does not amend Medicaid payment rates or the rate methodology in the Attachment 4.19A (for Medicaid inpatient services such as inpatient hospital services), 4.19B (for Medicaid non-institutional services such as physician services), or 4.19D (for Medicaid nursing facility services) State plan pages, CMS will not necessarily disapprove that SPA on the basis of insufficient Medicaid payment rates as the payment rates were not submitted along with the corresponding coverage and benefit changes for our consideration. States certainly can submit payment rate information to CMS of the State's own volition or upon request during review of a coverage SPA; however, CMS provides States in this situation (where the SPA would amend State plan coverage, but not payment, pages) with an option to instead defer review of the payment rate compliance issue through a mechanism called a "companion letter," as noted in the 2010 SMDL #10-0020.³⁷⁵ As noted above, even in the absence of a SPA, the corrective action plan process under § 447.203(c)(5) (which we are recodifying from § 447.203(b)(8)) is available to for CMS to take compliance action where it is aware of an access problem due to insufficient rates.

With the policies finalized throughout this final rule, we hope and anticipate that both States and the public will more closely examine existing rates. Our policies around payment rate

³⁷⁵ SMDL #10-020, "Revised State Plan Amendment Review Process." Published October 1, 2010. <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SMD10020.pdf>.

transparency publications, comparative payment rate analyses, and payment rate disclosures will enhance opportunities to determine where an existing rate may not be supporting adequate access to care and identify for States where a need for increased payments and/or updated payment methodologies should be addressed. Our policies around the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) and addressing access questions and remediation of inadequate access to care in § 447.203(c)(5) will further provide beneficiaries, providers, and other interested parties opportunities to engage with States on existing payment rates and their impact on beneficiaries' access to care.

d. Compliance with requirements for State analysis for rate reduction or restructuring (§ 447.203(c)(3))

Comment: A few commenters applauded CMS for including a clear enforcement mechanism for these provisions at § 447.203(c)(3). One of the commenters specifically offered that this provision helpfully codifies CMS's longstanding authority to enforce access standards under section 1902(a)(30)(A) of the Act by denying SPAs or taking compliance action to protect access for Medicaid enrollees.

Response: We appreciate the support of the commenters.

Comment: One commenter opposed the provision at § 447.203(c)(3) that SPAs may be subject to disapproval. The commenter did not believe that approval of a SPA should be contingent on the submission of a satisfactory access analysis required under paragraphs (c)(1) and (c)(2) of this section of the final rule.

Response: The final rule requires States to submit information with their payment rate reduction or restructuring SPAs in circumstances where those types of rate changes may result in diminished access to care. We are requiring this information in order to determine compliance with section 1902(a)(30)(A) of the Act, which requires that a State plan for medical assistance "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least

to the extent that such care and services are available to the general population in the geographic area.” In the event that a State does not provide the information required under this final rule, we would be unable to determine that the State’s proposal is consistent with the statute, and therefore, we would be unable to approve the SPA.

e. Public Input Process (§ 447.203(c)(4))

Comment: Several commenters supported the proposal at § 447.203(c)(4) regarding ongoing mechanisms for beneficiary and provider input on access. One commenter specifically appreciated CMS’ recognition of the importance of ongoing feedback from providers and beneficiaries to the State regarding access to care and for the State to track and take account of those interactions in a meaningful way. Another commenter supported this requirement, noting that HCBS recipients enrolled in managed care are currently provided with a grievance system and indicating that FFS recipients must be afforded this same right.

Response: We appreciate the support of the commenters. We believe that the provision in § 447.203(c)(4) of this final rule provides beneficiaries with opportunities to raise their concerns through hotlines, surveys, ombudsman, grievance, and appeals processes that the State makes available, or other equivalent mechanisms offered by the State.

Comment: One commenter recommended that CMS update the public notice requirements in § 447.205 to require notice 30 days before the effective date in order to increase the transparency of the proposed SPA process and ensure that States provide interested parties with meaningful notice and opportunity to provide feedback.

Response: Changes to the public notice requirements in § 447.205 are outside the scope of this rulemaking.

Comment: One commenter recommended that CMS change “should” to “must” at § 447.203(c)(4)(ii). They pointed out that § 447.203(c)(4)(i) and (iii) under “Mechanisms for ongoing beneficiary and provider input,” both use “must,” while item (ii) notes States “should promptly respond to public input through these mechanisms citing specific access problems, with

an appropriate investigation, analysis, and response.” The commenter stated this provision is important and that if it is not mandated on States, some States may ignore it.

Response: This provision is being finalized as proposed because this section is carried over from prior regulatory language at § 447.203(b)(7) and was proposed to be recodified without change. We acknowledge that responses to public input can take time and resources to manage, and point out that this final rule provision is carrying forward the same regulatory language from the 2015 final rule with comment period. In our experience, States do respond timely and appropriately, and therefore did not think it necessary to propose a change to this provision. We note that § 447.203(c)(4)(iii) requires States to maintain a record of data on public input and how the State responded to this input, and the record of input and responses “will be made available to CMS upon request.”

Comment: One commenter supported requiring States to maintain a record of data on public input and how the State responded to this input, which will be made available to CMS upon request.

Response: We thank the commenter for their support and are finalizing the recodification of § 447.203(b)(7) at § 447.203(c)(4) as proposed.

Comment: One commenter stated that States should establish mechanisms for ongoing monitoring, evaluation, and feedback from beneficiaries, direct care workers, and underserved communities, and that States should create opportunities for meaningful engagement through advisory boards, focus groups, public comment periods, and partnerships with advocacy organizations. The commenter suggested that such an approach ensures that the perspectives and needs of these interested parties are considered in policy development and implementation.

Response: We are finalizing the provisions of § 447.203(c)(4) as proposed, as we believe that the mechanisms for ongoing beneficiary and provider input in paragraph (c)(4) provide opportunities for meaningful engagement by requiring States to develop some of the mechanisms suggested by the commenter. However, in addition to the mechanisms required under §

447.203(c)(4) for ongoing beneficiary and provider input, States are welcome to develop additional processes to facilitate beneficiary and provider feedback, as well as feedback from other interested parties.

Comment: One commenter stated that the mechanisms for ongoing beneficiary and provider input provision in § 447.203(c)(4) lack enforcement to get States to respond in a meaningful way to concerns about access, noting that the question of whether there is a “deficiency” will be left to the States themselves to determine. The commenter suggested that there needs to be some way for interested parties to elevate concerns to CMS in a formal fashion when this process does not work at the State level.

Response: The steps States must take to respond to concerns about access raised through input pursuant to § 447.203(c)(4) are detailed in § 447.203(c)(5), which we are finalizing as proposed as a recodification from § 447.203(b)(8). Section 447.203(c)(5) requires States to develop and submit a corrective action plan to CMS within 90 days of discovery of an access deficiency. The submitted action plan must aim to remediate the access deficiency within 12 months. This requirement ensures that the access deficiency is addressed in a timely manner while allowing the State time to address underlying causes of the access issue, be it payment rates, provider participation, etc. These remediation efforts can include but are not limited to: increasing payment rates; improving outreach to providers; reducing barriers to provider enrollment; providing additional transportation to services; or improving care coordination.

Because each State designs and administers its own Medicaid program within the Federal framework, we believe it is most appropriate for beneficiaries and interested parties to raise access concerns with the State directly, rather than to CMS. To the extent that a beneficiary or interested parties’ access concerns are not addressed by the State adequately, we continue to urge interested parties to elevate concerns to the State through the § 447.203(c)(4) mechanisms for ongoing beneficiary and provider feedback. We further note that we are finalizing as proposed

compliance actions for access deficiencies that have not been remedied under § 447.203(c)(6), as recodified from § 447.204(d).

Comment: One commenter noted that some of the proposed policies, such as strengthening the role of Medicaid beneficiaries in the policymaking process, have been pioneered at the State level.

Response: We appreciate the perspective of the commenter and agree that many of these activities have been pioneered at the State level. We often look to actions undertaken by our State partners to identify areas of policy that may be appropriate to enact at the Federal level.

f. Addressing access questions and remediation of inadequate access to care (§ 447.203(c)(5))

Comment: A couple commenters strongly supported the retention of § 447.203(b)(8) language concerning a State's response to problems with access to Medicaid services, which now appears in § 447.203(c)(5). However, one commenter also expressed concerns about whether that requirement has historically served to require States to make meaningful efforts to correct access issues, considering that the commenter stated there are serious problems with access to Medicaid services in many States today, which the commenter asserted CMS has also acknowledged. The commenter suggested this may be a problem of the resources that CMS devotes to enforcement and insisted that CMS needs to commit to stricter and more effective enforcement of this language.

Response: We appreciate the support of the commenters and the sentiment expressed in the comment. CMS is committed to an agency-wide strategy for oversight and enforcement of Federal requirements concerning access to care. Although the language pointed out by the commenter is unchanged from how it previously appeared in § 447.203(b)(8), we are confident the changes to § 447.203(c)(1)(iii), § 447.203(c)(2)(vi), and § 447.203(c)(4) in this final rule will enhance oversight of access and work to enhance the importance of input from beneficiaries, providers, and other interested parties.

Comment: One commenter noted that concerns around timely access may be identified

by enrollees, patient advocacy organizations, or providers long before they become apparent to Medicaid managed care plans or State officials, particularly if those access challenges are specific to a disease group such as complex and rare cancers. The commenter urged CMS to clarify that, if such groups present plausible access concerns to State officials, that can be sufficient to make the State aware of the access issue, such that the State must submit a proposed remedy plan to CMS within 90 days of receiving a report of such concern.

Response: We encourage beneficiaries, patient advocacy organizations, and providers to work closely with States in order to raise issues such as inability to connect patients to care, or inability to find an appointment within the patient's geographic area, through the mechanisms for ongoing beneficiary and provider input the State established under § 447.203(c)(4). Section 447.203(c)(5), which was formerly § 447.203(b)(8), then requires States to submit a corrective action plan to remedy the access deficiency within 90 days from when it is identified to the State. We agree with the commenters that beneficiaries, patient advocacy organizations, and providers raising plausible access concerns to State officials would be considered as identifying an access deficiency when raised to the State through appropriate State channels.

g. Compliance actions for access deficiencies (§ 447.203(c)(6))

Comment: One commenter supported the proposal to clarify that CMS may use the procedures set forth in § 430.35 when necessary to ensure compliance with access requirements.

Response: We appreciate the support of the commenter. We are finalizing as proposed to recodify § 447.204(d) at § 447.203(c)(6).

After consideration of public comments, we are finalizing the provisions of § 447.203(c) as proposed aside from minor typographical corrections.

4. Medicaid provider participation and public process to inform access to care (§ 447.204)

In § 447.204, we proposed conforming changes to reflect proposed changes in § 447.203, if finalized. These conforming edits are limited to § 447.204(a)(1) and (b) and are necessary for

consistency with the newly proposed changes in § 447.203(b). The remaining paragraphs of § 447.204 would be unchanged.

Specifically, we proposed to update the language of § 447.204(a)(1), which previously referenced § 447.203, to reference § 447.203(c). Because we proposed wholesale revisions to § 447.203(b) and the addition of § 447.203(c), the proposed data and analysis referenced in the previous citation to § 447.203 would be located more precisely in § 447.203(c). Previous § 447.204(b)(1) referred to the State's most recent AMRP performed under previous § 447.203(b)(6) for the services at issue in the State's payment rate reduction or payment restructuring SPA; we proposed to remove this requirement to align with our proposal to rescind the previous AMRP requirements in § 447.203(b). Previous § 447.204(b)(2) and (3) required the State to submit with such a payment SPA an analysis of the effect of the change in the payment rates on access and a specific analysis of the information and concerns expressed in input from affected interested parties; we noted our belief that the previous requirements are addressed in proposed § 447.203(c)(1) and (2), as applicable. We explained our belief that the continued inclusion of these paragraphs (b)(2) and (3) would be unnecessary or redundant in light of the proposals in § 447.203(c)(1) and (2), if finalized. The objective processes proposed under § 447.203(c)(1) and (2), which would require States to submit quantitative and qualitative information with a proposed payment rate reduction or payment restructuring SPA, would be sufficient for us to obtain the information necessary to assess the State's proposal with the same or similar information as previously required under § 447.204(b)(2) and (3).

With the removal of § 447.204(b)(1) through (b)(3), we proposed to revise § 447.204(b) to read, "[t]he State must submit to us with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter."

Finally, as noted in the previous section, we proposed to remove and relocate § 447.204(d), as we believed the nature of that provision is better suited to codification in § 447.203(c)(6).

We solicited comments on the proposed amendments to § 447.204. We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the conforming edits to § 447.204. Another commenter specifically supported the proposal to make technical changes to § 447.204(a) to cross-reference the analysis that CMS proposes to require under § 447.203(c).

Response: We appreciate the support of the commenters.

Comment: One commenter recommended that CMS amend § 447.204(a)(2) to specifically include reference to the interested parties advisory group described in § 447.203(b)(6).

Response: We appreciate the recommendation of the commenter. We are confident that the mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4) of the final rule will provide interested parties opportunity for meaningful input on State rate actions.

After consideration of public comments, we are finalizing the provisions of § 447.204 as proposed.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information” requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purpose of the PRA and this section of the rule, collection of information is defined under 5 CFR 1320.3(c) of the PRA’s implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the proposed rule (88 FR 28037 through 28066) we solicited public comment on each of these issues for the following sections of the proposed rule (CMS-2442-P, RIN 0938-AU68) that contained collection of information requirements. Comments were received with respect to ICR #4 (Incident Management System). A summary of the comment and our response is set out below.

A. Wage Estimates

States and the Private Sector :To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ (BLS’) May 2022³⁷⁶ National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/2022/may/oes_nat.htm). In this regard,

³⁷⁶ In this final rule, we used the most recently available data, May 2022, from the BLS. This is an update from the proposed rule, (88 FR 27960), which used data from the BLS’ May 2021 National Occupational Employment and Wage Estimates for salary estimates.

Table 2 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs³⁷⁷ (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 2: National Occupational Employment and Wage Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs(\$/hr)	Adjusted Hourly Wage (\$/hr)
Administrative Services Manager	11-3012	55.59	55.59	111.18
Business Operations Specialist	13-1000	40.04	40.04	80.08
Business Operations Specialist, All Other	13-1199	39.75	39.75	79.50
Chief Executive	11-1011	118.48	118.48	236.96
Compensation, Benefits, and Job Analyst	13-1141	36.50	36.50	73.00
Computer and Information Analyst	15-1210	53.15	53.15	106.30
Computer Programmer	15-1251	49.42	49.42	98.84
Data Entry Keyers	43-9021	18.26	18.26	36.52
General and Operations Manager	11-1021	59.07	59.07	118.14
Human Resources Manager	11-3121	70.07	70.07	140.14
Management Analyst	13-1111	50.32	50.32	100.64
Social and Community Service Managers	11-9151	38.13	38.13	76.26
Social Science Research Assistants	19-4061	27.77	27.77	55.54
Statistician	15-2041	50.73	50.73	101.46
Survey Researcher	19-3022	31.94	31.94	63.88
Training and Development Specialist	13-1151	33.59	33.59	67.18

For States and the private sector, the employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Beneficiaries: We believe that the costs for beneficiaries undertaking administrative and other tasks on their own time is a post-tax hourly wage rate of \$20.71/hr.

We adopt an hourly value of time based on after-tax wages to quantify the opportunity cost of changes in time use for unpaid activities. This approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on

³⁷⁷ <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>.

their own time, which are outlined in an ASPE report on “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.” [*] We start with a measurement of the usual weekly earnings of wage and salary workers of \$998. [**] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of \$24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in a post-tax hourly wage rate of \$20.71. We adopt this as our estimate of the hourly value of time for changes in time use for unpaid activities.^{378, 379} Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

B. Adjustment to State Cost Estimates

To estimate the financial burden on States, it was important to consider the Federal government’s contribution to the cost of administering the Medicaid program. For medical assistance services, the Federal government provides funding based on an FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capital incomes. For Medicaid, all States receive a 50 percent Federal matching rate for most administration expenditures. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. As such, and taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimate State burden with respect to

³⁷⁸ Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.” <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>.

³⁷⁹ U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; <https://fred.stlouisfed.org/series/LEU0252881500A>. Annual Estimate, 2021.

collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be smaller.

C. Information Collection Requirements (ICRs)

1. ICRs Regarding Medicaid Advisory Committee and Beneficiary Advisory Council (§ 431.12)

The following changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10845).

Currently, most States have an established Medical Care Advisory Committee (MCAC), which we are renaming the Medicaid Advisory Committee (MAC), whereby each State has the discretion on how to operate its MCAC. A small number of States also use consumer advisory subcommittees as part of their current MCACs, similar to the Beneficiary Advisory Council (BAC) in § 431.12. We reviewed data from 10 States to determine the current status of MCACs and to determine the burden needed to comply with the § 431.12 requirements across 50 States and the District of Columbia.

Under the provision, States will be required to:

- Select members to the MAC and BAC on a rotating and continuous basis.
- Develop and publish a process for MAC and BAC member recruitment and selection of MAC and BAC leadership.

- Develop and publish:

++ Bylaws for governance of the MAC.

++ A current list of MAC and BAC membership.³⁸⁰

++ Past meeting minutes, including a summary from the most recent BAC Meeting.

- Develop, publish, and implement a regular meeting schedule for the MAC and BAC.

Additionally, the State must provide and post to its website an annual report written by the MAC to the State describing its activities, topics discussed, recommendations. The report must also include actions taken by the State based on the MAC recommendations.

³⁸⁰ BAC members may choose to not have their names listed on the publicly posted membership list.

The requirements will require varying levels of effort by States. For example, a handful of States already have a BAC. However, we believe that most States will be required to create new structures and processes. The majority of States reviewed are already meeting some of the new requirements for MACs, such as publication of meeting schedules, publication of membership lists, and publication of bylaws. However, all MAC bylaws will need to be updated to meet the new requirements. Our review showed that most States are not currently publishing their recruitment and appointment processes for MAC members, and those that did will need to update these processes to meet the new requirements. About half of the States reviewed published meeting minutes with responses and State actions, as required under the new requirements. However, only one State reviewed published an annual report, so this will likely be a new requirement for almost all State MACs. States will not need to modify or build reporting systems to create and post these annual reports. Due to the wide range in the use and maturity of current MCACs across the States, we are providing a range of estimates to address these variations.

We recognize that some States, which do not currently operate a MCAC, will have a higher burden to implement the requirements of § 431.12 to shift to the MAC and BAC structure. However, our research showed that the majority of States do have processes and procedures for their current MCACs, which will require updating, but at a much lower burden. Therefore, we believe it is appropriate to offer average low and high burden estimates.

For a low estimate, we estimate it will take a team of business operations specialists 120 hours at \$79.50/hr to develop and publish the processes and report. In aggregate, we estimate an annual burden of 6,120 hours (120 hr/response x 51 responses) at a cost of \$486,540 (6,120 hr x \$79.50/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$243,270 (\$486,540 x 0.50). We also estimate that it will take 40 hours at \$140.14/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAC leadership which will occur

every 2 years. In aggregate, we estimate a biennial burden of 2,040 hours (40 hr/response x 51 responses) at a cost of \$285,885 (2,040 hr x \$140.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$142,942 (\$285,885 x 0.50). Additionally, we estimate it will take 10 hours at \$118.14/hr for an operations manager to review the updates and prepare the required reports for annual publication. In aggregate, we estimate an annual burden of 510 hours (10 hr/response x 51 responses) at a cost of \$60,251 (510 hr x \$118.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$30,125 (\$60,251 x 0.50).

We derived the high estimate by doubling the hours from the low estimate. We used this approach because all States already have a MCAC requirement which means the type of work being discussed is already underway in most States and that there is reference point for the type of work described. For example, we estimate it will take a team of business operations specialists 240 hours at \$79.50/hr to develop and publish the processes and annual report. In aggregate, we estimate an annual burden of 12,240 hours (240 hr/response x 51 responses) at a cost of \$973,080 (12,240 hr x \$79.50/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$486,540 (\$973,080 x 0.50). We also estimate that it will take 80 hours at \$140.14/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAC leadership which will occur every 2 years. In aggregate, we estimate a biennial burden of 4,080 hours (80 hr/response x 51 responses) at a cost of \$571,771 (4,080 hr x \$140.14). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$285,885 (\$571,771 x 0.50). Additionally, we estimate it will take 20 hours at \$118.14/hr for an operations manager to review the updates and prepare the required annual report for publication. In aggregate, we estimate an annual burden of 1,020 hours (20 hr/response x 51 responses) at a cost of \$120,503 (1,020 hr x \$118.14/hr). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$60,251 (\$120,503 x 0.50).

We have summarized the total burden in Table 3. To be conservative and not underestimate our burden analysis, we are using the high end of our estimates to score the PRA-related impact of the finalized requirements.

TABLE 3: Summary of High Burden Estimates for Medical Care Advisory Committee Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 431.12 (develop/publish report)	51	51	Annual	240	12,240	79.50	973,080	486,540
§ 431.12 (review/approve bylaws)	51	51	Biennial	80	4,080	140.14	571,771	285,885
§ 431.12 (review updates/prepare reports)	51	51	Annual	20	1,020	118.14	120,503	60,251
Total	51	153	varies	Varies	17,340	varies	1,665,354	832,676

While a few commenters made general or high-level comments regarding concerns about burden (which are addressed in section II.A of this final rule) we did not receive specific comments on this ICR. The general comments we received were about the overall burden related to the MAC and BAC provisions and not about the burden estimated in the ICR Table 3 nor the information outlined in this section. In this rule we are finalizing the MAC and BAC reporting requirements and burden estimates as proposed.

2. ICRs Regarding Person-Centered Service Plans (§ 441.301(c)(3); applied to other HCBS authorities at §§ 441.450(c), 441.540(c), and 441.725(c), and 438.72(b) and to managed care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's

changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as “person-centered service plans” or “service plans”). Existing Federal regulations at § 441.301(c)(1) through (3) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised upon reassessment of functional need, at least every 12 months, when the individual’s circumstances or needs change significantly or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs³⁸¹ (hereinafter the “2014 guidance”) that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. The expectation is that, since the issuance of this guidance, States have been tracking and reporting on person-centered planning performance measures.

In this rule, we are finalizing a new requirement at § 441.301(c)(3)(i) to specify that States demonstrate that the person-centered service plan **for every individual** is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by §

³⁸¹ Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.

441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual. At § 441.301(c)(3)(ii)(A) we are finalizing a requirement that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We are also finalizing, at new § 441.301(c)(3)(ii)(B), that States demonstrate that they reviewed for every individual the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We are finalizing the application of these requirements to services delivered under FFS or managed care delivery systems. Further, we are finalizing the application of the finalized requirements sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

In addition, we also proposed (and are finalizing) several changes to current regulations for person-centered planning at § 441.301(c)(1) to reposition, clarify, and remove extraneous language from § 441.301(c)(1).

We are finalizing the person-centered planning requirements at § 441.301(c)(1) and (3) without substantive changes. Below are our burden estimates for these requirements.

a. One Time Person-Centered Service Plan Requirements: State (§ 441.301(c)(3))

As discussed above, at new § 441.301(c)(3)(ii)(A), we are finalizing a requirement that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We are also finalizing, at § 441.301(c)(3)(ii)(B), a requirement that States demonstrate for every individual that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365

days. The burden associated with the person-centered service plan reporting requirements at § 441.301(c)(3)(ii)(A) and (B) affects the 48 States (including the District of Columbia) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.³⁸² We anticipate that States will need to update State policy, as well as oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with these requirements.

However, because we are codifying a minimum performance level associated with existing regulations but not otherwise changing the regulatory requirements under § 441.301(c)(3)(ii)(A) and (B), we do not estimate any additional burden related to those requirements. We also hold that there is no additional burden associated with repositioning, clarifying, and removing extraneous language from the regulatory text at § 441.301(c)(1). In this regard we are only estimating burden for updating State policy and oversight and monitoring processes related to the codification of the finalized 90 percent minimum performance level requirement.

We estimate it will take 8 hours at \$111.18/hr for an administrative services manager to update State policy and oversight and monitoring processes, 2 hours at \$118.14/hr for a general and operations manager to review and approve the updates to State policy and oversight and monitoring processes, and 1 hour at \$236.96/hr for a chief executive to review and approve the updates to State policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 528 hours (48 States x [8 hr + 2 hr + 1 hr]) at a cost of \$65,409 (48 States x [(8 hr x \$111.18/hr) + (2 hr x \$118.14/hr) + (1 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost is \$32,704 (\$65,409 x 0.50).

³⁸² Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

TABLE 4: Summary of One-Time Burden Estimates for States for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Update State policy and oversight and monitoring processes	48	48	Once	8	384	111.18	42,693	21,347
Review and approval of State policy update at the management level	48	48	Once	2	96	118.14	11,341	5,671
Review and approval of State policy update at the chief executive level	48	48	Once	1	48	236.96	11,374	5,687
Total	48	48	Once	Varies	528	Varies	65,409	32,704

b. One Time Person-Centered Service Plan Requirements: Managed Care Plans (§ 441.301(c)(3))

As discussed above, we are requiring managed care delivery systems to also comply with the requirements finalized at § 441.301(c)(3) to demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days and to demonstrate that they reviewed the person centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. As with the burden estimate for States, we do not estimate an ongoing burden related to the codification of a minimum performance level associated with the requirements at § 441.301(c)(3).

For managed care plans, we estimate it would take 5 hours at \$111.18/hr for an administrative services manager to update organizational policy and oversight and monitoring processes related to the codification of a new minimum performance level and 1 hour at \$236.96/hr for a chief executive to review and approve the updates to organizational policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 966 hours

(161 managed care plans x [5 hr + 1 hr]) at a cost of \$127,650 (161 managed care plans x [(5 hr x \$111.18/hr) + (1 hr x \$236.96/hr)]).

TABLE 5: Summary of One-Time Burden Estimates for Managed Care Plans for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Update organizational policy and oversight and monitoring processes	161	161	Once	5	805	111.18	89,500	n/a
Review and approval of policy and oversight and monitoring processes	161	161	Once	1	161	236.96	38,151	n/a
Total	161	161	Once	Varies	966	Varies	127,650	n/a

3. ICRs Regarding Grievance System (§ 441.301(c)(7); applied to other HCBS authorities at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our reporting tools and survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

At § 441.301(c)(7), we are finalizing requirements that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system to file a complaint or expression or dissatisfaction related to the

State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6).

We are finalizing at § 441.301(c)(7)(vii) a list of recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we are finalizing that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(I) through (7), we are finalizing that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we are finalizing that grievance records be accurately maintained and in a manner that would be available upon our request.

We are finalizing the application of these requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively. However, to avoid duplication with the grievance requirements for managed care plans at part 438, subpart F, we did not propose to apply these requirements to managed care delivery systems.

We are finalizing the grievance process requirements we proposed at § 441.301(c)(7) with one substantive change. As discussed in section II.B.2. of this final rule, we are not finalizing the requirements we proposed at § 441.301(c)(7)(iv)(B) that States must have a 14-day expedited resolution process in addition to a standard 90-day resolution process for grievances. We do not anticipate that this change affects the burden estimates, as it does not change the recordkeeping requirements finalized at § 441.301(c)(7)(vii). In general, even with this change, the States will still have to perform all activities described below in order to establish and maintain the standard grievance process outlined in § 441.301(c)(7). Additionally, as we

encourage States to develop their own expedited grievance process, we are calculating the burden estimate with the assumption that all States will choose to create their own version of an expedited resolution process within the grievance process required at § 441.301(c)(7).

We are finalizing the other grievance process proposals without substantive changes. Burden estimates for our finalized grievance process requirements are below.

a. States

The burden associated with the grievance system requirements finalized at § 441.301(c)(7) affect the 48 States (including the District of Columbia) that deliver at least some HCBS under sections 1915(c), (i), (j), or (k) authorities through FFS delivery systems.^{383,384} While some States may have existing grievance systems in place for their FFS delivery systems, we were unable to determine the number of States with existing grievance systems or whether those grievance systems would meet the finalized requirements at § 441.301(c)(7). As a result, we do not take this information into account in our burden estimate calculated below. We estimate a one-time and ongoing burden to implement these requirements at the State level.

Specifically, States will have to: (1) develop and implement policies and procedures; (2) establish processes and data collection tools for accepting, tracking, and resolving, within required timeframes, beneficiary grievances, including processes and tools for: providing beneficiaries with reasonable assistance with filing a grievance, for accepting grievances orally and in writing, for reviewing grievance resolutions with which beneficiaries are dissatisfied, and for providing beneficiaries with a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance; (3) inform beneficiaries, providers,

³⁸³ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

³⁸⁴ While some States deliver the vast majority of HCBS through managed care delivery systems, States would be subject to these requirements if they deliver any HCBS under section 1915(c), (i), (j), or (k) authorities through a fee-for service delivery system. Based on data showing that the percent of LTSS expenditures delivered through managed LTSS delivery systems varied between 3 percent and 93 percent in 2019 across all States with managed LTSS, we assume that all States deliver at least some HCBS through fee-for-service delivery systems (<https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-expenditures2019.pdf>). We anticipate that the burden associated with implementing these requirements will be lower for States that deliver the vast majority of HCBS through managed care delivery systems.

and subcontractors about the grievance system; and (4) develop beneficiary notices; and (5) collect and maintain information on each grievance, including the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed.

i. One-Time Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the one-time requirements, we estimate it will take: 240 hours at \$111.18/hr for an administrative services manager to draft policy and procedure content, prepare notices and informational materials, draft rules for publication, and conduct public hearings; 100 hours at \$98.84/hr for a computer programmer to build, design, and operationalize internal systems for data collection and tracking; 120 hours at \$67.18/hr for a training and development specialist to develop and conduct training for staff; 40 hours at \$118.14/hr for a general and operations manager to review and approve policies, procedures, rules for publication, notices, and training materials; and 20 hours at \$236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate a one-time burden of 24,960 hours (520 hr x 48 States) at a cost of \$2,596,493 (48 States x [(240 hr x \$111.18/hr) + (100 hr x \$98.84/hr) + (120 hr x \$67.18/hr) + (40 hr x \$118.14/hr) + (20 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$1,298,246 (\$2,596,493 x 0.50).

TABLE 6: Summary of One-Time Burden Estimates for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy and procedures, rules for publication; prepare beneficiary notices, informational materials; conduct public hearings	48	48	Once	240	11,520	111.18	1,280,794	640,397
Build, design,	48	48	Once	100	4,800	98.84	474,432	237,216

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
operationalize internal systems for data collection and tracking								
Develop and conduct training for staff	48	48	Once	120	5,760	67.18	386,957	193,478
Review and approve policies, procedures, rules for publication, notices, and training materials at the management level	48	48	Once	40	1,920	118.14	226,829	113,415
Review and approve all operations in collection of information requirement at the chief executive level	48	48	Once	20	960	236.96	227,482	113,741
TOTAL	48	48	Once	Varies	24,960	Varies	2,596,493	1,298,246

ii. Ongoing Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the on-going requirements, we estimate that approximately 2 percent of 1,460,363 Medicaid beneficiaries who receive HCBS under section 1915(c), (i), (j), or (k) authorities through FFS delivery systems annually³⁸⁵ will file a grievance or appeal (29,207 grievances = $1,460,363 \times 0.02$)³⁸⁶. We estimate it will take: 0.333 hours or 20 minutes at \$79.50/hr for a business operations specialist to collect the required information for each grievance from the beneficiary (29,207 total grievances), 0.166 hours or 10 minutes at \$36.52/hr for a data entry worker to record the required information on each grievance (29,207 total grievances), 20 hours at \$98.84/hr for a computer programmer to maintain the system for storing information on grievances (48 States), 12 hours at \$118.14/hr for a general and operations manager to monitor and oversee the collection and maintenance of the required information (48 States), and 2 hours at \$236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement (48 States). In aggregate, we estimate an on-going burden of 16,206 hours at a cost of \$1,135,949 ($[(29,207 \text{ grievances} \times 0.333 \text{ hr} \times$

³⁸⁵ <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf>.

³⁸⁶ We based this percent on an estimate of the percent of Medicaid beneficiaries that file appeals and grievances in Medicaid managed care in Supporting Statement A for the information collection requirements for the Medicaid Managed Care file rule (CMS-2408-F, RIN 0938-AT40). See <https://omb.report/icr/202205-0938-015/doc/121334100> for more information.

\$79.50/hr) + (29,207 grievances x 0.166 hr x \$36.52/hr) + (48 States x 20 hr x \$98.84/hr) + (48 States x 12 hr x \$118.14/hr) + (48 States x 2 hr x \$236.96/hr)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost is \$567,975 (\$1,135,949 x 0.50) per year.

TABLE 7: Summary of Ongoing Burden for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect required grievance data and information	48	29,207	On occasion	0.333	9,726	79.50	773,217	386,609
Enter required grievance data and information into data collection and tracking system	48	29,207	On occasion	0.166	4,848	36.52	177,049	88,525
Perform maintenance on system for storing data and information on grievances	48	48	Annually	20	960	98.84	94,886	47,443
Monitor and oversee the collection and maintenance of the required information at the management level	48	48	Annually	12	576	118.14	68,049	34,025
Review and approve all operations associated with collection of information requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
TOTAL	48	29,255 (29,207 + 48)	Varies	Varies	16,206	Varies	1,135,949	567,975

4. ICRs Regarding Incident Management System (§ 441.302(a)(6); applied to other HCBS

Authorities at §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and to managed care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are

setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

At § 441.302(a)(6), we are finalizing a requirement that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. At § 441.302(a)(6)(i)(A), we are finalizing that States must establish a minimum standard definition of a critical incident. At § 441.302(a)(6)(i)(B) we are finalizing a requirement that States must have electronic incident management systems that, at a minimum, enable electronic collection, tracking (including tracking of the status and resolution of investigations), and trending of data on critical incidents.

We are finalizing the requirements we proposed at § 441.302(a)(6)(i) without substantive changes, but we are finalizing a change to the applicability date for the electronic management system requirement. We had proposed that States would need to comply with the requirements at § 441.302(a)(6) in 3 years. We are finalizing the 3-year applicability date for the requirements at § 441.302(a)(6) with the exception of the electronic incident management system finalized at § 441.302(a)(6)(i)(B), which has a finalized applicability date of 5 years. We do not anticipate that this change will affect the activities described in these burden estimates; the primary effect of this change is to grant States two additional years in which to develop electronic incident management systems, for which they will perform the same activities.

At § 441.302(a)(6)(i)(C), we finalized that States require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan or are a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(D), we finalized that States must use claims

data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(E) we finalized a new requirement that the State must ensure medical records being used as part of the incident management system are handled in compliance with 45 CFR 164.510(b) to ensure that records with protected health information used during critical incident review are obtained and used with beneficiaries' consent. We are finalizing at § 441.302(a)(6)(i)(F) a requirement that States share information on the status and resolution of investigations if the State refers critical incidents to other entities for investigation. We are finalizing at § 441.302(a)(6)(i)(G) a requirement that States separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. We are finalizing at § 441.302(a)(6)(i)(H) a requirement that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems.

At § 441.302(a)(6)(iii), we are the application of these requirements to services delivered under FFS or managed care delivery systems. We also finalized the application of the requirements finalized at § 441.302(a)(6) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively.

With the exception of the change to the effective date for electronic incident management systems noted above, we are finalizing the requirements described herein without substantive modification. Burden estimates for these requirements are discussed below.

We received one comment on the proposed burden estimate for the incident management provision. This comment, and our response, is summarized below.

Comment: One commenter noted that when their State investigated developing a single electronic incident management system in 2014, the State estimated the cost of consolidating

multiple State systems into a single system would be \$100 million and believed that it would be even more expensive to create such a system now.

Response: We thank the commenter for their feedback. Without more detailed information, provided, we decline to update our burden estimate for the incident management ICR based on this comment. We believe most States that require upgrades to their system could do so within the costs that we estimated; we will provide technical assistance on an as-needed basis for States to identify efficient ways to upgrade their systems.

We also note that according to the finalized requirements in § 441.302(a)(6), States must have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We are recommending, but not requiring, that States develop a single electronic critical incident system for all of their HCBS programs under sections 1915(c), (i), (j), and (k) authorities, as we believe that a single system will best enable States to prevent the occurrence of critical incidents and protect the health and safety of beneficiaries across their lifespan. We recognize that States may have to make certain decisions about the development of their electronic incident management system according to current system constraints.

a. States

The burden associated with the incident management system requirements proposed at § 441.302(a)(6) will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), (i), (j), or (k) authorities.³⁸⁷ We estimate a one-time and on-going burden to implement these requirements at the State level. The burden for the reporting requirements at § 441.311(b)(1) is included in the ICR #8, which is the ICRs Regarding Compliance Reporting (§ 441.311(b)).

All of the States impacted by § 441.302(a)(6)(i)(B), requiring that States use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, have

³⁸⁷ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

existing incident management systems in place. However, we assume that all States will need to make at least some changes to their existing systems to fully comply with the proposed requirements. Specifically, States will have to update State policies and procedures; implement new or update existing electronic incident management systems; publish revised provider requirements through State notice and publication processes; update provider manuals and other policy guidance; amend managed care contracts; collect required information from providers; use other required data sources to identify unreported incidents; and share information with other entities in the State responsible for investigating critical incidents.

i. One Time Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the one-time requirements related to §441.302(a)(6), we estimate it will take: 120 hours at \$111.18/hr for an administrative services manager to draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 20 hours at \$100.64/hr for a management analyst to update provider manuals; 80 hours at \$67.18/hr for a training and development specialist to develop and conduct training for providers; 80 hours at \$79.50/hr for a business operations specialist to establish processes for information sharing with other entities; 80 hours at \$106.30/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; 24 hours at \$118.14/hr for a general and operations manager to review and approve managed care contract modifications, policy and rules for publication, and training materials; and 10 hours at \$236.96/hr for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate a one-time burden of 19,872 hours (414 hr x 48 States) at a cost of \$1,958,292 (48 States x [(120 hr x \$111.18/hr) + (20 hr x \$100.64/hr) + (80 hr x \$67.18/hr) + (80 hr x \$79.50/hr) + (80 hr x \$106.30/hr) + (24 hr x \$118.14/hr) + (10 hr x \$236.96/hr)]).

Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$979,146 (\$1,958,292 x 0.50).

In addition, we estimate that States, based on the results of the incident management system assessment discussed earlier in section II.B.3. of this preamble, that 82 percent of States, or 39 States ($48 \text{ States} \times 0.82$), will need to update existing electronic incident management systems, while the remaining 9 States would need to implement new electronic incident management systems, to meet the proposed requirement at § 441.302(a)(6)(i)(B). We estimate based on information reported by some States in spending plans for section 9817 of the American Rescue Plan Act of 2021 that the cost per State to update existing electronic systems is \$2 million while the cost per State to implement new electronic systems is \$5 million.³⁸⁸ In aggregate, we estimate a one-time technology burden of \$123,000,000 [$(\$2,000,000 \times 39 \text{ States}) + (\$5,000,000 \times 9 \text{ States})$]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$61,500,000 ($\$123,000,000 \times 0.50$).

³⁸⁸ Enhanced Federal Financial Participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP rate is also available for operations of such systems, in accordance with applicable Federal requirements. However, the receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. As a result, we do not assume for the purpose of this burden estimate that States will qualify for the enhanced Federal match. This estimate overestimates State burden to the extent that States qualify for the enhanced Federal match.

TABLE 8: Summary of One-Time Burden for States for the Incident Management System Requirements (§ 441.302(a)(6))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans	48	48	Once	120	5,760	111.18	640,397	320,198
Update provider manuals	48	48	Once	20	960	100.64	96,614	48,307
Develop and conduct training for providers	48	48	Once	80	3,840	67.18	257,971	128,986
Establish processes for information sharing with other entities	48	48	Once	80	3,840	79.50	305,280	152,640
Build, design, and implement reports for using claims and other data to identify unreported incidents	48	48	Once	80	3,840	106.30	408,192	204,096
Review and approve managed care contract modifications, policy and rules for publication, and training materials at the management level	48	48	Once	24	1,152	118.14	136,097	68,049
Review and approve all operations associated with this requirement at the executive level	48	48	Once	10	480	236.96	113,741	56,871
<i>Subtotal Labor-Related Burden</i>	<i>48</i>	<i>48</i>	<i>Once</i>	<i>Varies</i>	<i>19,872</i>	<i>Varies</i>	<i>1,958,292</i>	<i>979,146</i>
Update existing electronic incident management systems	48	39	Once	n/a	n/a	\$2,000,000/ system (contractor)	78,000,000	39,000,000
Implement new electronic systems	48	9	Once	n/a	n/a	\$5,000,000/ system (contractor)	45,000,000	22,500,000
<i>Subtotal Non-Labor Burden</i>	<i>48</i>	<i>48</i>	<i>Once</i>	<i>n/a</i>	<i>n/a</i>	<i>Varies</i>	<i>123,000,000</i>	<i>61,500,000</i>
TOTAL	48	96	Once	varies	19,872	Varies	124,958,292	62,479,146

ii. Ongoing Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the ongoing requirements § 441.302(a)(6), we estimate that there are 0.5 critical incidents annually³⁸⁹ for each of the 1,889,640 Medicaid beneficiaries who receive HCBS under sections 1915(c), (i), (j), or (k) authorities annually, or 944,820 ($1,889,640 \times 0.5$) critical incidents annually.³⁹⁰ We further estimate that, based on data on unreported incidents, these requirements will result in the identification of 30 percent more critical incidents annually, or 283,446 ($944,820 \times 0.3$) critical incidents;³⁹¹ that 76 percent, or 215,419 ($283,446 \times 0.76$) will be reported for individuals enrolled in FFS delivery systems;³⁹² and that 10 percent of those for individuals enrolled in FFS delivery systems ($21,542 = 215,419 \times 0.1$) will be made through provider reports and 90 percent ($193,877 = 215,419 \times 0.9$) through claims identification and other sources.³⁹³ We estimate 0.166 hr or 10 minutes at \$36.52/hr for a data entry worker to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. In aggregate, we estimate an ongoing burden each year of 3,576 hours ($21,542 \text{ incidents} \times 0.166 \text{ hr}$) at a cost of \$130,594 ($3,576 \text{ hr} \times \$36.52/\text{hr}$) to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. While States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting critical incidents and identification of critical incidents through claims and other data sources to managed care plans and that the managed care plans would be responsible for reporting the identified critical incidents to the State.³⁹⁴ We further assume that the information reported by managed care plans to the State and

³⁸⁹ Data on the number of critical incidents is limited. We base our estimate on available public information, such as <https://oig.hhs.gov/oas/reports/region7/71806081.pdf> and <https://dhs.sd.gov/servicetotheblind/docs/2015%20CIR%20Annual%20Trend%20Analysis.pdf>.

³⁹⁰ <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf>.

³⁹¹ Data on the number of unreported critical incidents is limited. We base our estimate on available public information, such as <https://pennlive.com/news/2020/01/possible-abuse-of-group-home-residents-wasnt-adequately-tracked-in-pa-federal-audit.html> and <https://www.kare11.com/article/news/local/federal-audit-finds-maine-dhhs-failed-to-investigate-multiple-deaths-critical-incidents/97-463258015>.

³⁹² <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf>.

³⁹³ Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of more critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

³⁹⁴ Addressing Critical Incidents in the MLTSS Environment: Research Brief, ASPE, <https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0>.

identified by the State through claims and other data sources would be in an electronic form. For the 68,027 more critical incidents for individuals enrolled in managed care (283,446 more critical incidents identified x 24 percent for individuals enrolled in managed care), and the 193,877 more critical incidents identified through claims and other data sources for individuals enrolled in FFS (283,446 more critical incidents identified x 76 percent for individuals enrolled in FFS x 90 percent identified through claims and other sources), we estimate 2 minutes (0.0333 hr) at \$36.52/hr for a data entry worker to record the information on each of these 261,904 critical incidents (68,027 + 193,877). In aggregate, for § 441.302(a)(6), we estimate an ongoing annual burden of 8,721 hours (261,904 incidents x 0.0333 hr) at a cost of \$318,491 (8,721 hr x \$36.52/hr) on these critical incidents.

In total, for § 441.302(a)(6), we estimate an ongoing burden each year of 12,297 hours (3,576 hr + 8,721 hr) at a cost of \$449,085 (\$130,594 + \$318,491) to record the information on all critical incidents for individuals enrolled in FFS and managed care delivery systems across all States. We further estimate it would take 12 hours at \$79.50/hr for a business operations specialist to maintain processes for information sharing with other entities; 20 hours at \$106.30/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents; 24 hours at \$118.14/hr for a general and operations manager to monitor the operations associated with this requirement; and 4 hours at \$236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement in each State. In aggregate, we estimate an ongoing burden of 15,177 hours ($[60 \text{ hr} \times 48 \text{ States}] + 12,297 \text{ hr}$) at a cost of \$778,520 ($\$449,085 + [48 \text{ States} \times ((12 \text{ hr} \times \$79.50/\text{hr}) + (20 \text{ hr} \times \$106.30/\text{hr}) + (24 \text{ hr} \times \$118.14/\text{hr}) + 4 \text{ hr} \times \$236.96/\text{hr})]$). In addition, we estimate an on-going annual technology-related cost of \$500,000 per State for States to maintain their electronic incident management systems. In aggregate, we estimate an ongoing burden of \$24,000,000 ($\$500,000 \times 48 \text{ States}$) for States to maintain their electronic incident management systems. In total, we estimate an ongoing annual burden of 15,177 hours

at a cost \$24,778,520 (\$778,520 + \$24,000,000). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$12,389,260 (\$24,778,520 x 0.50).

TABLE 9: Summary of Ongoing Burden for States for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems	48	21,542	Annually	0.166	3,576	36.52	130,596	65,298
Record the information on critical incidents for individuals enrolled in managed care and critical incidents identified through claims and other data sources for individuals enrolled in FFS	48	261,904	Annually	0.033	8,721	36.52	318,491	159,245
Maintain processes for information sharing with other entities	48	48	Annually	12	576	79.50	45,792	22,896
Update and maintain reports for using claims and other data to identify unreported incidents	48	48	Annually	20	960	106.30	102,048	51,024
Monitor operations associated with this requirement at the management level	48	48	Annually	24	1,152	118.14	136,097	68,048
Review and approve all operations associated with this collection of information requirement at the executive level	48	48	Annually	4	192	236.96	45,496	22,748
<i>Subtotal: Labor Related Burden</i>	48	283,494 (21,542 + 261,904 + 48)	<i>Annually</i>	<i>Varies</i>	15,177	<i>Varies</i>	778,520	389,260
Maintain electronic incident management systems (specifically, §	48	48	Annually	n/a	n/a	500,000/ system (contractor)	24,000,000	12,000,000

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
441.302(a)(6)(i)(B))								
<i>Total Technology Cost</i>	48	48	<i>Annually</i>	<i>n/a</i>	<i>n/a</i>	<i>500,000 system (contractor)</i>	<i>24,000,000</i>	<i>12,000,000</i>
TOTAL	48	283,542 (283,494 + 48)	Annually	Varies	15,177	Varies	24,778,520	12,389,260

b. Service Providers and Managed Care Plans

The burden associated with this final rule will affect service providers that provide HCBS under sections 1915(c), (i), (j), and (k) authorities, as well as managed care plans that States contract with to provide managed long-term services and supports.

The following discussion estimates an ongoing burden for service providers to implement these requirements and both a one-time and ongoing burden for managed care plans.

i. On-going Incident Management System Requirements: Service Provider

To estimate the number of service providers that will be impacted by this final rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i), (j), and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally x 48 States subject to the proposed requirement / 51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention³⁹⁵ to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers x 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers x 0.85). To be conservative and not

³⁹⁵ https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.

underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the changes.

As discussed earlier, we estimate that providers will report 10 percent, or 28,345, of the more critical incidents (283,446 more critical incidents x 0.10) identified annually as a result of these requirements. Based on these figures, we estimate that, on average, each provider will report 1.8 (28,345 incidents / 15,742 providers) more critical incidents annually. We further estimate that, on average, it would take a provider 1 hour at \$118.14/hr for a general and operations manager to collect the required information and report the information to the State or to the managed care plan as appropriate for each incident.³⁹⁶ In aggregate, for § 441.302(a)(6), we estimate an ongoing burden of 28,345 hours (28,345 incidents x 1 hr) at a cost of \$3,348,678 (28,345 hr x \$118.14/hr).

TABLE 10: Summary of Ongoing Burden for Service Providers for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect the required information and report the information to the State or to the managed care plan (§ 441.302(a)(6)(i)(C))	15,742 providers	28,345 incidents	Annually	1	28,345	118.14	3,348,678	n/a
Total	15,742 providers	28,345 incidents	Annually	1	28,345	118.14	3,348,678	n/a

ii. One Time Incident Management System Requirements: Managed Care Plans (§ 441.302(a)(6))

As required under § 441.302(a)(6), while States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the

³⁹⁶ The actual amount of time for each incident will vary depending on the nature of the critical incident and the specific reporting requirements of each State and managed care plan. This estimate assumes that some critical incidents will take substantially less time to report, while others could take substantially less time.

purpose of this analysis that the States will delegate provider reporting of critical incidents and identification of critical incidents through claims and other data sources to managed care plans and that the plans will be responsible for reporting the identified critical incidents to the State.³⁹⁷ We further assume that the information reported by managed care plans to the State would be in an electronic form.

We estimated that there are 161 managed long-term services and supports plans providing services across 25 States.³⁹⁸ With regard to the one-time requirements at § 441.302(a)(6), we estimate it would take: 20 hours at \$111.18/hr for an administrative services manager to draft policy for contracted providers; 20 hours at \$100.64/hr for a management analyst to update provider manuals; 40 hours at \$67.18/hr for a training and development specialist to develop and conduct training for providers; 80 hours at \$106.30/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; and 6 hours at \$236.96/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 26,726 hours (161 managed care plans x 166 hr) at a cost of \$2,712,747 (161 managed care plans x [(20 hr x \$111.18/hr) + (20 hr x \$100.64/hr) + (40 hr x \$67.18/hr) + (80 hr x \$106.30/hr) + (6 hr x \$236.96/hr)]).

³⁹⁷ Addressing Critical Incidents in the MLTSS Environment: Research Brief, available at <https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0>.

³⁹⁸ “A View from the States: Key Medicaid Policy Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2019 and 2020,” <https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/>.

TABLE 11: Summary of One-Time Burden for Managed Care Plans for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy for contracted providers	161	161	Once	20	3,220	111.18	358,000	n/a
Update provider manuals	161	161	Once	20	3,220	100.64	324,061	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	67.18	432,639	n/a
Build, design, and implement reports for using claims and other data to identify unreported incidents	161	161	Once	80	12,880	106.30	1,369,144	n/a
Review and approve all operations associated with this requirement	161	161	Once	6	966	236.96	228,903	n/a
Total	161	161	Once	Varies	26,726	Varies	2,712,747	n/a

iii. Ongoing Incident Management System Requirements: Managed Care Plans (§ 441.302(a)(6))

The ongoing burden to managed care plans consists of the collection and maintenance of information on critical incidents. As noted earlier, we estimate that these requirements will result in the identification of 283,446 more critical incidents annually than are currently identified by States. We further estimate that 24 percent, or 68,027 (283,446 x 0.24), will be reported for individuals enrolled in managed care delivery systems³⁹⁹ and that 10 percent, or 6,803 (68,027 x 0.10), will be made through provider reports and 90 percent, or 61,224 (68,027 x 0.90), through claims identification and other sources.⁴⁰⁰ We estimate that it will take 0.166 hr at \$36.52/hr for a data entry worker to record the information on each reported critical incident reported by providers (§ 441.302(a)(6)(i)(B)(2)). In aggregate, we estimate an ongoing burden of 1,129 hours (6,803 critical incidents made through provider reports x 0.166 hr) at a cost of \$41,231 (1,129 hr x \$36.52/hr). We also estimate that it will take: 20 hours at \$106.30/hr for a computer and information analyst to update and maintain reports for using claims and other data

³⁹⁹ <https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf>.

⁴⁰⁰ Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of additional critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

to identify unreported incidents (§ 441.302(a)(6)(i)(B)(3)); 6 hours at \$118.14/hr for a general and operations manager to monitor the operations associated with this requirement and report the information to the State (§ 441.302(a)(6)(i)(E)); and 1 hour at \$236.96/hr for a chief executive to review and approve all operations associated with this collection of information requirement (§ 441.302(a)(6)(i)(G)). In aggregate, we estimate an ongoing burden of 5,476 hours (1,129 hr + [161 managed care plans x 27 hr]) at a cost of \$535,791 (\$41,231 + (161 managed care plans x [(20 hr x \$106.30/hr) + (6 hr x \$118.14/hr) + (1 hr x \$236.96/hr)]).

TABLE 12: Summary of Ongoing Burden for Managed Care Plans for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Record the information on each reported critical incident reported by providers (§441.302(a)(6)(i)(B)(2))	161	6,803	Annually	0.166	1,129	36.52	41,231	n/a
Update and maintain reports for using claims and other data to identify unreported incidents (§441.302(a)(6)(i)(B)(3))	161	161	Annually	20	3,220	106.30	342,286	n/a
Monitor the operations associated with this requirement and report the information to the State (§441.302(a)(6)(i)(E))	161	161	Annually	6	966	118.14	114,123	n/a
Review and approve all operations associated with this requirement (§441.302(a)(6)(i)(G))	161	161	Annually	1	161	236.96	38,151	n/a
Total	161	6,964 (6,803 + 161)	Annually	Varies	5,476	Varies	535,791	n/a

5. ICRs Regarding Payment Adequacy Reporting (§ 441.311(e); applied to other HCBS authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to managed care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We finalized at § 441.311(e)(2) a new requirement that States report to us annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that are spent on compensation for direct care workers.

Section 441.311(e)(1)(i), as finalized, defines compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.*, 29 CFR parts 531 and 778); benefits (such as health and dental benefits, paid leave, and tuition reimbursement); and the employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act. Section 441.311(e)(1)(ii), as finalized, defines direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating), or provide support with instrumental activities of daily living (such as cooking, grocery shopping, managing finances). Specifically, direct care workers include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other

individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living. Direct care workers include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. (Refer to section II.B.5. of this final rule for complete discussion of these definitions.)

We are also finalizing § 441.311(e) to include a definition of excluded costs at § 441.311ek)(1)(iii). Excluded costs are costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to: costs of required trainings for direct care workers (such as costs for qualified trainers and training materials); travel reimbursements (such as mileage reimbursement or public transportation subsidies) provided to direct care workers; and personal protective equipment for direct care workers. This policy was not included in the NPRM calculations. While we do not believe the policy of allowing providers to deduct excluded costs will affect the activities described in this cost estimate, we acknowledge that they may require additional time for some of the activities (such as drafting policy manuals or training providers on the policy.) These costs have been added to the revised burden estimate.

As discussed in section II.B.7. of this rule, we had initially proposed at § 441.311(e) that States would be required to report on the percent of Medicaid compensation spent on compensation for direct care workers providing homemaker, home health aide, and personal care services as defined at § 440.180(b)(2) through (4), and that the State must report this data for each service, with self-directed services reported separately. We are finalizing this requirement to include reporting on an additional service (habilitation services, as defined at § 440.180(b)(6)). We are also finalizing a new requirement that in addition to reporting by service, with separate reporting for self-directed services, States must also report facility-based services separately. Below, we include in our revised calculations the increased anticipated burden

associated with the addition of reporting on habilitation services and separate reporting for facility-based services in § 441.311(e). We anticipate an increased burden on States and managed care plans to address data collection on the additional services. While we are increasing our estimate of the number of impacted providers, we do not believe this will change providers' activities associated with this requirement.

To ensure that States are prepared to comply with the reporting requirement at § 441.311(e)(2), we are finalizing a requirement at § 441.311(e)(3) to require that one year prior to the first payment adequacy report, States must provide a status update on their readiness to report the data required in § 441.311(e)(2). This will allow us to identify States in need of additional support to come into compliance with § 441.311(e)(2) and provide targeted technical assistance to States as needed. Our burden estimate below has been revised to include the activities associated with the State's one-time submission of this report. We do not anticipate an additional burden on managed care plans or providers associated with this requirement.

We also finalized at § 441.311(e)(4) an exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641, which exempts these providers from the requirements in § 441.311(e). Based on internal figures, we believe that about 100 HCBS provide As discussed in section II.B.7. of this final rule, we are applying the finalized requirements at § 441.311(e) to services delivered in both FFS and managed care delivery systems. We are applying the requirements to services that are delivered in 1915(c), (i) and (k) programs. We note also that the reporting requirement will go into effect 4 years after this rule is finalized.

We are finalizing the requirements at §§ 441.311(e) with the substantive modifications as described above. Burden estimates for the finalized requirements are below. We note an additional change to the burden estimates. As presented in the proposed rule at 88 FR 28047, we had presented the burden estimate of both the payment adequacy reporting requirement at § 441.311(e) and the HCBS payment adequacy minimum performance requirements at §

441.302(k) in a single ICR. Since the publication of the NPRM, upon further consideration we have determined that as §§ 441.302(k) and 441.311(e) represent distinct sets of requirements, it is more appropriate to present the costs associated with § 441.302(k) under a separate ICR (ICR 11) in this section IV. of the final rule.

However, while § 441.311(e) represents a distinct set of requirements from those in § 441.302(k), we also expect that States will employ certain efficiencies in complying with both §§ 441.302(k) and 441.311(e). In particular, we expect that States will build a single IT infrastructure and use the same processes both for collecting data for the reporting requirement at § 441.311(e) and for determining providers' compliance with HCBS payment adequacy performance requirements at § 441.302(k). The burden associated with States' development of infrastructure and processes to determine what percentage of HCBS providers' Medicaid payments for certain HCBS is spent on direct care worker compensation, as well as providers' reporting of this information to the State, is included in this ICR for § 441.311(e). We believe representing these costs under only one ICR avoids duplicative or inflated burden estimates. Burden estimates associated specifically with the minimum performance requirements in § 441.302(k) are presented in ICR 11 of this Collection of Information (section IV. of this final rule.)

a. State Burden

The burden associated with the requirements at § 441.311(e) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.^{401,402} We estimate both a one-time and ongoing burden to implement these requirements at the State level.

Under § 441.311(e), we expect that States will have to: (1) draft new policy (one-time); (2) update provider manuals and other policy guidance to include reporting requirements

⁴⁰¹ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

⁴⁰² For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

(including information regarding excluded costs) for each of the services subject to the requirement (one-time); (3) inform providers of services through State notification processes, both initially and annually of reporting requirements (one-time and ongoing); (4) assess State systems and submit a one-time report to us on the State's readiness to comply with the ongoing reporting requirement at 441.311(e)(2) (one-time); (5) collect the information from providers for each service required (ongoing); (6) aggregate the data broken down by each service, as well as self-directed services (ongoing); (7) derive an overall percentage for each service including self-directed services (ongoing); and (8) report to us on an annual basis (ongoing)

i. One Time Payment Adequacy Reporting Requirements (§ 441.311(e)): State Burden

With regard to the one-time requirements, we estimate it will take: 40 hours at \$111.18/hr for an administrative services manager to: draft policy content, and draft provider agreements and contract modifications for managed care plans; 20 hours at \$100.64/hr for a management analyst to update provider manuals for each of the affected services; 32 hours at \$98.84/hr for a computer programmer to build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice; 50 hours at \$67.18/hr for a training and development specialist to develop and conduct training for providers on the reporting elements and reporting process; 20 hours at \$118.14/hr for a general and operations manager to: review, approve managed care contract modifications, policy and rules for publication, and training materials, and to complete the annual reporting and complete the reporting readiness report (required at § 441.311(e)(3)) for submission to CMS; and 10 hours at \$236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate a one-time burden of 7,776 hours (172 hr x 48 States) at a cost of \$850,285 (48 States x [(40 hr x \$111.18/hr) + (20 hr x \$100.64/hr) + (32 hr x \$98.84/hr) + (50 hr x \$67.18/hr) + (20 hr x \$118.14/hr) + (10 hr x \$236.96/hr)]). Taking into account the Federal

contribution to Medicaid administration, the estimated State share of this cost would be \$425,143 (\$850,285 x 0.50).

TABLE 13: Summary of One-Time Burden for States for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy content, and draft provider agreements and contract modifications for managed care plans	48	48	Once	40	1,920	111.18	213,466	106,733
Update provider manuals for each of the affected service	48	48	Once	20	960	100.64	96,614	48,307
Build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice	48	48	Once	32	1,536	98.84	151,818	75,909
Develop and conduct training for providers on the reporting elements and reporting process	48	48	Once	50	2,400	67.18	161,232	80,616
Review, approve managed care contract modifications, policy and rules for publication, and training materials, and to complete the annual reporting and complete the reporting readiness report (required at § 441.311(e)(3)) for submission to CMS	48	48	Once	20	960	118.14	113,414	56,707
Review and approve all operations associated with this requirement	48	48	Once	10	480	236.96	113,74	56,780
Total	48	48	Once	Varies	7,776	varies	850,285	425,173

ii. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): State Burden

With regard to the ongoing requirements, we estimate it will take 8 hours at \$98.84/hr for a computer programmer to: (1) collect the information from all providers for each service

required; (2) aggregate and stratify by each service as well as self-directed services; (3) derive an overall percentage for each service including self-directed and facility-based services; and (4) develop the reports for CMS on an annual basis. We also estimate it will take: 10 hours at \$67.18 for a training and development specialist to develop and conduct training for providers on the reporting elements and reporting process; 5 hours at \$118.14/hr by a general and operations manager to review, verify, and approve reporting required at § 441.311(e)(2) to CMS; and 2 hours at \$236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate an ongoing burden of 1,200 hours (25 hr x 48 States) at a cost of \$121,302 (48 States x [(8 hr x \$98.84/hr) + (10 hr x \$67.18) + (5 hr x \$118.14/hr) + (2 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$60,651 (\$121,302 x 0.50) per year.

TABLE 14: Summary of Ongoing Burden for States for Payment Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; identify percentages for providers subject to flexibilities; and develop report annually	48	48	Annually	8	384	98.84	37,954	18,977
Develop and conduct annual training for providers on the reporting elements and reporting process	48	48	Annually	10	480	67.18	32,246	16,123
Review, verify and approve reporting as required in § 441.302(k) and § 441.311(e) -to CMS	48	48	Annually	5	240	118.14	28,354	14,177
Review and approve all operations associated with reporting requirements at § 441.302(k) and § 441.311(e)	48	48	Annually	2	96	236.96	22,748	11,374
Total	Varies	48	Annually	Varies	1,200	Varies	121,302	60,651

b. Service Providers and Managed Care Plans

The burden associated with this final rule will affect both service providers that provide the services listed at § 440.180(b)(2) through (4) and (6) across HCBS programs as well as managed care plans that contract with the States to provide managed long-term services and supports. We estimate both a one-time and ongoing burden to implement the reporting requirements § 441.311(e) for both service providers and managed care plans.

As noted in the proposed rule at 88 FR 28049, we had estimated an impact on 11,155 HCBS providers that provided homemaker, home health aide, or personal care services. We are adjusting this burden estimate to account for the inclusion of providers that also provide habilitation services in the finalized requirements in § 441.311(e). To estimate the number of service providers that will be impacted by this final rule, we used unpublished data from the

Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i) and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally x 48 States subject to the requirement / 51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention⁴⁰³ to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers x 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers x 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the changes. We also note that it is possible that some of the providers included in this count do not provide the services impacted by § 441.311(e) (homemaker, home health aide, personal care, or habilitation services.) However, as we believe a significant number of the providers included in this count do provide at least one of these services. We note that from this number (15,742) we are subtracting 100 providers to represent the providers we believe will be eligible for the exemption at § 441.311(e)(4) for HIS and Tribal providers subject to 25 U.S.C. 1641. This brings the estimated number of providers impacted by the reporting requirement at § 441.311(e) to 15,642.

i. One Time HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the one-time requirements, we estimate it would take: 35 hours at \$73.00/hr for a compensation, benefits and job analysis specialist to calculate compensation, as defined by § 441.311(e)(1)(i) for each direct care worker defined at § 441.311(e)(1)(ii); 40 hours at \$98.84/hr for a computer programmer to build, design and operationalize an internal system to calculate each direct care worker's compensation as a percentage of total revenues

⁴⁰³ https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.

received, aggregate the sum of direct care worker compensation as an overall percentage, and separate self-directed services to report to the State; and 8 hours at \$118.14/hr for a general and operations manager to review and approve reporting to the State.

In aggregate, we estimate a one-time burden of 1,298,286 hours (15,642 providers x 83 hr) at a cost of \$116,591,088 (15,642 providers x [(35 hr x \$73.00/hr) + (40 hr x \$98.84/hr) + (8 hr x \$118.14/hr)]).

TABLE 15: Summary of One-Time Burden for Service Providers for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Calculate compensation for each direct care worker	15,642	15,642	Once	35	547,470	73.00	39,965,310	n/a
Build, design and operationalize an internal system for reporting to the State	15,642	15,642	Once	40	625,680	98.84	61,842,211	n/a
Review and approve reporting to the State	15,642	15,642	Once	8	125,136	118.14	14,783,567	n/a
Total	15,642	15,642	Once	Varies	1,298,286	varies	116,591,088	n/a

ii. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): Service Providers

With regard to the on-going requirements, we estimate it will take 8 hours at \$73.00/hr for a compensation, benefits, and job analysis specialist to account for new hires and/or contracted employees; 8 hours at \$98.84/hr for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 5 hours at \$118.14/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate an on-going burden of 328,482 hours (15,742 providers x 21 hr) at a cost of \$30,743,100 (15,642 providers x [(8 hr x \$73.00/hr) + (8 hr x \$98.84/hr) + (5 hr x \$118.14/hr)]).

TABLE 16: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Account for new hires and/or contracted employees	15,642	15,642	Once	8	125,136	73.00	9,134,928	n/a
Calculate compensation, aggregate data, and report to the State	15,642	15,642	Once	8	125,136	98.84	12,368,442	n/a
Review and approve reporting to the State	15,642	15,642	Once	5	78,210	118.14	9,239,729	n/a
Total	15,642	15,642	Once	Varies	328,482	varies	30,743,100	n/a

iii. One-time Payment Adequacy Reporting Requirements (§ 441.311(e)): Managed Care Plans

As noted earlier, the burden associated with this final rule will affect managed care plans that contract with the States to provide managed long-term services and supports. We estimate that there are 161 managed long-term services and supports plans providing services across 25 States.⁴⁰⁴ We estimate both a one-time and ongoing burden for managed care plans to implement these requirements. Specifically, managed care plans would have to: (1) draft new policy (one-time); (2) update provider manuals for each of the services subject to the requirement (one-time); (3) inform providers of requirements (one-time and ongoing); (4) collect the information from providers for each service required (ongoing); (5) aggregate the data as required by the States (ongoing); and (6) report to the State on an annual basis (ongoing).

With regard to the one-time requirements, we estimate it would take 50 hours at \$111.18/hr for an administrative services manager to draft policy for contracted providers; 32 hours at \$98.84/hr for a computer programmer to build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting; 40 hours at \$67.18/hr for a training and development specialist to develop and conduct training for

⁴⁰⁴ [https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/; Profiles & Program Features | Medicaid](https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/;Profiles%20&%20Program%20Features%20|%20Medicaid).

providers; and 4 hours at \$236.96/hr for a chief executive to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 20,286 hours (161 MCPs x 126 hr) at a cost of \$1,989,464 (161 MCPs x [(50 hr x \$111.18/hr) + (32 hr x \$98.84/hr) + (40 hr x \$67.18/hr) + (4 hr x \$236.96/hr)]).

TABLE 17: Summary of One-time Burden for Managed Care Plans for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy for contracted providers	161	161	Once	50	8,050	111.18	894,999	n/a
Build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting	161	161	Once	32	5,152	98.84	509,224	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	67.18	432,639	n/a
Review and approve reporting to the State	161	161	Once	4	644	236.96	152,602	n/a
Total	161	161	Once	Varies	20,286	varies	1,989,464	n/a

iv. Ongoing Payment Adequacy Reporting Requirements (§ 441.311(e)): Managed Care Plans

With regard to the ongoing requirements, we estimate it will take: 8 hours at \$98.84/hr for a computer programmer to: (1) collect the information from all providers for each service required, (2) aggregate and stratify data as required, and (3) develop report to the State on an annual basis; and 2 hours at \$236.96/hr for a chief executive to review and approve the reporting to the State. In aggregate, we estimate an ongoing burden of 1,610 hours (161 MCPs x 10 hr) at a cost of \$203,607 (161 MCPs x [(8 hr x \$98.84/hr) + (2 hr x \$236.96/hr)]).

TABLE 18: Summary of Ongoing Burden for Managed Care Plans for the Payment Adequacy Reporting Requirements at § 441.311(e)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect information from providers; aggregate and stratify data as required; and develop report annually	161	161	Annually	8	1,288	98.84	127,306	n/a
Review and approve the report	161	161	Annually	2	322	236.96	76,301	n/a
Total	161	161	Annually	Varies	1,610	varies	203,607	n/a

6. ICRs Regarding Supporting Documentation for HCBS Access (§§ 441.303(f)(6) and 441.311(d)(1); applied to managed care at § 438.72(b)))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. States vary in the way they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Some States permit individuals to join a waiting list as an

expression of interest in receiving waiver services, while other States require individuals to first be determined eligible for waiver services to join the waiting list. States have not been required to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI⁴⁰⁵ discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists.

In this final rule, we are finalizing an amendment to § 441.303(f)(6) by adding language to the end of the regulatory text to specify that if the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1). Per the finalized requirements at §441.311(d)(1), for States that limit or cap enrollment in a section 1915(c) waiver and maintain a waiting list, States will be required to provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program. The description must include, but not be limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically rescreens individuals on the waiver list for eligibility, and the frequency of rescreening, if applicable. In addition, States will be required to report on the number of people on the waiting list if applicable, as well as the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable.

We are finalizing these proposals without substantive modifications. Burden estimates for this requirement are presented below.

a. One Time Waiting List Reporting Requirements: States (§ 441.311(d)(1))

⁴⁰⁵ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see <https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

The one-time State burden associated with the waiting list reporting requirements in § 441.311(d)(1) will affect the 39 State Medicaid programs with waiting lists for section 1915(c) waivers.⁴⁰⁶ We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the number of people on existing waiting lists and how long they wait; and write or update their existing waiting list policies and the information collected. In some States, HCBS waivers are administered by more than one operating agency, in these cases each will have to report this data up to the Medicaid agency for submission to us.

With regard to the one-time requirements, we estimate it will take: 16 hours at \$111.18/hr for an administrative services manager to write or update State policy, direct information collection, compile information, and produce a report; 20 hours at \$98.84/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at \$118.14/hr for a general and operations manager to review and approve report; and 2 hours at \$236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 1,599 hours (39 States x 41 hr) at a cost of \$178,777 (39 States x [(16 hr x \$111.18/hr) + (20 hr x \$98.84/hr) + (3 hr x \$118.14/hr) + (2 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$89,388 (\$178,777 x 0.50).

Assuming no changes to the State waiting list policies, each year States will only need to update the report to reflect the number of people on the list of individuals who are waiting to enroll in the waiver program and average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list.

⁴⁰⁶ <https://www.kff.org/report-section/state-policy-choices-about-medicaid-home-and-community-based-services-amid-the-pandemic-issue-brief/>.

TABLE 19: Summary of One-Time Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Write or update State policy, direct information collection, compile information, and produce a report	39	39	Once	16	624	111.18	69,376	34,688
Query internal systems for reporting requirements	39	39	Once	20	780	98.84	77,095	38,548
Review and approve report at management level	39	39	Once	3	117	118.14	13,822	6,911
Review and approve all reports associated with this requirement at the executive level	39	39	Once	2	78	236.96	18,483	9,242
Total	39	39	Once	Varies	1,599	Varies	178,777	89,388

b. Ongoing Waiting List Reporting Requirements: States (§ 441.311(d)(1))

With regard to the on-going burden for the section 1915(c) waiver waiting list reporting requirements at § 441.311(d)(1), we estimate it will take: 4 hours at \$111.18/hr for an administrative services managers across relevant operating agencies to direct information collection, compile information, and produce a report; 6 hours at \$98.84/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at \$118.14/hr for a general and operations manager to review and approve report; and 2 hours at \$236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 585 hours (39 States x 15 hr) at a cost of \$72,778 (39 States x [(4 hr x \$111.18/hr) + (6 hr x \$98.84/hr) + (3 hr x \$118.14/hr) + (2 hr x

\$236.96/hr)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be \$36,389 (\$72,778 x 0.50) per year.

TABLE 20: Summary of Ongoing Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report	39	39	Annually	4	156	111.18	17,344	8,672
Query internal systems for reporting requirements	39	39	Annually	6	234	98.84	23,129	11,564
Review and approve report at the management level	39	39	Annually	3	117	118.14	13,822	6,911
Review and approve all reports associated with this requirement at the executive level	39	39	Annually	2	78	236.96	18,483	9,241
Total	39	39	Annually	Varies	585	Varies	72,778	36,389

7. ICRs Regarding Additional HCBS Access Reporting (§ 441.311(d)(2)(i); applied to other HCBS authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to managed care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden

estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this will be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We proposed additional HCBS access reporting at § 441.311(d)(2)(i). We proposed at § 441.311(d)(2)(i) to require States to report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, listed in § 440.180(b)(2) through (4), are initially approved to when services began for individuals newly approved to begin receiving services within the past 12 months. We also proposed at § 441.311(d)(2)(ii) to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. States are allowed to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months.

We are finalizing the requirements at § 441.311(d)(2) with a modification to add reporting on habilitation services as defined at § 440.180(b)(6), in addition to the other services. We have adjusted our burden estimates below to reflect additional reporting on habilitation services.

The burden associated with the additional HCBS access reporting requirements at § 441.311(d)(2) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915I, (i), (j), or (k) authorities.⁴⁰⁷ Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the average amount of time from which homemaker services, home health aide services, personal care, and habilitation services, as listed in § 440.180(b)(2) through (4) and (6), are initially approved to when services began,

⁴⁰⁷ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

for individuals newly approved to begin receiving services within the past 12 months, and the percent of authorized hours for these services that are provided within the past 12 months. We expect many States will need to analyze report this metric for a statistically valid random sample of beneficiaries. They will then need to produce a report for us within such information. For States with managed long-term services and supports, they will need to direct managed care plans to report this information up to them.

We estimate one-time and ongoing burden to implement the requirements at § 441.311(d)(2) at the State level.

One-Time HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the one-time burden related to the HCBS access reporting requirements, we estimate it will take: 30 hours at \$111.18/hr for an administrative services manager across relevant operating agencies to direct information collection, compile information, and produce a report; 80 hours at \$98.84/hr for a computer programmer or contractor to analyze service authorization and claims data; 50 hours at \$101.46/hr for a statistician to conduct data sampling; 4 hours at \$118.14/hr for a general and operations manager to review and approve report; and 3 hours at \$236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a one-time burden of 8,016 hours (48 States x 167 hr) at a cost of \$839,954 (48 States x [(20 hr x \$111.18/hr) + (60 hr x \$98.84/hr) + (40 hr x \$101.46/hr) + (3 hr x \$118.14/hr) + (2 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be \$419,977 (\$839,954 x 0.50) per year.

TABLE 21: Summary of One-Time Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report	48	48	Once	30	1,440	111.18	160,099	80,050
Analyze service authorization and claims data	48	48	Once	80	3,840	98.84	379,546	189,773
Conduct data sampling	48	48	Once	50	2,400	101.46	243,504	121,752
Review and approve report at the management level	48	48	Once	4	192	118.14	22,683	11,341
Review and approve all reports associated with this requirement at the executive level	48	48	Once	3	144	236.96	34,122	17,061
Total	48	48	Once	Varies	8,016	Varies	839,954	419,977

b. Ongoing HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the on-going burden related to the HCBS access reporting requirements for States, we estimate it will take: 15 hours at \$111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report; 30 hours at \$98.84/hr for a computer programmer or contractor to analyze service authorization and claims data; 15 hours at \$101.46/hr for a statistician to conduct data sampling; 4 hours at \$118.14/hr for a general and operations manager to review and approve report; and 2 hours at \$236.96/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 3,168 hours (48 States x 67 hr) at a cost of \$340,861 (48 States x [(15 hr x \$111.18/hr) + (30 hr x \$98.84/hr) + (15 hr x \$101.46/hr) + (4 hr x \$118.14/hr) + (2 hr x

\$236.96/hr])). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be \$170,431 (\$340,861 x 0.50) per year.

TABLE 22: Summary of Ongoing Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report	48	48	Annually	15	720	111.18	80,050	40,025
Analyze service authorization and claims data	48	48	Annually	30	1,440	98.84	142,330	71,165
Conduct data sampling	48	48	Annually	15	720	101.46	73,051	36,526
Review and approve report at the management level	48	48	Annually	4	192	118.14	22,683	11,341
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
Total	48	48	Annual	Varies	3,168	Varies	340,861	170,431

c. One-Time HCBS Access Reporting Requirements: Managed Care Plans (§ 441.311(d)(2))

With regard to the one-time HCBS access reporting requirements at § 441.311(d)(2) for managed care plans, we estimate it will take: 15 hours at \$111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 45 hours at \$98.84/hr for a computer programmer to analyze service authorization and claims data; 15 hours at \$101.46/hr for a statistician to conduct data sampling; and 2 hours at \$236.96/hr for a chief executive review and approval. In aggregate, we estimate a one-time

burden of 12,397 hours (161 MCPs x 77 hr) at a cost of \$1,305,923 (161 MCPs x [(15 hr x \$111.18/hr) + (45 hr x \$98.84/hr) + (15 hr x \$101.46/hr) + (2 hr x \$236.96/hr)]).

TABLE 23: Summary of One-Time Burden for Managed Care Plans for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report to the State	161	161	Once	15	1,610	111.18	179,000	n/a
Analyze service authorization and claims data	161	161	Once	45	5,635	98.84	556,963	n/a
Conduct data sampling	161	161	Once	15	1,610	101.46	163,351	n/a
Review and approve report	161	161	Once	2	322	236.96	76,301	n/a
Total	161	161	Once	Varies	12,397	Varies	1,305,923	n/a

d. Ongoing HCBS Access Reporting Requirements: Managed Care Plans (§ 441.311(d)(2))

With regard to the ongoing requirements associated with the annual collection, aggregation, and reporting of the HCBS access measures at § 441.311(d)(2), we estimate it will require: 5 hours at \$111.18/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 25 hours at \$98.84/hr for a computer programmer to analyze service authorization and claims data; 10 hours at \$101.46/hr for a statistician to conduct data sampling; and 2 hours at \$236.96/hr for a chief executive to review and approve. In aggregate, we estimate a burden of 6,762 hours (161 MCPs x 42 hr) at a cost of \$726,983 (161 MCPs x [(5 hr x \$111.18/hr) + (25 hr x \$98.84/hr) + (10 hr x \$101.46/hr) + (2 hr x \$236.96/hr)]).

TABLE 24: Summary of Ongoing Burden for Managed Care Plans for Additional HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report to the State	161	161	Annually	5	805	111.18	89,500	n/a
Analyze service authorization and claims data	161	161	Annually	25	4,025	98.84	397,831	n/a
Conduct data sampling	161	161	Annually	10	1,610	101.46	163,351	n/a
Review and approve report	161	161	Annually	2	322	236.96	76,301	n/a
Total	161	161	Annually	Varies	6,762	Varies	726,983	n/a

8. ICRs Regarding Compliance Reporting (§ 441.311(b); applied to other HCBS authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to managed care at § 438.72(b))

a. Ongoing Incident Management System Assessment Requirements: States (§ 441.311(b)(1))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10692 (OMB control number 0938-1362).

As discussed in II.B.3 of this final rule, we are finalizing at § 441.302(a)(6), a requirement that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends

critical incidents. We are finalizing at § 441.311(b)(1)(i) a requirement that States must report, every 24 months, on the results of an incident management system assessment to demonstrate that they meet the requirements in § 441.302(a)(6). We are also finalizing at § 441.311(b)(1)(ii) a flexibility in which we may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

The reporting requirements finalized at § 411.311(b)(1) are intended to standardize our expectations and States' reporting requirements to ensure that States operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. The requirements were informed by the responses to the HCBS Incident Management Survey (CMS-10692; OMB 0938-1362) recently released to States.

We estimate that the reporting requirement at § 441.311(b)(1) would apply to the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. Some States employ the same incident management system across their waivers, while others employ an incident management system specific to each waiver and will require multiple assessments to meet the requirements at § 441.311(b)(1). Based on the responses to the previously referenced survey, we estimate that on average States will conduct assessments on two incident management systems, totaling approximately 96 unique required assessments (48 State Medicaid programs x 2 incident management system assessments per State). Because the requirements under § 441.311(b)(1) are required every 24 months, we estimate 48 assessments on an annual basis (96 unique assessments every 2 years). With regard to the ongoing requirements, we estimate that it will take 1.5 hours at \$76.26/hr for a social/community service manager to gather information and complete the required assessment; and 0.5 hours at \$118.14/hr for a general and operations manager to review and approve the assessment. In aggregate, we estimate an ongoing annual burden of 96 hours (48 States x 2 hr) at a cost of \$8,326 (48 States x [(1.5 hr x \$76.26/hr)+(0.5 hr x \$118.14/hr)]). Taking into account the

Federal contribution to Medicaid administration, the estimated State share of this cost would be \$4,163 (\$8,326 x 0.50) per year.

TABLE 25: Summary of the Ongoing Burden for States for the Incident Management System Assessment Requirements at § 441.311(b)(1)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Gather information and complete the required assessment	48	48	Annually	1.5	72	76.26	5,491	2,745
Review and approve the assessment	48	48	Annually	0.5	24	118.14	2,835	1,418
Total	48	48	Annually	Varies	96	varies	8,326	4,163

b. Reporting on Critical Incidents (§ 441.311(b)(2)), Person-Centered Planning (§ 441.311(b)(3)), and Type, Amount, and Cost of Services (§ 441.311(b)(4))

The following changes will be submitted to OMB for approval after our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS 0938–0272 (CMS–372(S)).

This final rule codifies existing compliance reporting requirements on critical incidents, person-centered planning, and type, amount, and cost of services. At § 441.311(b)(2), we are finalizing a reporting requirement which requires States to report annually on the minimum performance standards for critical incidents that are finalized at § 441.302(a)(6). At § 441.311(b)(3), we are finalizing a reporting requirement to require States to report annually on the minimum performance standards for person-centered planning that are finalized at §

441.301(c)(3). Similar reporting requirements were previously described in 2014 guidance.⁴⁰⁸

We are also finalizing a redesignation of the existing requirement at § 441.302(h)(1) to report on type, amount, and cost of services as § 441.311(b)(4), to make the requirement part of the new consolidated compliance reporting section finalized at § 441.311.

This final rule removes our currently approved burden and replaces it with the burden associated with the amendments to § 441.311(b)(2) through (4). In aggregate, the change will remove 11,132 hours (253 waivers x 44 hr) and \$891,451 (11,132 hr x \$80.08/hr for a business operations specialist). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost reduction would be minus \$445,725 (-\$891,451 x 0.50).

TABLE 26: Summary of the Removal of Approved Ongoing Burden for Form 372(S) as a Result of the Requirements at § 441.311(b)(2) through (b)(4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Remove currently approved burden under control number 0938–0272 (CMS–372(S))	48	(253)	Annually	(44)	(11,132)	80.08	(891,451)	(445,725)
Total	48	(253)	Annually	(44)	(11,132)	80.08	(891,451)	(445,725)

We expect, as a result of the changes discussed in this section, to revise the Form CMS-372(S) and the form’s instructions based on the reporting requirements. The consolidated reporting requirements at § 441.311(b)(2) through (4) also assume that 48 States (including Washington DC) are required to submit the Form CMS-372(S) Report on an annual basis. However, a separate form will no longer be required for each of the 253 approved waivers currently in operation. We estimate a burden of 50 hours at \$80.08/hr for a business operations specialist to draft each Form CMS-372(S) Report submission. The per response increase reflects the increase to the minimum State quality performance level for person-centered planning

⁴⁰⁸ https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.

(finalized at § 441.301(c)(3)(ii)) and critical incident reporting (finalized at § 441.302(a)(6)(ii)) from the 86 percent threshold established by the 2014 guidance to 90 percent in this final rule. This slight increase to the minimum performance level will help ensure that States are sufficiently meeting all section 1915(c) waiver requirements but may also increase the evidence that some States may need to submit to document that appropriate remediation is being undertaken to resolve any compliance deficiencies. As a result, we estimate a total of 50 hours for each Form CMS-372(S) Report submission, comprised of 30 hours of recordkeeping, collection and maintenance of data, and 20 hours of record assembly, programming, and completing the Form CMS-372(S) Report in the required format. We also estimate 3 hours at \$118.14/hr for a general and operations manager to review and approve the report to CMS; and 2 hours at \$236.96/hr for a chief executive to review and approve all reports associated with this requirement.

TABLE 27: Summary of the New Burden for Form 372(S) Annual Report on HCBS Waivers, Inclusive of Updates to § 441.311(b)(2) through (4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft Form CMS 372(S) Report submission	48	48	Annually	50	2,400	80.08	192,192	96,096
Review and approve the report at the management level	48	48	Annually	3	144	118.14	17,012	8,506
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	236.96	22,748	11,374
Total	48	48	Annually	Varies	2,640	varies	231,952	115,976

The net change resulting from reporting requirements on critical incidents, person-centered service planning, and type, amount, and cost of services, finalized in

§ 441.311(b)(2) through (4) is a burden decrease of 8,492 hours (2,640 hr - 11,132 hr) and \$329,749 (State share) (\$115,976 - \$445,725).

9. ICRs Regarding Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c); applied to other HCBS authorities at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii) and to managed care at § 438.72(b)))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

At § 441.311(c), we finalized a requirement that States report every other year on the HCBS Quality Measure Set, which is described in section II.B.8. of this final rule. The reporting requirement will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), 1915(i), 1915(j), and 1915(k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. Unlike other reporting requirements finalized at § 441.311, the effective date of § 441.311(c) will be 4 years, rather than 3 years, after the effective date of the final rule.

As finalized at § 441.311(c), the data collection includes reporting every other year on all measures in the HCBS Quality Measure Set that are identified by the Secretary.⁴⁰⁹ For certain measures which are based on data already collected by us, the State can elect to have the Secretary report on their behalf.

As finalized at § 441.312(c)(1)(iii), States are required to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.

We are finalizing the requirements at § 441.312 without substantive modification. Our burden estimates are described below.

i. One Time HCBS Quality Measure Set Requirements: States (§ 441.311(c))

This one-time burden analysis assumes that States must newly adopt one of the “experience of care” surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community-Based (HCBS CAHPS®) Survey, National Core Indicators®-Intellectual and Developmental Disabilities (NCI®-IDD), National Core Indicators-Aging and Disability (NCI-AD)TM, or Personal Outcome Measures (POM)® to fully meet the HCBS Quality Measures Set mandatory requirements. Currently most States use at least one of these surveys; however, States may need to use multiple “experience of care” surveys, depending on the populations served by the States’ HCBS program and the particular survey instruments that States select to use, to ensure that all major population groups are assessed using the measures in the HCBS Quality Measure Set.

The estimate of one-time burden related to the effort associated with the requirements is for the first year of reporting. It assumes that the Secretary will initially require 25 of the 97 measures currently included in the HCBS Quality Measure Set. The estimate disregards costs

⁴⁰⁹ Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

associated with the voluntary reporting of measures in the HCBS Quality Measure Set that are not yet mandatory, and voluntary stratification of measures ahead of the phase-in schedule, discussed later in this section.

Additionally, we are finalizing a requirement at § 441.312(f) that the Secretary will require stratification by demographic characteristics of 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified 4 years after the effective date of these regulations, 50 percent of such measures by 6 years after the effective date of these regulations, and 100 percent of measures by 8 years after the effective date of these regulations. The burden associated with stratifying data is considered in the ongoing cost estimate only. We anticipate that certain costs will decline after the first year of reporting, but that some of the reduction will be supplanted with costs associated with stratifying data.

With regard to the one-time requirements at § 441.311(c) for reporting on the initial mandatory elements of the HCBS Quality Measure Set, we estimate that will take: 540 hours at \$111.18/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report; 40 hours at \$101.46/hr for a statistician to determine survey sampling methodology; 500 hours at \$63.88/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 200 hours at \$36.52/hr for a data entry worker to input the data; 60 hours at \$98.84/hr for a computer programmer to synthesize the data; and 5 hours at \$236.96/hr for a chief executive to verify, certify, and approve the report. In aggregate, we estimate a one-time burden of 64,560 hours (48 States x 1,345 hr) at a cost of \$5,301,830 (48 States x [(540 hr x \$111.18/hr) + (40 hr x \$101.46/hr) + (500 hr x \$63.88/hr) + (200 hr x \$36.52/hr) + (60 hr x \$98.84/hr) + (5 hr x \$236.96/hr)]) Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be \$2,650,915 (\$5,301,830 x 0.50).

TABLE 28: Summary of the One-Time Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report	48	48	Once	540	25,920	111.18	2,881,786	1,440,893
Determine survey sampling methodology	48	48	Once	40	1,920	101.46	194,803	97,402
Receive training in survey administration and administer an in-person survey	48	48	Once	500	24,000	63.88	1,533,120	766,560
Input data	48	48	Once	200	9,600	36.52	350,592	175,296
Synthesize data	48	48	Once	60	2,880	98.84	284,659	142,330
Verify, certify, and approve the report	48	48	Once	5	240	236.96	56,870	28,435
Total	48	48	Once	Varies	64,560	varies	5,301,830	2,650,915

ii. Ongoing HCBS Quality Measure Set Requirements: States (§ 441.311(c))

With regard to the ongoing burden of fulfilling requirements at § 441.311(c), every other year, for reporting on mandatory elements of the HCBS Quality Measure Set, including data stratification by demographic characteristics, we estimate it will take: 520 hours at \$111.18/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report; 80 hours at \$101.46/hr for a statistician to determine survey sampling methodology; 1,250 hours at \$63.88/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 500 hours at \$36.52/hr for a data entry worker to input the data; 100 hours at \$98.84/hr for a computer programmer to synthesize the data; and 5 hours at \$236.96/hr for a chief executive to verify, certify, and approve a State data submission to us. In aggregate, we estimate an ongoing burden of 117,840 hours (48 States x

2,455 hr) at a cost of \$8,405,242 (48 States x [(520 hr x \$111.18/hr) + (80 hr x \$101.46/hr) + (1,250 hr x \$63.88/hr) + (500 hr x \$36.52/hr) + (100 hr x \$98.84/hr) + (5 hr x \$236.96/hr)]).

Given that reporting is every other year, the annual burden will be 58,920 hours (117,840 hr/2 years) and \$4,202,621 (\$8,405,242/2 years). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$2,101,310 (\$4,202,621 x 0.50).

TABLE 29: Summary of the Ongoing Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses *	Frequency	Time per Response (hr)	Total Time (hr)*	Wage (\$/hr)	Total Cost (\$)*	State Share (\$)*
Conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report	48	12 per year) (24 biennially)	Biennial	520	12,480	111.18	1,387,526	1,387,526
Determine survey sampling methodology	48	12 per year) (24 biennially)	Biennial	80	1,920	101.46	194,803	194,803
Receive training in survey administration and administer an in-person survey	48	12 per year) (24 biennially)	Biennial	1,250	30,000	63.88	1,916,400	958,200
Input data	48	12 per year) (24 biennially)	Biennial	500	12,000	36.52	438,240	219,120
Synthesize data	48	12 per year) (24 biennially)	Biennial	100	2,400	98.84	237,216	118,608
Verify, certify, and approve the report	48	12 per year) (24 biennially)	Biennial	5	120	236.96	28,435	14,218
Total	48	12 per year) (24 biennially)	Biennial	Varies	58,920	Varies	4,202,620	2,101,310

*Annualized over 2 years.

b. HCBS Quality Measure Set Requirements: Beneficiary Experience Survey (§ 441.311(c))

State adoption of existing beneficiary experience surveys, contained in the HCBS Quality Measure Set, to fulfill the mandatory reporting requirements includes a burden on beneficiaries. As finalized in § 441.312, a State must newly adopt one of the “experience of care” surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community Based (HCBS CAHPS®) Survey, National Core Indicators® Intellectual and Developmental Disabilities (NCI® IDD), National Core Indicators Aging and Disability (NCI AD)TM, or Personal Outcome Measures (POM)®.

With regard to beneficiary burden, we estimate it will take 45 minutes (0.75 hr) at \$20.71/hr for a Medicaid beneficiary to complete a survey every other year that will be used to derive one or more of the measures in the HCBS Quality Measure Set. At 1,000 beneficiaries/State and 48 States, we estimate an aggregate burden of 36,000 hours (1,000 beneficiary responses/State x 48 States x 0.75 hr/survey) at a cost of \$745,560 (36,000 hr x \$20.71/hr). Given that survey is every other year, the annual burden will be 18,000 hours (36,000 hr/2 years) and \$372,780 (\$745,560/2 years).

TABLE 30: Summary of Ongoing Beneficiary Experience Survey Burden for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondents	Total Responses *	Frequency	Time per Response (hr)	Total Time (hr)*	Wage (\$/hr)	Total Cost (\$)*	State Share (\$)
Complete beneficiary experience survey	48,000	24,000	Biennial	0.75	18,000	20.71	372,780	n/a
Total	48,000	24,000	Biennial	0.75	18,000	20.71	372,780	n/a

*Annualized over 2 years.

10. ICRs Regarding Website Transparency (§ 441.313; applied to other HCBS authorities at §§ 441.486, 441.595, and 441.750, and to managed care at § 438.72(b))

The following changes will be submitted to OMB for approval after our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. In the meantime, we are setting out our burden

figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We are finalizing a new section, at § 441.313, titled, "Website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS under section 1915(c) of the Act." Specifically, at § 441.313(a), we proposed to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) and that provides the data and information that States are required to report under the newly finalized reporting section at § 441.311. At § 441.313(a)(1), we proposed to require that the data and information that States are required to report under § 441.311 be provided on one website, either directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. At § 441.313(a)(2), we proposed to require that the web page include clear and easy to understand labels on documents and links.

At § 441.313(a)(3), we proposed to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. At § 441.313(c), we proposed to apply these requirements to services delivered under FFS or managed care delivery systems. At § 441.313(a)(4), we proposed to require that States explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. Further, we proposed to apply the proposed requirements at

§ 441.313 to sections 1915(j), (k), and (i) State plan services by finalizing §§ 441.486, 441.595, and 441.750, respectively.

We are finalizing the requirements without substantive changes. Our burden estimates are described below. The burden associated with the website transparency requirements at § 441.313 will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We are requiring at § 441.313(c) to apply the website transparency requirements to services delivered under FFS or managed care delivery systems, and we are providing States with the option to meet the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. However, we are not requiring managed care plans to report the data and information required under § 441.311 on their website. As such, we estimate that there is no additional burden for managed care plans associated with the requirements to link to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services for § 441.313. Further, the burden associated with the requirements for managed care plans to report the data and information required under § 441.311 is estimated in the ICRs Regarding Compliance Reporting (§ 441.311(b)).

If a State opts to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services, the State will incur a burden. However, such burden will be less than the burden associated with posting the information required under § 441.311 on their own website. We are unable to estimate the number of States that may opt to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. As a

result, we do not take into account the option in our burden estimate and conservatively assume that all States subject to the requirements at § 441.313 by posting the information required under § 441.311 on their own website.

We estimate both a one-time and ongoing burden to implement these requirements at the State level.

a. One Time Website Transparency Requirements: States (§ 441.313)

The burden associated with the website transparency requirements at § 441.313 will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. In developing our burden estimate, we assumed that States will provide the data and information that States are required to report under newly proposed § 441.311 through an existing website, rather than develop a new website to meet this requirement.

With regard to the one-time burden, based on the website transparency requirements, we estimate it will take: 24 hours at \$111.18/hr for an administrative services manager to determine the content of the website; 80 hours at \$98.84/hr for a computer programmer or contractor to develop the website; 3 hours at \$118.14/hr for a general and operations manager to review and approve the website; and 2 hours at \$236.96/hr for a chief executive to review and approve the website. In aggregate, we estimate a one-time burden of 5,232 hours (48 States x 109 hr) at a cost of \$547,385 (48 States x [(24 hr x \$111.18/hr) + (80 hr x \$98.84/hr) + (3 hr x \$118.14/hr) + (2 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost will be \$273,693 (\$547,385 x 0.50) per year.

TABLE 31: Summary of the One-Time Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$/year)
Determine content of website	48	48	Once	24	1,152	111.18	128,080	64,040
Develop website	48	48	Once	80	3,840	98.84	379,546	189,773
Review and approve the website at the management level	48	48	Once	3	144	118.14	17,012	8,506
Review and approve the website at the executive level	48	48	Once	2	96	236.96	22,748	11,374
Total	48	48	Once	Varies	5,232	Varies	547,385	273,693

b. Ongoing Website Transparency Requirements: States (§ 441.313)

With regard to the State on-going burden related to the website transparency requirement, per quarter we estimate it will take: 8 hours at \$111.18/hr for an administrative services manager to provide updated data and information for posting and to verify the accuracy of the website; 20 hours at \$98.84/hr for a computer programmer or contractor to update the website; 3 hours at \$118.14/hr for a general and operations manager to review and approve the website; and 2 hours at \$236.96/hr for a chief executive to review and approve the website. In aggregate, we estimate an ongoing annual burden of 6,336 hours (33 hr x 48 States x 4 quarters) at a cost of \$709,359 (48 States x 4 quarters x [(8 hr x \$111.18/hr) + (20 hr x \$98.84/hr) + (3 hr x \$118.14/hr) + (2 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$354,680 (\$709,359 x 0.50) per year.

TABLE 32: Summary of the Ongoing Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Provide updated data and information for posting and verify the accuracy of the website	48	192	Quarterly	8	1,536	111.18	170,772	85,386
Update website	48	192	Quarterly	20	3,840	98.84	379,546	189,773
Review and approve website at the management level	48	192	Quarterly	3	576	118.14	68,049	34,024
Review and approve website at the executive level	48	192	Quarterly	2	384	236.96	90,993	45,496
Total	48	192	Quarterly	Varies	6,336	Varies	709,359	354,680

11. ICRs Regarding HCBS Payment Adequacy (§ 441.302(k); applied to other HCBS authorities at §§ 441.464(f), 441.570(f), 441.745(a)(1)(vi), and to managed care at § 438.72(b))

The following changes will be submitted to OMB for approval after this final rule is finalized and when our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our burden figures (see below) as a means of scoring the impact of this rule's changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

We proposed, and are finalizing, a new policy at § 441.302(k)(3)(i), which requires that 80 percent of Medicaid payments for the following services for homemaker services, home health aide services, and personal care services (as set forth in § 440.180(b)(2) through (4)) be spent on compensation for direct care workers. We proposed, and are finalizing, definitions for compensation and direct care workers at §§ 441.302(k)(1) and (2), respectively, which are discussed in greater detail in section II.B.5. of this final rule. As finalized, States must comply with the requirements in § 441.302(k) 6 years after this rule is finalized.

As discussed in greater detail in section II.B.5. of this final rule, we are finalizing this policy with additional modifications which have an impact on our burden estimates. We are finalizing a policy at § 441.302(k)(3)(ii) that allows States to apply a different minimum performance threshold for small providers. We are finalizing a requirement at § 441.302(k)(4)(i) that allows States to develop reasonable, objective criteria through a transparent process (which includes public notice and opportunities for comment from interested parties) to identify small providers that the State would require to meet this alternative minimum performance requirement. We are finalizing a requirement at § 441.302(k)(4)(ii) that the State must set the percentage for a small provider to meet the minimum performance level based on reasonable, objective criteria that it develops through a transparent process that includes public notice and opportunities for comment from interested parties. The costs associated with establishing the small provider threshold (including activities related to public notice and opportunities for comment) have been added to this burden estimate for States. We do not estimate an impact on managed care plans associated with the small provider threshold. We estimate a small impact on providers associated with this requirement; while we believe providers' activities would remain the same whether they were complying with the 80 percent threshold or a State-set small provider threshold, we also assume an additional activity associated with demonstrating eligibility for the State-set small provider threshold. We note that while we have not specified a process by which a State would have providers determine eligibility for a small provider

threshold, we are calculating a burden based on the assumption that States would have such a process.

We are also finalizing at § 441.302(k)(5) a flexibility to allow States to offer certain providers temporary hardship exemptions. As finalized, this requirement would allow States to develop reasonable, objective criteria through a transparent process (which includes public notice and opportunities for comment from interested parties) to exempt from the minimum performance requirement at paragraphs (k)(3) of this section a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with either the 80 percent threshold requirement or the State's small provider threshold. The costs associated with establishing the hardship exemption (including activities related to public notice and opportunities for comment) have been added to this burden estimate for States. We do not anticipate a specific impact on managed care plans as a result of this requirement. We do not estimate an impact on managed care plans associated with the hardship exemption. We estimate a small impact on providers associated with this requirement, as we assume an additional activity associated with demonstrating eligibility for the State-set hardship exemption. We note that while we have not specified a process by which a State would have providers determine eligibility for a hardship exemption, we are calculating a burden based on the assumption that States would have such a process.

We are finalizing at § 441.302(k)(6) reporting requirements for small provider minimum performance levels and hardship exemptions. Under this requirement, States that establish a small provider minimum performance level must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS: the State's small provider criteria developed in accordance with paragraph (k)(4)(i) of this section; the State's small provider minimum performance level; the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider minimum performance level; and a plan, subject to CMS review and approval, for small providers to meet the minimum

performance requirement at paragraph (k)(3)(i) of this section within a reasonable period of time. States that provide a hardship exemption must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS: the State's hardship criteria; the percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption; and a plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time. We also finalized a flexibility at § 441.302(k)(6)(iii) that CMS may waive the reporting requirements if the State demonstrates it has applied the small provider minimum performance level or the hardship exemption to less than 10 percent of the State's providers.

We have added the burden associated with the reporting requirement finalized at § 441.302(k)(6) to the burden estimate. We do not expect that all States will need to submit such a report (because some States will expect most, if not all, of their providers to comply with the minimum performance threshold); we also expect that over time, fewer States will need to submit such a report (again, as more States begin to require that more than 90 percent of their providers comply with the minimum performance threshold.) However, to avoid underestimating burden, we have calculated the burden of this requirement based on the assumption that all 48 States will submit such a report annually. We do not anticipate an impact on managed care plans or providers associated with this additional requirement.

We also finalized at § 441.302(k)(7) an exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641, which exempts these providers from the requirements in § 441.302(k). Based on internal data, we believe that about 100 providers would be eligible for this exclusion as § 441.302(k)(7) requires no additional action on the part of the State or providers impacted by this exemption) we did not calculate a change in the burden activities as a result of this exemption.

We are finalizing the application of these requirements to services delivered under FFS or managed care delivery systems. Further, we are finalizing the application of the finalized

requirements sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively.

We are finalizing the requirements at §§ 441.302(k) with the substantive modifications as described above. Burden estimates for the finalized requirements are below. We note an additional change to the burden estimates. As presented in the proposed rule at 88 FR 28047, we had presented the burden estimate of both the HCBS payment adequacy provision at § 441.302(k) and the payment adequacy reporting requirement at § 441.311(e) in a single ICR. Since the publication of the NPRM, upon further consideration we have determined that as §§ 441.302(k) and 441.311(e) represent distinct sets of requirements, it is more appropriate to present the costs associated with § 441.311(e) under a separate ICR in this section IV. of the final rule.

However, while § 441.311(e) represents a distinct set of requirements from those in § 441.302(k), we also expect that States will employ certain efficiencies in complying with both §§ 441.302(k) and 441.311(e). In particular, we expect that States will build a single IT infrastructure and use the same processes both for collecting data for the reporting requirement at § 441.311(e) and for determining providers' compliance with the 80 percent threshold at § 441.302(k)(3)(i) or the small provider threshold at § 441.302(k)(3)(ii). The burden associated with States' development of infrastructure and processes to determine what percentage of HCBS providers' Medicaid payments for homemaker, home health aide, or personal care services is spent on direct care worker compensation, as well as providers' reporting of this information to the State, is included in the ICR for § 441.311(e) (ICR 5 of this section IV. of the final rule). We believe representing these costs under only one ICR avoids duplicative or inflated burden estimates.

The burden estimates below include costs associated specifically with § 441.302(k), namely: development and application of the small provider threshold under § 441.302(k)(3)(ii)

and (4), development and application of the hardship exemption under § 441.302(k)(5), and the reporting on the small provider threshold and hardship exemption under § 441.302(k)(6).

a. States

The burden associated with the requirements at § 441.302(k) will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.^{410,411} We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, under §§ 441.302(k) States will have to: (1) draft new policy regarding the application of the 80 percent minimum performance level at § 441.302(k)(3), the small provider performance level and criteria described in § 441.302(k)(4), and the hardship exemptions described in § 441.302(k)(5) (one-time); (2) publish the proposed requirements for the small provider performance level described in § 441.302(k)(4) and threshold and the hardship exemption described in § 441.302(k)(5) through State notice and publication processes (one-time); (3) update provider manuals and other policy guidance regarding the performance levels described in § 441.302(k)(3) and (4) and the hardship exemption described in § 441.302(k)(5) for each of the services subject to the requirement (one-time); (4) inform providers of the process for demonstrating eligibility for the small provider performance level described at § 441.302(k)(4) or the hardship exemption described at § 441.302(k)(5) through State notification processes, both initially and annually (one-time and ongoing); (5) review providers' eligibility for the small provider performance level described at § 441.302(k)(4) or hardship exemption described in § 441.302(k)(5) (ongoing); and (6) provide the report on the small provider performance level and the hardship exemption required at § 441.302(k)(6) to us on an annual basis (ongoing).

i. One Time HCBS Payment Adequacy Requirements (§ 441.302(k)): State Burden

⁴¹⁰ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

⁴¹¹ For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

With regard to the one-time requirements, we estimate it will take 100 hours at \$111.18/hr for an administrative services manager to: draft policy content; prepare notices and draft rules for publication, conduct public hearings on the small provider performance level and hardship exemptions in accordance with § 441.302(k)(4) and (5), respectively. We estimate it will take 50 hours at \$100.64/hr for a management analyst to: update provider manuals for each of the affected services (explaining the policies for § 441.302(k) generally, and the policies and criteria related to the small provider performance level and hardship exemption described at § 441.302(k)(4) and (5), respectively; and draft provider agreement and managed care contract amendments regarding the requirements at § 441.302(k)(3), (4) and (5). We estimate it will take 8 hours at \$98.84/hr for a computer programmer to build, design, and operationalize internal systems for identifying providers falling under § 441.302(k)(4) or (5). We estimate it will take 40 hours at \$67.18/hr for a training and development specialist to: develop and conduct training for providers specific to the requirements associated with § 441.302(k)(3), (4), and (5). We estimate it will take 20 hours at \$118.14/hr for a general and operations manager to: review and approve provider agreement amendment sand managed care contract modifications; and to review and approve policy guidance for publication. We estimate it will take 10 hours at \$236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate a one-time burden of 10,944 hours (228 hr x 48 States) at a cost of \$1,169,295 (48 States x [(100 hr x \$111.18/hr) + (50 hr x \$100.64/hr) + (8 hr x \$98.84/hr) + (40 hr x \$67.18/hr) + (20 hr x \$118.14/hr) + (10 hr x \$236.96/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$584,648 (\$1,169,295 x 0.50).

TABLE 33: Summary of One-Time Burden for States for the HCBS Payment Adequacy Requirements at § 441.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy content; prepare notices and draft rules for publication, conduct public hearings for § 441.302(k)(4) and (5)	48	48	Once	100	4,800	111.18	533,664	266,832
Update provider manuals for each of the affected services (explaining the policies related to § 441.302(k) (4) and (5); and draft provider agreement and managed care contract amendments	48	48	Once	50	2,400	100.64	241,536	120,768
Build, design, and operationalize internal systems for marking providers identified as under § 441.302(k)(4) or (5)	48	48	Once	8	384	98.84	37,955	18,977
Develop and conduct training for providers for the requirements associated with § 441.302(k)	48	48	Once	40	1,920	67.18	128,986	64,493
Review, approve managed care contract modifications, provider agreement updates, policy and rules for publication, and training materials	48	48	Once	20	960	118.14	113,414	56,707
Review and approve all operations associated with this requirement	48	48	Once	10	480	236.96	113,740	56,780
Total	48	48	Once	Varies	10,944	varies	1,169,295	584,648

ii. Ongoing HCBS Payment Adequacy Requirements (§ 441.302(k)): State Burden

We also expect that States will have to review, on an ongoing basis, providers' requests to be considered under the small provider performance level at § 441.302(k)(4) or the hardship exemption at § 441.302(k)(5). As noted in the Collection of Information in the proposed rule at

88 FR 28049, we estimate that 11,555 HCBS providers provide homemaker, home health aide, or personal care services and thus are subject to the requirements at § 441.302(k). We estimate that around 15 percent of these providers will request consideration under either the small provider performance level or hardship exemption; 10 percent is selected as we expect States will set criteria to apply to 10 percent or less of providers. Thus, we expect that States (collectively) will need to review 1,155 requests for flexibilities under § 441.302(k)(4) or (5) on an ongoing, annual basis; we expect that it will take 0.5 hours at \$100.64/hr for a management analyst to review each request.

With regard to additional ongoing requirements, we estimate it will take 2 hours at \$98.84/hr for a computer programmer to update providers' status in any system that tracks providers subject to the small provider performance level and hardship exemptions under § 441.302(k)(4) or (5), respectively, and calculate the percent of providers subject to 441.302(k)(4) or (5). We also estimate it will take 2 hours at \$118.14/hr by a general and operations manager to generate the report required at § 441.302(k)(6) for submission to CMS. We estimate it will take 2 hours at \$236.96/hr for a chief executive to review and approve all operations associated with these requirements.

In aggregate, we estimate an ongoing burden of 866 hours $[(0.5 \text{ hr} \times 1,155 \text{ providers}) + (6 \text{ hr} \times 48 \text{ States})]$ at a cost of \$101,698 $[1,155 \text{ providers} \times (0.5 \text{ hr} \times \$100.65) + (48 \text{ States} \times [(2 \text{ hr} \times \$98.84/\text{hr}) + (2 \text{ hr} \times \$118.14/\text{hr}) + (2 \text{ hr} \times \$236.96/\text{hr})])]$. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$50,849 $(\$101,698 \times 0.50)$ per year.

TABLE 34: Summary of Ongoing Burden for States for the HCBS Payment Adequacy Requirements at §§ 441.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Review providers' requests for classification under § 441.302(k)(4) or (5)	1,155	1,155	Annually	0.5	576	100.64	58,120	29,060
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; identify percentages for providers subject to flexibilities; and develop report annually	48	48	Annually	2	96	98.84	9,489	4,744
Review, verify and approve reporting as required in § 441.302(k) and § 441.311(e) -to CMS	48	48	Annually	2	96	118.14	11,341	5,671
Review and approve all operations associated with reporting requirements at § 441.302(k) and § 441.311(e)	48	48	Annually	2	96	236.96	22,748	11,374
Total	Varies	1,203 (1,155 + 48)	Annually	Varies	866	Varies	101,698	50,849

b. Service Providers

The burden associated with § 441.302(k) being finalized in this final rule will affect service providers that provide the services listed at § 440.180(b)(2) through (4) and (6). We estimate an ongoing burden on providers to request, on an ongoing basis, either qualification as a small provider under the small provider criteria (in accordance with § 441.302(k)(4)) or eligibility for the hardship exemption (in accordance with § 441.302(k)(5)). (We do also expect there to be a burden on providers to implement the separate payment adequacy reporting requirement at § 441.311(e); these costs are addressed in a separate ICR.)

As noted above, we expect that annually, we estimate that 1,155 providers will request consideration for eligibility for the small provider performance level or the hardship exemption under § 441.302(k)(4) or (5), respectively.

With regard to the ongoing requirement, we estimate it would take: 1 hour at \$118.14/hr for a general and operations manager to file the request for the State. In aggregate, we estimate an ongoing burden of 1,155 hours (1,155 providers x 1 hr) at a cost of \$136,452 (1,155 providers x (1 hr x \$118.14/hr).

TABLE 35: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 442.302(k)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Request qualification under § 441.302(k)(4) or (5)	1,155	1,155	Once	1	1,155	118.14	136,452	n/a
Total	1,155	1,155	Once	1	1,155	118.14	136,452	n/a

12. ICRs Regarding Payment Rate Transparency (§ 447.203)

The following changes will be submitted to OMB for approval under control number 0938–1134 (CMS–10391).

This final rule will update documentation requirements in § 447.203. To develop the burden estimates associated with these changes, we account for the removal of existing information collection requirements in current § 447.203(b), and the introduction of new requirements at 447.203(b) and (c). As described later in this section, we estimate the impact of the revisions to § 447.203 will result in a net burden reduction. We do not anticipate any additional information collection burden from the conforming edits finalized in § 447.204, as the conforming edits merely alter the items submitted as part of an existing submission requirement, and the burden of producing those items is reflected in the estimates related to § 447.203, including instances where we move language from § 447.204 to § 447.203.

a. Removal of Access Monitoring Review Plan: States (§ 447.203(b)(1) through (8))

The burden reduction associated with the removal of § 447.203(b)(1) through (8) consists of the removal of time and effort necessary to develop and publish AMRPs, perform ongoing monitoring, and corrective action plans.

Former § 447.203(b)(1) and (2) described the minimum factors that States must consider when developing an AMRP. Specifically, the AMRP must include: input from both Medicaid beneficiaries and Medicaid providers, an analysis of Medicaid payment data, and a description of the specific measures the State will use to analyze access to care. Section 447.203(b)(3) required that States include aggregate percentage comparisons of Medicaid payment rates to other public (including, as practical, provider payments rates in Medicaid managed care or Medicare rates) and private health coverage rates within geographic areas of the State. Section 447.203(b)(4) described the minimum content that must be included in the monitoring plan. States were required to describe: measures the State uses to analyze access to care issues, how the measures relate to the overarching framework, access issues that are discovered as a result of the review, and the State Medicaid agency's recommendations on the sufficiency of access to care based on the review. Section 447.203(b)(5) described the timeframe for States to develop the AMRP and complete the data review for the following categories of services: primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health, any services for which the State has submitted a SPA to reduce or restructure provider payments which changes could result in diminished access, and additional services as determined necessary by the State or CMS based on complaints or as selected by the State. While the initial AMRPs have been completed, the plan had to be updated at least every 3 years, but no later than October 1 of the update year. Section 447.203(b)(6)(i) required that any time a State submits a SPA to reduce provider payment rates or restructure provider payments in a way that could diminish access, the State must submit an AMRP associated with the services affected by the payment rate reduction or payment restructuring that has been completed within the prior 12 months.

Former § 447.203(b)(6)(ii) required that States have procedures within the AMRP to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures were required to be in place for a period of at least 3 years following the effective date of the SPA. However, States were already required to submit information on compliance with section 1902(a)(30)(A) of the Act prior to the 2015 final rule with comment period. Therefore, removal of § 447.203(b)(6)(ii) results in a burden reduction.

Finally, we note that this section references the rescission of the AMRP process contained in § 447.203(b)(1) through (b)(8). However, the requirements of former paragraph (b)(7) are reflected in new paragraph (b)(4), and the requirements of former paragraph (b)(8) are reflected in new paragraph (c)(5). As such, there is not a change in impact related to the rescission of these specific aspects of the AMRP process and are not reflected in this section.

In our currently approved information collection request, we estimated that the requirements to develop and make the AMRPs publicly available for the specific categories of Medicaid services will affect each of the 50 State Medicaid programs and the District of Columbia (51 total respondents). We will use that estimate here as well, although we note that the requirements may not be limited to solely those States, as some territories may not be exempt under waivers; however, because these figures fluctuate, we are maintaining the estimate for consistency. As such, for consistency, we will maintain the estimate of 51 respondents subject to this final rule. We further note that the one-time cost estimates have already been met for AMRPs, and the ongoing monitoring requirements are every 3 years. As such, the estimates in this section for burden reduction are for 17 respondents, which is one-third of the 51 affected respondents, to provide an annual estimate of the reduced burden.

We estimated that every 3 years, it would take: 80 hours at \$55.54/hr for a social science research analyst to gather data, 80 hours at \$106.30/hr for a computer and information analyst to analyze the data, 100 hours at \$100.64/hr for a management analyst to develop the content of the AMRP, 40 hours at \$80.08/hr for a business operations specialist to publish the AMRP, and

10 hours at \$118.14/hr for a general and operations manager to review and approve the AMRP. In aggregate, and as shown in Table 36, we estimate the reduced annual burden of the rescission of the ongoing AMRP requirements would be minus 5,270 hours (17 States x 310 hr) and minus \$465,729 (17 States x [(80 hr x \$55.54/hr) + (80 hr x \$106.30/hr) + (100 hr x \$100.64/hr) + (40 hr x \$80.08/hr) + (10 hr x \$118.14/hr)]). Taking into account the 50 percent Federal contribution for administrative expenditures, the rescission represents a saving to States of minus \$232,865 (\$465,729 x 0.50).

The currently approved ongoing burden associated with the requirements under § 447.203(b)(6)(ii) is the time and effort it takes each of the State Medicaid programs to monitor continued access following the implementation of a SPA that reduces or restructures payment rates. In our currently approved information collection request, we estimated that in each SPA submission cycle, 22 States will submit SPAs to implement rate changes or restructure provider payments based on the number of submissions received in FY 2010. Using our currently approved burden estimates we estimate a reduction of: 40 hours at \$100.64/hr for a management analyst to develop the monitoring procedures, 24 hours at \$100.64/hr for a management analyst to periodically review the monitoring results, and 3 hours at \$118.14/hr for a general and operations manager to review and approve the monitoring procedures. In aggregate, we estimate burden reduction of minus 1,474 hours (22 responses x 67 hr) and minus \$149,498 (22 States x [(40 hr x \$100.64/hr) + (24 hr x \$100.64/hr) + (3 hr x \$118.14/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost reduction is adjusted to minus \$74,749 (\$149,498 x 0.50).

TABLE 36: Summary of Annual Burden Reduction Associated with Removal of Access Monitoring Review Plan Requirements (§ 447.203(b)(1) through (8))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Rescission of §447.203(b)(1) through (b)(6)(i)	17	17	Triennial (figures are annualized)	(310)	(5,270)	Varies	(465,729)	(232,865)
Rescission of § 447.203(b)(6)(i)	22	22	Varies (figures are annualized)	(67)	(1,474)	Varies	(149,498)	(74,749)
TOTAL	39	39	Varies	Varies	(6,744)	Varies	(615,227)	(307,614)

b. Payment Rate Transparency (§ 447.203(b)(1) through (5))

We proposed to replace the AMRP requirements with new payment rate transparency and analysis requirements at § 447.203(b)(1) through (5), which we are finalizing as proposed apart from minor technical adjustments. The burden associated with these requirements consists of the time and effort to develop and publish a Medicaid FFS provider payment rate information and analysis.

Section 447.203(b)(1) specifies that all FFS Medicaid payments must be published on a publicly accessible website that is maintained by the State. Section 447.203(b)(2) specifies the service types that are subject to the proposed payment analysis, which include: primary care services; obstetrical and gynecological services; outpatient mental health and substance use disorder services; and certain HCBS. Section 447.203(b)(3) describes the required components of the payment analysis to include, for services in § 447.203(b)(2)(i) through (iii), a percentage comparison of Medicaid payment rates to the most recently published Medicare payment rates effective for the time period for each of the service categories specified in paragraph (b)(2). We also specify that the payment analysis must include percentage comparisons made on the basis of Medicaid base payments. For HCBS described in § 447.203(b)(2)(iv), we require a State-based comparison of average hourly payment rates. Section 447.203(b)(4) details the payment analysis timeframe, with the first payment analysis required to be published by the State agency by July

1, 2026, which is a change from our proposed date of January 1, 2026, and updated every 2 years by July 1. Section 447.203(b)(5) describes our mechanism for ensuring compliance and that we may take compliance action against a State that fails to meet the requirements of the payment rate transparency, comparative payment rate analysis, and payment rate disclosure provisions in preceding paragraphs in § 447.203(b), including a deferral or disallowance of certain of the State's administrative expenditures following the procedures described at part 430, subpart C.

We estimate that the requirements to complete and make publicly available all FFS Medicaid payments and the comparative payment rate analysis and payment rate disclosures under § 447.203(b)(1) through (5) for the specific categories of Medicaid services will affect 51 total respondents, based on the estimate in the prior section regarding the variation in States and territories subject to these requirements. We require applicable States and territories to publish all FFS Medicaid payments initially by July 1, 2026, while future updates to the payment rate transparency information would depend on when a State submits a SPA updating provider payments and we have approved that SPA. As such, we assume 51 one-time respondents for the initial rates publication. Because the comparative payment rate analysis and payment rate disclosure requirement is biennial, we assume 26 annual respondents in any given year, and we will assume this figure would account for the updates made following a rate reduction SPA or rate restructuring SPA approval. The comparative payment rate analysis will be similar to the prior requirement at § 447.203(b)(3) that required AMRPs to include a comparative payment rate analysis against public or private payers. The inclusion of levels of provider payment available from other payers is also one of five required components of the AMRP as specified by current § 447.203(b)(1). To estimate the burden associated with our comparative payment rate analysis and payment rate disclosure provisions, we assume this work will require approximately 25 percent of the ongoing labor hour burden that we previously estimated to be required by the entire AMRP, to account for the service categories subject to the comparative payment rate analysis and payment rate disclosure in § 447.203(b)(2) as decreased from the full body of

AMRP service requirements. We invited comment on these estimated proportions. We are finalizing this requirement to include reporting on an additional service (habilitation services, as defined at § 440.180(b)(6)) in the payment rate disclosure. Below, we include in our burden calculations the minimal increased anticipated burden associated with the addition of reporting on habilitation services.

With regard to the developing and publishing the payment rate transparency data under § 447.203(b)(1), we estimate a low one-time and ongoing burden due to the data being available, and the main work required to meet the proposed requirement would be formatting and web publication. As such, we estimate it will initially take: 5 hours at \$55.54/hr for a research assistant to gather the data, 5 hours at \$80.08/hr for a business operations specialist to publish, and 1 hour at \$118.14/hr for a general and operations manager to review and approve the rate transparency data. In aggregate, we estimate a one-time burden of 561 hours (51 responses x 11 hr) at a cost of \$40,608 (51 responses x [(5 hr x \$55.54/hr) + (5 hr x \$80.08/hr) + (1 hr x \$118.14/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$20,304 (\$40,608 x 0.50).

For the ongoing cost to update assumed to take place every 2 years (although we proposed that updates would only be required as necessary to keep the data current, with any update made no later than 1 month following the date of CMS approval of the SPA or similar amendment providing for the change), we estimate an annualized impact on 26 respondents (51 respondents every 2 years) of: 2 hours at \$55.54/hr for a research assistant to update the data, 1 hour at \$80.08/hr for a business operations specialist to publish the updates, and 1 hour at \$118.14/hr for a general and operations manager to review and approve the rate transparency update. In aggregate, we estimate an annualized burden of 104 hours (26 responses x 4 hr) at a cost of \$8,042 (26 responses x [(2 hr x \$55.54/hr) + (1 hr x \$80.08/hr) + (1 hr x \$118.14/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$4,021 (\$8,042 x 0.50).

With regard to developing and publishing the comparative payment rate analysis and payment rate disclosure at § 447.203(b)(2), we estimate it will take: 22 hours at \$55.54/hr for a research assistant to gather the data, 22 hours at \$106.30/hr for an information analyst to analyze the data, 25 hours at \$100.64/hr for a management analyst to design the comparative payment rate analysis, 11 hours at \$80.08/hr for a business operations specialist to publish the comparative payment rate analysis and payment rate disclosure, and 3 hours at \$118.14/hr for a general and operations manager to review and approve the comparative payment rate analysis and payment rate disclosure. In aggregate, we estimate an annualized burden, based on 51 respondents every 2 years, of 2,054 (26 responses x 79 hr) at a cost of \$190,107 (26 States x [(22 hr x \$55.54/hr) + (22 hr x \$106.30/hr) + (25 hr x \$100.64/hr) + (11 hr x \$80.08/hr) + (3 hr x \$118.14/hr)]). We then adjust the total cost to \$95,053 (\$190,107 x 0.50) to account for the 50 percent Federal administrative match. We have summarized the total burdens in Table 37.

TABLE 37: Summary of Burden Associated with Payment Rate Transparency Requirements (§ 447.203(b)(1) through (5))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(b)(1) Rate Transparency	51	51	One-time	11	561	Varies	40,608	20,304
§ 447.203(b)(1) Rate Transparency	26	26	Biannual (figures are annualized)	4	104	Varies	8,042	4,021
§ 447.203(b)(2) and (3) Rate Analysis	26	26	Biannual (figures are annualized)	79	2,054	Varies	190,107	95,053
TOTAL	51	103	Varies	Varies	2,719	Varies	238,757	119,378

c. Medicaid Payment Rate Interested Parties' Advisory Group (§ 447.203(b)(6))

The burden associated with the recordkeeping requirements at § 447.203(b)(6), specifically the online publication associated with the reporting and recommendations of the interested parties advisory group, will consist of the time and effort for all 50 States and the District of Columbia to:

- Appoint members to the interested parties' advisory group.
- Provide the group members with materials necessary to:

++ Review current and proposed rates.

++ Hold meetings.

++ Provide a written recommendation to the State.

- Publish the group's recommendations to a website maintained by the single State agency.

The requirements will require varying levels of efforts for States depending on the existence of groups that may fulfil the requirements of this group. However, because it is unknown how many States will be able to leverage existing practices, and to what extent, this estimate does not account for those differences. We are finalizing the requirements at § 447.203(b)(6) with a modification to add habilitation services as defined at § 440.180(b)(6), in addition to the previously identified services, to the group's purview. However, this addition is not expected to create any additional burden. We estimate that it will take 40 hours at \$140.14/hr for a human resources manager to recruit interested parties and provide the necessary materials for the group to meet. In aggregate, we estimate a one-time burden of 2,040 hours (51 responses x 40 hr) at a cost of \$285,886 (2,040 hr x \$140.14/hr). Taking into account the 50 percent administrative match, the total one-time State cost is estimated to be \$142,943 (\$285,886 x 0.50).

We believe the ongoing work to maintain the needs of this group will take a human resources manager 5 hours at \$140.14/hr annually. Additionally, we estimate it will take 4 hours for the biennial requirement, or 2 hours annually at \$118.14/hr for an operations manager to review and prepare the recommendation for publication. In aggregate, we estimate an ongoing annualized burden of 182 hours (26 responses x 7 hr) at a cost of \$24,361 (26 Respondents x [(5 hr x \$140.14/hr) + (2 hr x \$118.14/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to \$12,181 (\$24,361 x 0.50). We have summarized the total burden in Table 38.

TABLE 38: Summary of Burden for Medicaid Payment Rate Interested Parties' Advisory Group

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(b)(6) (Establish advisory group)	51	51	One-time	40	2,040	140.14	285,886	142,943
§ 447.203(b)(6) (Support and publish recommendation)	51	26	Biennial (figures are annualized)	7	182	Varies	24,361	12,181
TOTAL	51	77	Varies	Varies	2,222	Varies	310,247	155,124

d. State Analysis Procedures for Payment Rate Reductions or Payment Restructuring

(§ 447.203(c))

The State analysis procedures for payment rate reductions and payment restructurings at § 447.203(c)(1) through (3) within this final rule effectively will replace payment rate reduction or payment restructuring procedures in current § 447.203(b)(6). As noted, the burden reduction associated with the removal of § 447.203(b)(6)(i) has already been accounted for in the recurring burden reduction estimate shown in Table 36 for the removal of the AMRP requirements, and the burden reduction associated with the removal of monitoring requirements at current § 447.203(b)(6)(ii) has been accounted for in Table 36 as well. Our replacement procedures at § 447.203(c)(1) through (3) will introduce new requirements as follows.

i. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Section 447.203(c)(1) will require that for States proposing to reduce or restructure provider payment rates, the State must document that their program and proposal meet all of the following requirements: (1) Medicaid rates in the aggregate for the service category following the proposed reduction(s) or restructurings are at or above 80 percent of most recent Medicare prices or rates for the same or a comparable set of services; (2) Proposed reductions or restructurings result in no more than a 4 percent reduction of overall spending for each service category affected by a proposed reduction or restructuring in a single State fiscal year; and (3)

Public process yields no significant access concerns or the State can reasonably respond to concerns.

Section 447.203(c)(1) will apply to all States that submit a SPA that proposes to reduce or restructure provider payment rates. We limited our estimates for new information collection burden to the requirements at § 447.203(c)(1)(i) through (ii). Our estimates assume States will build off the comparative analysis required by § 447.203(b)(2) through (4) to complete the requirements by § 447.203(c)(1)(i), which will limit the additional information collection burden. We also assume no additional information collection burden posed by the public review process required by § 447.203(c)(1)(iii), as this burden is encapsulated by current public process requirements at § 447.204.

The requirements of § 447.203(c) apply to all 50 States and the District of Columbia, as well as US territories. We will again use the estimate of 51 utilized in preceding sections, although we note some territories may be subject to these requirements if not exempt under waivers, and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this rule. While we cannot predict how many States will submit a rate reduction SPA or rate restructuring SPA in a given year, the figures from 2019 provide the best recent estimate, as the years during the COVID pandemic do not reflect typical behavior. In 2019, we approved rate reduction and rate restructuring SPAs from 17 unique State respondents. Therefore, to estimate the annualized number of respondents subject to this information collection burden, we will utilize a count of 17 respondents.

With regard to the burden associated with completing the required State analysis for rate reductions or restructurings at § 447.203(c)(1), we estimate that it will take: 20 hours at \$100.64/hr for a management analyst to structure the rate reduction or restructuring analysis, 25 hours at \$106.30/hr for an information analyst to complete the rate reduction or restructuring analysis, and 3 hours at \$118.14/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 816 hours (17

States x 48 hr) at a cost of \$85,420 (17 States x [(20 hr x \$100.64/hr) + (25 hr x \$106.30/hr) + (3 hr x \$118.14/hr)]). Accounting for the 50 percent Federal administrative reimbursement, this adjusts to a total State cost of \$42,710 (\$85,420 x 0.50).

TABLE 39: Burden Associated with Tier 1 State Analysis Procedures for Rate Reductions or Restructurings (§ 447.203(c)(1))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(c)(1)	17	17	Annual	48	816	Varies	85,420	42,710
TOTAL	17	17	Annual	48	816	Varies	85,420	42,710

We solicited public comment on these estimates as well as relevant State data to further refine the burden and time estimates. We did not receive public comments on this issue, and therefore, we are finalizing as proposed.

ii. Additional State Rate Analysis (§ 447.203(c)(2))

Section 447.203(c)(2) describes requirements for payment proposals that do not meet the requirements in paragraph (c)(1), requiring the State to provide the nature of the change and policy purpose, the rates compared to Medicare and/or other payers pre- and post-reduction or restructuring, counts/trends of actively participating providers by geographic areas, counts of FFS Medicaid beneficiaries residing in geographic areas/characteristics of the beneficiary population, service utilization trends, access to care complaints from beneficiaries, providers, and other interested parties, and the State’s response to access to care complaints.

The information collection requirements at § 447.203(c)(2) applies to those States that submit rate reduction or restructuring SPAs that do not meet one or more of the criteria proposed by § 447.203(c)(1). Using 2019 rate reduction and restructuring SPA figures, we estimate that 17 States will submit rate reduction or restructuring SPAs per year. Then, a 2019 Urban Institute analysis⁴¹² indicates that 22 States (or 43 percent) have rates that meet the 80 percent fee ratio

⁴¹² Zuckerman, S. et al. “Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019.”, *Health Affairs*, Volume 40, Number 2, February 2021, p. 343-348, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00611>, accessed August 31, 2022.

threshold proposed in § 447.203(c)(1)(i) across all services. Although our proposal did not include all services, using this all services amount is our best method to estimate how many States may fall below on any given service without knowing which. Because we cannot predict the amount a State may propose to reduce, once or cumulatively for the SFY, and because failure of any one criterion in § 447.203(c)(1) will require additional analysis under § 447.203(c)(2), we will use that percentage to assess how many States will need to perform additional analysis. Using this percentage, we estimate that 7 (43 percent x 17) of the estimated 17 unique State respondents may submit rate reduction or restructuring SPAs meet the criteria for the streamlined analysis process under proposed § 447.203(c)(1). Therefore, we assume that 10 out of 17 unique annual State respondents who submit rate reduction or restructuring SPAs will also need to perform the additional analysis § 447.203(c)(2).

The required components of the review and analysis in § 447.203(c)(2) are similar to the AMRP requirements found at current § 447.203(b)(1). However, due to the availability of a template for States to facilitate completion of the required analysis, as well as the lack of a requirement to publish the analysis, we anticipate a moderately reduced burden associated with § 447.203(c)(2) when compared to the burden estimated for the AMRPs.

With regard to our requirements, we estimate that it would take: 64 hours at \$55.54/hr for a social science research assistant to gather data, 64 hours at \$106.30/hr for a computer and information analyst to analyze data, 80 hours at \$100.64/hr for a management analyst to structure the analyses and organize output, and 8 hours at \$118.14/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 2,160 hours (10 States x 216 hr) at a cost of \$193,541 (10 States x [(64 hr x \$55.54/hr) + (64 hr x \$106.30/hr) + (80 hr x \$100.64/hr) + (8 hr x \$118.14/hr)]). The total cost is adjusted down to \$96,771 (\$193,541 x 0.50) for States after accounting for the 50 percent Federal administrative match. We solicited public comment on these estimates as well as relevant State

data to further refine the burden and time estimates. We did not receive public comments on this issue, and therefore, we are finalizing as proposed.

We do not assume any additional information collection imposed by the compliance procedures at § 447.203(c)(3).

Table 40 shows our estimated combined annualized burden for § 447.203(c), which includes 17 States for § 447.203(c)(1) and 10 States for § 447.203(c)(2). In total, we estimate an annualized burden of 2,976 (816 hours + 2,160 hours) hours at a cost of \$278,961 (\$85,420 + \$193,541). This cost to States is then adjusted to \$139,481 after the 50 percent Federal administrative reimbursement is applied.

TABLE 40: Summary of Burden Associated with State Analysis Procedures for Rate Reductions or Restructurings (§ 447.203(c))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(c)(1) (initial State analysis)	17	17	Annual	48	816	Varies	85,420	42,710
§ 447.203(c)(2) (additional State analysis)	10	10	Annual	216	2,160	Varies	193,541	96,771
TOTAL	17	27	Annual	264	2,976	Varies	278,961	139,481

D. Burden Summary

TABLE 41: Summary of Annual Burden Estimates

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Beneficiary Cost (\$)
§431.12 (Table 3) (MACs & BACs)	0938-TBD (CMS-10845)	51 States	153	Varies	17,340	Varies	1,665,354	832,676	n/a
§441.301(c)(3) – One-time burden to States (Table 4) (Person-Centered Service Plans)	0938-TBD (CMS-10854)	48 States	48	Varies	528	Varies	65,409	32,704	n/a
§441.301(c)(3) – One-time burden to Managed Care Plans (Table 5) (Person-Centered Service Plans)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	966	Varies	127,650	n/a	n/a
§441.301(c)(7) – One-time burden to States (Table 6) (Grievance Systems)	0938-TBD (CMS-10854)	48 States	48	Varies	24,960	Varies	2,596,493	1,298,246	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Beneficiary Cost (\$)
§441.301(c)(7) – Ongoing burden to States (Table 7) (Grievance Systems)	0938-TBD (CMS-10854)	48 States	29,255	Varies	16,206	Varies	1,135,949	567,975	n/a
§441.302(a)(6) – One-time burden to States (Table 8) (Incident Management System)	0938-TBD (CMS-10854)	48 States	96	Varies	19,872	Varies	124,958,292	62,479,146	n/a
§441.302(a)(6) – Ongoing burden to States (Table 9) (Incident Management System)	0938-TBD (CMS-10854)	48 States	283,542	Varies	15,177	Varies	24,778,520	12,389,260	n/a
§441.302(a)(6) – Ongoing burden to Service Providers (Table 10) (Incident Management System)	0938-TBD (CMS-10854)	15,742 Providers	28,345	1	28,345	118.14	3,348,678	n/a	n/a
§441.302(a)(6) – One-time burden to Managed Care Plans (Table 11) (Incident Management System)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	26,726	Varies	2,712,747	n/a	n/a
§441.302(a)(6) – Ongoing burden to Managed Care Plans (Table 12) (Incident Management System)	0938-TBD (CMS-10854)	161 Managed Care Plans	6,964	Varies	5,476	Varies	535,791	n/a	n/a
§441.311(b)(1) Ongoing burden to States (Table 25) (Incident Management System Assessment)	0938-1362 (CMS-10692)	48 States	48	Varies	96	Varies	8,326	4,163	n/a
§ 441.311(e) – One-time burden to States (Table 13) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	7,776	Varies	850,285	425,173	n/a
§ 441.311(e) – Ongoing burden to States (Table 14) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	1,200	Varies	121,302	60,651	n/a
§ 441.311(e) – One-time burden to service providers (Table 15) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	15,642 Providers	15,642	Varies	1,298,286	Varies	116,591,088	n/a	n/a
§ 441.311(e) – Ongoing burden to service providers (Table 16) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	15,642 Providers	15,642	Varies	328,482	Varies	30,743,100	n/a	n/a
§ 441.311(e) – One-time burden to managed care plans (Table 17) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	20,286	Varies	1,989,464	n/a	n/a
§ 441.311(e) – Ongoing burden to managed care plans (Table 18) (Payment Adequacy Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	1,610	Varies	203,607	n/a	n/a
§ 441.302(k) One-time burden to States (Table 33) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	48 States	48	Varies	10,944	Varies	1,169,295	584,648	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Beneficiary Cost (\$)
§ 441.302(k) Ongoing burden to States (Table 34) (HCBS Payment Adequacy)	0938-TBD (CMS-10854)	Varies	1,203	Varies	866	Varies	101,698	50,849	n/a
§441.303(f)(6), § 441.311(d)(1) – One-Time burden to States (Table 19) (Supporting Documentation for HCBS Access)	0938-TBD (CMS-10854)	39 States	39	Varies	1,599	Varies	178,777	89,388	n/a
§441.303(f)(6), § 441.311(d)(1) – Ongoing burden to States (Table 20) (Supporting Documentation for HCBS Access)	0938-TBD (CMS-10854)	39 States	39	Varies	585	Varies	72,778	36,389	n/a
§441.311(d)(2)(i) One-Time burden to States (Table 21) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	8,016	Varies	839,954	419,977	n/a
§441.311(d)(2)(i) Ongoing burden to States (Table 22) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	48 States	48	Varies	3,168	Varies	340,861	170,431	n/a
§441.311(d)(2)(i) One-Time burden to managed care plans (Table 23) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	12,397	Varies	1,305,923	n/a	n/a
§441.311(d)(2)(i) Ongoing burden to managed care plans (Table 24) (Additional HCBS Access Reporting)	0938-TBD (CMS-10854)	161 Managed Care Plans	161	Varies	6,762	Varies	726,983	n/a	n/a
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 26)	0938–0272 (CMS–372(S))	48 States	253	(44)	(11,132)	75.32	(891,451)	(445,725)	n/a
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)-(4) (Table 27)	0938-TBD (CMS-10854)	48 States	48	Varies	2,640	Varies	231,952	115,976	n/a
§441.311(c) One-time burden to States (Table 28) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	48 States	48	Varies	64,560	Varies	5,301,830	2,650,915	n/a
§441.311(c) Ongoing burden to States (Table 29) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	24 States	24	Varies	58,920	Varies	4,202,621	2,101,310	n/a
§441.311(c) Ongoing burden to beneficiaries (Table 30) (HCBS Quality Measure Set)	0938-TBD (CMS-10854)	48,000 Beneficiaries	24,000	0.75	18,000	20.71	n/a	n/a	372,780
§441.313 One-time burden to States (Table 31) (Website Transparency)	0938-TBD (CMS-10854)	48 States	48	Varies	5,232	Varies	547,385	273,693	n/a
§441.313 Ongoing burden to States (Table 32) (Website Transparency)	0938-TBD (CMS-10854)	48 States	192	Varies	6,336	Varies	709,359	354,680	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number)	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Beneficiary Cost (\$)
Removal of § 447.203(b)(1)-(6)(i) (Table 36) (Removal of AMRP)	0938–1134 (CMS–10391)	51 States and Territories	17	(310)	(5,270)	<i>varies</i>	(465,729)	(232,865)	n/a
Removal of § 447.203(b)(6)(ii) (Table 36) (Removal of AMRP)	0938–1134 (CMS–10391)	51 States and Territories	22	(67)	(1,474)	<i>varies</i>	(149,498)	(74,749)	n/a
§ 447.203(b)(1) (Table 37) (Rate transparency)	0938–1134 (CMS–10391)	51 States and Territories	26	4	104	<i>varies</i>	8,042	4,021	n/a
§ 447.203(b)(2) (Table 37) (Rate analysis)	0938–1134 (CMS–10391)	51 States and Territories	26	83	2,158	<i>varies</i>	190,107	95,053	n/a
§ 447.203(b)(6) (Table 38) (advisory group)	0938–1134 (CMS–10391)	51 States and Territories	26	7	182	<i>varies</i>	24,361	12,181	n/a
§ 447.203(c)(1) (Table 39) (initial State analysis)	0938–1134 (CMS–10391)	51 States and Territories	17	48	816	<i>varies</i>	85,420	42,710	n/a
§ 447.203(c)(2) (Table 39) (additional State analysis)	0938–1134 (CMS–10391)	51 States and Territories	12	216	2,160	<i>varies</i>	193,541	96,771	n/a
TOTAL		Varies	407,029	Varies	2,200,901	Varies	327,156,264	84,435,647	372,380

IV. Regulatory Impact Analysis

A. Statement of Need

1. Medicaid Advisory Committee

The changes to § 431.12 are intended to provide beneficiaries a greater voice in State Medicaid programs. In making policy and program decisions, it is vital for States to include the perspective and experience of those served by the Medicaid program. States are currently required to operate a MCAC, made up of health professionals, consumers, and State representatives to “advise the Medicaid agency about health and medical care services.” This rule establishes new requirements for a MAC in place of the MCAC, with additional membership requirements to include a broader group of interested parties, to advise the State Medicaid agency on matters related to the effective administration of the Medicaid program. We seek to expand the viewpoints represented on the MAC, to provide States with richer feedback on Medicaid program and policy issues. States are already required to set up and use MCACs. The changes will result in the State also setting up a smaller group, the BAC, which will likely have a cost implication. The additional cost will depend on whether or not States already have a beneficiary committee – we know that many States already do. This smaller group which feeds into the larger MAC will benefit the Medicaid program by creating a forum for beneficiaries to weigh in on key topics and share their unique views as Medicaid program participants. The new provisions of § 431.12 also enhance transparency and accountability through public reporting requirements related to the operation and activities of the MAC and BAC, and guidelines for operation of both bodies.

2. Home and Community-Based Services (HCBS)

The proposed changes at part 441, subpart G, seek to amend and add new Federal requirements, which are intended to improve access to care, quality of care, and health outcomes, and strengthen necessary safeguards that are in place to ensure health and welfare, and promote health equity for people receiving Medicaid-covered HCBS. The provisions in this final rule are

intended to achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs in accordance with section 2402(a) of the Affordable Care Act, and is made applicable to part 441, subparts J, K, and M, as well as part 438 to achieve these goals.

Specifically, the proposed rule seeks to: strengthen person-centered services planning and incident management systems in HCBS; require minimum percentages of Medicaid payments for certain HCBS to be spent on compensation for the direct care workforce; require States to establish grievance systems in FFS HCBS programs; report on waiver waiting lists in section 1915(c) waiver programs, service delivery timeframes for certain HCBS, and a standardized set of HCBS quality measures; and promote public transparency related to the administration of Medicaid-covered HCBS through public reporting on measures related to incident management systems, critical incidents, person-centered planning, quality, access, and payment adequacy.

In 2014, we released guidance⁴¹³ for section 1915(c) waiver programs, which described a process in which States were to report on State-developed performance measures to demonstrate that they meet the six assurances that are required for section 1915(c) waiver programs. Those six assurances include the following:

1. Level of Care: The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facilities for Individuals with Intellectual Disabilities.

2. Service Plan: The State demonstrates it has designed and implemented an effective system for reviewing the adequacy of service plans for waiver participants.

3. Qualified Providers: The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers.

⁴¹³ https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.

4. Health and Welfare: The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.

5. Financial Accountability: The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program.

6. Administrative Authority: The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.

Despite these assurances, there is evidence that State HCBS systems still need to be strengthened and that there are gaps in existing reporting requirements. We believe that this final rule is necessary to address these concerns and strengthen HCBS systems. The requirements in this final rule are intended to supersede and fully replace reporting and performance expectations described in the 2014 guidance for section 1915(c) waiver programs. They are also intended to promote consistency and alignment across HCBS programs, as well as delivery systems, by applying the requirements (where applicable) to sections 1915(i), (j), and (k) authorities State plan benefits and to both FFS and managed care delivery systems.

3. Fee-for-Service (FFS)

Provisions under § 447.203 from this final rule will impact States' required documentation of compliance with section 1902(a)(30)(A) of the Act to "assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." We have received comments from State agencies that the existing AMRP requirement first established by the 2015 final rule with comment period imposes excessive administrative burden for its corresponding value in demonstrating compliance with section 1902(a)(30)(A) of the Act.

This final rule will replace the existing AMRP requirement with a more limited payment rate transparency requirement under proposed § 447.203(b), while requiring a more detailed access impact analysis (as described at proposed § 447.203(c)(2)) when a State proposes provider rate reductions or restructurings that exceed certain thresholds for a streamlined analysis process under proposed § 447.203(c)(1). By limiting the data collection and publication requirements imposed on all States, while targeting certain provider rate reductions or restructuring proposals for a more detailed analysis, this final rule will provide administrative burden relief to States while maintaining a transparent and data-driven process to assure State compliance with section 1902(a)(30)(A) of the Act.

B. Overall Impact

We have examined the impacts of this rule as required by EO 12866 on Regulatory Planning and Review (September 30, 1993), EO 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), EO 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 et seq.), OMB's Office of Information and Regulatory Affairs has determined that this final rule does meet the criteria set forth in 5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity,

competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for rules that meet section 3(f)(1) of the Executive Order. This final rule does meet that criterion as the aggregate amount of benefits and costs may meet the \$200 million threshold in at least 1 year.

Based on our estimates using a "no action" baseline in accordance with OMB Circular A-4, (available at

https://www.whitehouse.gov/wpcontent/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf),

OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is significant or otherwise meets section 3(f)(1). Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

As mentioned in the prior section, and in accordance with OMB Circular A-4, the following estimates were determined using a "no action" baseline. That is, our analytical baseline for impact is a direct comparison between the provisions and not proposing them at all.

1. Benefits

a. Medicaid Advisory Committees (MAC)

We believe the changes to § 431.12 will benefit State Medicaid programs and those they serve by ensuring that beneficiaries have a significant role in advising States on the experience of receiving health care and services through Medicaid. These benefits cannot be quantified.

However, the BAC and a more diverse and transparent MAC will provide opportunities for richer interested parties feedback and expertise to positively impact State decision making on

Medicaid program and policy changes. For example, beneficiary feedback on accessing health care services and the quality of those services can inform decisions on provider networks and networks adequacy requirements. Issues that States need to address, like cultural competency of providers, language accessibility, health equity, and disparities and biases in the Medicaid program, can be revealed through beneficiary experiences. The MAC falls into the Public Administration 921 Executive, Legislative, and Other General Government Support.

b. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

The changes benefit Medicaid beneficiaries and States by requiring States to demonstrate through reporting requirements that they provide safeguards to assure eligibility for Medicaid-covered care and services is determined and provided in a manner that is in the Medicaid beneficiaries' best interest, although these potential benefits cannot be monetarily quantified at this time. The changes will provide further safeguards that ensure health and welfare by strengthening the person-centered service plan requirements, establishing grievance systems, amending requirements for incident management systems, and establishing new reporting requirements for States, and contracted managed care plans identified by the North American Industry Classification System (NAICS) industry code (Direct Health and Medical Insurance Carriers (524114)).

These changes will benefit individuals on HCBS waiver wait lists, and individuals who receive homemaker, home health aide, personal care, and habilitation services under the finalized regulations found at §§ 441.301(c), 441.302(a)(6), 441.302(h), 441.303(f), 441.311, 441.725, and amended regulations in §§ 441.464, 441.474, 441.540, 441.555, 441.570, 441.580, and 441.745. These benefits cannot be monetarily quantified at this time.

c. Home and Community-Based Services (HCBS) Payment Adequacy and Payment Adequacy Reporting

This final rule adds a new reporting requirement at § 441.311(e) (and amends §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii)) to require States to demonstrate through

reporting what percent of payments to providers of certain HCBS (homemaker, home health aide, personal care, and habilitation services) are spent on compensation to direct care workers. The goal of this requirement is to promote transparency and to assure that payments are consistent with efficiency, economy, and quality of care, in accordance with section 1902(a)(30)(A) of the Act. This final rule seeks to address access to care that is being affected by direct care workforce shortages. States will be required to report annually and will be required to separately report on payments for services that are self-directed and services that include facility costs. benefit from reporting in the aggregate for each service subject to the requirement across HCBS programs and delivery systems, which minimizes administrative burden while providing us better oversight of compensation of the direct care workforce. These potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

Additionally, through this final rule, we are finalizing § 441.302(k), which establishes certain minimum thresholds for the percent of Medicaid payments for certain HCBS must be spent on compensation for direct care workers. We believe this requirement will help to ensure that payments to workers are sufficient to provide access to care that is at least comparable to that of the general population in the same geographic location, in accordance with section 1902(a)(30)(A) of the Act. We are also finalizing a number of flexibilities to allow States to address needs of specific providers, such as providers that are small or rural, or are experiencing particular hardship that would temporarily prevent the provider from adhering to the minimum payment level. Through this requirement, we can better ensure payment adequacy to a provider population experiencing worker shortages that impact beneficiary access. While we believe this requirement will promote increases in direct care worker compensation in some regions, these potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

d. Home and Community-Based Services (HCBS) Quality Measure Set Reporting

As described in section II.B.8. of this final rule, on July 21, 2022, we issued State

Medicaid Director Letter (SMDL) # 22-003⁴¹⁴ to release the first official version of the HCBS Quality Measure Set. This final rule provides definitions and sets forth requirements at § 441.312 that expand on the HCBS Quality Measure Set described in the SMDL. By expanding and codifying aspects of the SMDL, we can better drive improvement in quality of care and health outcomes for beneficiaries receiving HCBS. States will also benefit from the clarity afforded by this final rule, and from the assurance that other States they may be looking to for comparison are adhering to the same requirements. The clarity and assurance, at this time, cannot be measured.

e. Fee-for-Service (FFS) Payment Transparency

The changes to § 447.203 will update requirements placed on States to document access to care and service payment rates. The updates create a systematic framework through which we can assess compliance with section 1902(a)(30)(A) of the Act, while reducing existing burden on States and maximizing the value of their efforts, as described in section III.C.11.a. of this rule.

The payment rate transparency provisions at § 447.203(b) create a process that will facilitate transparent oversight by us and other interested parties. By requiring States to calculate Medicaid payment rates as a percent of corresponding Medicare payment rates, this provision offers a uniform benchmark through which CMS and interested parties can assess payment rate sufficiency. When compared to the existing AMRP requirement, the rate analysis proposed by § 447.203(b) should improve the utility of the reporting, while reducing the associated administrative burden, as reflected in the Burden Estimate Summary Table 38. Updates at § 447.203(c) specify required documentation and analysis when States propose to reduce or restructure provider payment rates. By establishing thresholds at § 447.203(c)(1), this final rule will generally limit the more extensive access review prescribed by § 447.203(c)(2) to those SPAs that we believe more likely to cause access concerns. In doing so, these proposed updates reduce the State administrative burden imposed by existing documentation requirements for

⁴¹⁴ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

proposed rate reductions or restructurings, without impeding our ability to ensure proposed rate reduction and restructuring SPAs comply with section 1902(a)(30)(A) of the Act. These burden reductions are reflected in the Collection of Information section of this rule.

When considering the benefits of these regulatory updates, we considered the possibility that the improved transparency required by § 447.203(b) could create upward pressure on provider payment rates, and that the tiered nature of documentation requirements set by § 447.203(c) could create an incentive for States to moderate proposed payment reductions or restructurings that were near the proposed thresholds that would trigger additional analysis and documentation requirements. If either of these rate impacts were to occur, existing literature implies there could be follow-on benefits to Medicaid beneficiaries, including but not limited to increased physician acceptance rates,⁴¹⁵ increased appointment availability,⁴¹⁶ and even improved self-reported health.⁴¹⁷ However, nothing in this final rule will require States to directly adjust payment rates, and we recognize that multiple factors influence State rate-setting proposals, including State budgetary pressures, legislative priorities, and other forces. These competing influences create substantial uncertainty about the specific impact of the provisions at § 447.203 on provider payment rate-setting and beneficiary access. Rather, the specific intent and anticipated outcome of these provisions is the creation of a more uniform, transparent, and less burdensome process through which States can conduct required payment rate and access analyses and we can perform our oversight role related to provider payment rate sufficiency.

2. Costs

a. Medicaid Advisory Committee (MAC)

In addition to the costs reflected in section III.C.1 of this final rule, States will incur additional ongoing costs (estimated below in Table 42) in appointing and recruiting members to

⁴¹⁵ Holgash, K. and Martha Heberlein, *Health Affairs*, April 10, 2019.

⁴¹⁶ Candon, M., et al. *JAMA Internal Medicine*, January 2018, p. 145-146.

⁴¹⁷ Alexander, D., and Molly Schnell. “The Impacts of Physician Payments on Patient Access, Use, and Health”, National Bureau of Economic Research, Working Paper 26095, July 2019 (revised August 2020), p. 1-74. <https://www.nber.org/papers/w26095>. Accessed June 16, 2022.

the MAC and BAC and, also developing and publishing bylaws, membership lists, and meeting minutes for the MAC and BAC. All of these costs can be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support) since States are the only entity accounted for in the MAC and BAC. How often these costs occur will also vary in how often the State chooses to make changes such as add or replace members of the MAC and BAC or change its bylaws. Additionally, there will be new, ongoing costs, estimated below, for States related to meeting logistics and administration for the BAC. All of these new costs can also be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support). To derive average costs, as in the previous section of this final rule, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2022 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/2022/may/oes_nat.htm). Costs include our estimated cost of fringe benefits and other indirect costs, calculated at 100 percent of salary, in our adjusted hourly wage.

Since most States are already holding MAC meetings under current regulatory requirements, any new costs related to MAC requirements would likely be minimal. In terms of the MAC and BAC meeting costs, we estimate a total cost for 5 years of \$3.414 million or \$682,821 annually for States. We estimate it will take a business operations specialist 10 hours to plan and execute each BAC meeting, at a total cost of \$162,180 ($\$79.50/\text{hour} \times 10 \text{ hours} \times 4 \text{ meetings/year} \times 51 \text{ States and the District of Columbia}$). To satisfy the requirements of § 431.12(h)(3)(i), a public relations specialist will spend an estimated 80 hours/year supporting Medicaid beneficiary MAC and BAC members at a total cost of \$308,122 ($\$75.50/\text{hour} \times 80 \text{ hours} \times 51 \text{ States and the District of Columbia}$). A chief executive in State government, as required by § 431.12(h)(3)(iii) will spend a total of 8 hours a year attending BAC meetings, which we estimate will be 2 hours in duration, 4 times a year at a total cost of \$ 49,319 ($\$120.88/\text{hour} \times 2 \text{ hours/meeting} \times 4 \text{ meetings} \times 51 \text{ States and the District of Columbia}$). Each meeting of the BAC will cost States an estimated \$200 in meeting costs and telecommunication,

at an annual total cost of \$40,800 (\$200 x 4 meetings) x 51 States and the District of Columbia).

The meeting costs are estimated by adding the average cost for telecommunications (approximately \$130⁴¹⁸ per meeting) to the average cost of meeting supplies (approximately \$70 per meeting for photocopies, name tags, etc.). While we cannot estimate precisely the costs for meeting materials and additional items to support meetings, we are including a nominal estimate of \$70 per meeting to acknowledge these costs.

There will also be a per meeting cost to States for financial support for beneficiary members participating in MAC and BAC meetings, as described in § 431.12(h)(3)(ii). We estimate a cost of \$75/beneficiary/meeting in the form of transportation vouchers, childcare reimbursement, meals, and/or other financial compensation. Assuming 4 meetings per year (with BAC and MAC meetings co-located and occurring on the same day) and an average of 8 beneficiary members on the BAC and MAC, the cost of financial support for beneficiary members across States is estimated to cost approximately \$122,400 annually (($\$75/\text{beneficiary} \times 8 \text{ beneficiaries} \times 4 \text{ meetings/year}$) x 51 States and the District of Columbia). This cost will vary depending on the decisions States make around financial support, the number of beneficiary members of the BAC and MAC, and the number of meetings per year. We solicited comment on the costs associated with planning, execution, and participation in the MAC and BAC meetings.

We did not receive public comments specifically on these estimates, and therefore, we are finalizing as proposed.

⁴¹⁸ Sources: <https://www.usnews.com/360-reviews/business/best-conference-calling-services>; <https://money.com/best-conference-calling-services/>

TABLE 42: Projected Ten Year Costs for Proposed Updates

Provision	Year										Total CY 2024-2033 (\$ in millions)
	Year One (\$ in millions)	Year Two (\$ in millions)	Year Three (\$ in millions)	Year Four (\$ in millions)	Year Five (\$ in millions)	Year Six (\$ in millions)	Year Seven (\$ in millions)	Year Eight (\$ in millions)	Year Nine (\$ in millions)	Year Ten (\$ in millions)	
§ 431.12 MAC & BAC logistic and admin support	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	0.560	5.6
§ 431.12 Financial support to MAC/BAC beneficiary members (cost will range per State)	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	0.122	1.22
Total	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	0.682	6.82
Costs will vary depending by State, on how many in person meetings are held, and how many Medicaid beneficiaries are selected for the MAC and BAC											

b. Home and Community-Based Services (HCBS)

Costs displayed in Table 43 are inclusive of both one-time and ongoing costs. One-time costs are split evenly over the years leading up to the provision’s applicability date. For example, if a finalized provision is applicable 3 years after the final rule’s publication, the one-time costs would be split evenly across each of the years leading to that applicability date. Please note the following applicability dates (beginning after the effective date of this final rule): 2 years for the grievance process requirements finalized at § 441.302(c)(7); 3 years for the person-centered planning, incident management, changes to Form 372(S), access reporting, and website transparency requirements finalized at §§ 441.301(c)(3), 441.302(a)(6), 441.311(b), 441.311(d) and 441.313, respectively; 4 years for the reporting requirements for the HCBS Quality Measure Set and for payment adequacy reporting finalized at § 441.311(c) and (e), respectively; 5 years for the electronic incident management system requirement at § 441.302(a)(6); and 6 years for the HCBS payment adequacy requirements finalized at § 441.302(k). The estimates below do not account for higher costs associated with medical care, as the costs are related exclusively to reporting costs. Costs to States, the Federal government, and

managed care plans do not account for enrollment fluctuations, as they assume a stable number of States operating HCBS programs and managed care plans delivering services through these programs. Similarly, costs to providers and beneficiaries do not account for enrollment fluctuations. In the COI section, costs are based on a projected range of HCBS providers and beneficiaries. Given this uncertainty, here, we based cost estimates on the mid-point of the respective ranges and kept those assumptions consistent over the course of the 5-year projection. Per OMB guidelines, the projected estimates for future years do not include ordinary inflation. (that is, they are reported in constant-year dollars).

Table 44 summarizes the estimated ongoing costs for States, managed care plans (Direct Health and Medical Insurance Carriers (NAICS 524114)), and providers (Services for the Elderly and Persons with Disabilities (NAICS 624120) and Home Health Care Services (NAICS 621610)) from the Collection of Information section (section III. of this final rule) of the HCBS provisions of the final rule projected over 10 years. This comprises the entirety of anticipated quantifiable costs associated with changes to part 441, subpart G. It is also possible that increasing the threshold from 86 percent to 90 percent for compliance reporting at § 441.311(b)(2) through (3) may lead to additional costs to remediate issues pertaining to critical incidents or person-centered planning. However, the various avenues through which States could address these concerns creates substantial uncertainty as to what those costs may be. While we acknowledge the potential for increased costs in a limited number of States that may fall within the gap between the existing and the compliance thresholds, we do not quantify them here.

TABLE 43: Projected 10-Year Costs for Updates to 441 Subparts G, J, K, and M

Provision Costs (in millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Projected 10-year total*
§ 441.301(c)(3) (Person-Centered Service Plans)	0.06	0.06	0.06	-	-	-	-	-	-	-	0.19
§ 441.301(c)(7) (Grievance Systems)	1.30	1.30	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.14	11.68
§ 441.302(a)(6) (Incident Management System)	1.56	1.56	1.56	28.66	28.66	28.66	28.66	28.66	28.66	28.66	205.31
§ 441.302(a)(6) (Incident Management System – Electronic Incident Management System)	24.60	24.60	24.60	24.60	24.60	0	0	0	0	0	123.00
§ 441.311(b)(1)(Incident Management System Assessment)	-	-	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.06
§ 441.311(e) (Payment Adequacy Reporting)	29.86	29.86	29.86	29.86	31.07	31.07	31.07	31.07	31.07	31.07	305.84
§ 441.302(k) (HCBS Payment Adequacy)	0.19	0.19	0.19	0.19	0.19	0.19	0.24	0.24	0.24	0.24	2.12
§441.303(f)(6), § 441.311(d)(1) (Supporting Documentation for HCBS Access)	0.06	0.06	0.06	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.69
§441.311(d)(2)(i) (Additional HCBS Access Reporting)	0.71	0.71	0.71	1.07	1.07	1.07	1.07	1.07	1.07	1.07	9.62
Removal of Current Form 372(S) Ongoing Reporting Information Collection	-	-	-	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(0.89)	(6.24)
Form 372(S) Reporting Requirement to include § 441.311(b)(2)-(4)	-	-	-	0.23	0.23	0.23	0.23	0.23	0.23	0.23	1.62
§441.311(c) (HCBS Quality Measure Set)	1.33	1.33	1.33	1.33	4.58	4.58	4.58	4.58	4.58	4.58	32.75
§441.313 (Website Transparency)	0.18	0.18	0.18	0.71	0.71	0.71	0.71	0.71	0.71	0.71	5.51
Total*	59.85	59.85	59.69	87.00	91.44	66.84	66.88	66.88	66.88	66.88	692.17

* Totals were calculated based on actual figures, so the total row and projected 10-year total column may appear slightly different than had they been calculated based on estimates to the nearest million.

The costs displayed in Table 44 are inclusive of costs anticipated to be incurred by State Medicaid agencies, the Federal government, providers, managed care plans, and beneficiaries.

Table 44 distributes those costs across these respective entities.

TABLE 44: Projected Distribution of Costs for Updates to 42 CFR 441 Subpart G, J, K, and M

Costs (in millions)	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Projected 10-year total*
State Costs	14.41	14.41	14.34	26.36	27.75	15.45	15.41	15.41	15.41	15.41	175.35
Federal Government Costs	14.41	14.41	14.34	26.36	27.75	15.45	15.41	15.41	15.41	15.41	175.35
Managed Care Plan Costs	1.88	1.88	1.88	1.76	1.47	1.47	1.47	1.47	1.47	1.47	16.20
HCBS Provider Costs	29.15	29.15	29.15	32.50	34.09	34.09	34.23	34.23	34.23	34.23	325.03
Beneficiary costs	0	0	0	0	0.37	0.37	0.37	0.37	0.37	0.37	2.24
Total*	59.86	59.86	59.70	91.44	66.84	66.88	66.88	66.88	66.88	66.88	692.17

* Totals were calculated based on actual figures, so the total row and projected 10-year total column may appear slightly different than had they been calculated based on estimates to the nearest million.

c. Fee-for-Service (FFS) Payment Rate Transparency

The costs associated with the payment rate transparency proposals are wholly associated with information collection requirements, and as such those impacts are reflected in the COI section of this rule. For ease of reference, and for projection purposes, we are including those costs here in Table 45.

TABLE 45: Projected 5-Year State Costs for Updates to 42 CFR 447.203

Provision	Calendar year (CY)					Total CY 2024-2028 (\$ in millions)
	2024 (\$ in millions)	2025 (\$ in millions)	2026 (\$ in millions)	2027 (\$ in millions)	2028 (\$ in millions)	
Removal of current § 447.203 (AMRPs)	-0.615	-0.615	-0.615	-0.615	-0.615	-3.075
§ 447.203(b)	0.516	0.254	0.254	0.254	0.254	1.532
§ 447.203(c)(SPAs)	0.279	0.279	0.279	0.279	0.279	1.395
Total	0.18	-0.082	-0.082	-0.082	-0.082	-0.148

TABLE 46: NAICS Classification of Services and Their Distribution of Costs

Services	NAICS	Percentage of Costs
Managed Care Plans	Direct Health and Medical Insurance Carriers (524114)	100 Percent
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent

TABLE 47: One Time and Annual Costs Detailed

	Cost to States (\$)	Cost to Beneficiaries (\$)	Cost to Providers (\$)	Cost to Managed	Costs to Federal	One Time Burden	Annual Burden
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				Care Plans (\$)	Government (\$)	Overall Total (\$)	Overall Total (\$)
Regulatory Review	19,587.06	39,174.12	-	61,833.66	-	120,594.84	0
§ 431.12 Medical Care Advisory Committee Requirements	790,795	-	-		790,795	-	1,581,590
§ 441.301(c)(3) (Person-Centered Service Plans) (One-time Costs) (Tables 4, 5)	32,704	-	-	127,650	32,704	193,059	-
§ 441.301(c)(7) (Grievance Systems) (One-time Costs) (Table 6)	1,298,246	-	-	-	1,298,246	2,596,493	-
§441.301(c)(7) (Grievance Systems) (Ongoing Costs) (Table 7)	567,975	-	-	-	567,975	-	1,135,949
§ 441.302(a)(6) (Incident Management System) (One-time Costs) (Tables 8, 11)	62,479,146	-	-	2,712,747	62,479,146	127,671,039	-
§ 441.302(a)(6) (Incident Management System) (Ongoing Costs) (Tables 9, 10, 12)	12,389,260	-	3,348,678	535,791	12,389,260	-	28,662,989
§ 441.311(b)(1) (Incident Management System Assessment) (Ongoing Costs) (Table 25)	4,163	-	-	-	4,163	-	
§ 441.311(e) (Payment Adequacy Reporting) (One-time Costs) (Tables 13, 15, 17)	425,173	-	116,591,088	1,989,464	425,173	119,430,837	-
§ 441.311(e) (Payment Adequacy Reporting) (Ongoing) (Tables 15, 16, 18)	60,651	-	30,743,100	203,607	60,652	-	31,068,009

§ 441.302(k) (HCBS Payment Adequacy) (One-time Costs) (Table 33)	584,648	-	-	-	584,648	1,169,295	-
§ 441.302(k) (HCBS Payment Adequacy) (Ongoing Costs) (Tables 34, 36)	50,849	-	136,452	-	50,849	-	238,150
§§ 441.303(f)(6) and 441.311(d)(1) (Supporting Documentation for HCBS Access) (One- time Costs) (Table 19)	89,388	-	-	-	89,388	178,777	-
§§ 441.303(f)(6) and 441.311(d)(1) (Supporting Documentation for HCBS Access) (Ongoing Costs) (Table 20)	36,389	-	-	-	36,389	-	72,778
§ 441.311(d)(2)(i) (HCBS Access Reporting) (One-time Costs) (Tables 21, 23)	419,977	-	-	1,305,923	419,977	2,140,427	-
§ 441.311(d)(2)(i) (HCBS Access Reporting) (Ongoing Costs) (Tables 22, 24)	170,431	-	-	726,983	170,431	-	1,067,845
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Ongoing Costs) (Table 26)	(445,725)	-	-	-	(445,725)	-	(891,450)
Form 372(S) Reporting Requirement to include §	115,976	-	-	-	115,976	-	231,952

441.311(b)(2) through (4) (Ongoing Costs) (Table 27)							
§ 441.311(c) (HCBS Quality Measure Set) (One-time Costs) (Table 28)	2,650,915	-	-	-	2,650,915	5,302,480	-
§ 441.311(c) (HCBS Quality Measure Set) (Ongoing Costs) (Tables 29, 30)	2,101,310	372,780	-	-	2,101,310	-	4,575,400
§ 441.313 (Website Transparency) (One-time Costs) (Table 31)	273,693	-	-	-	273,693	547,385	-
§ 441.313 (Website Transparency) (Ongoing Costs) (Table 32)	354,680	-	-	-	354,680	-	709,359
Removal of § 447.203(b)(1) through (6) (Removal of AMRP) (Table 36)	(307,614)	-	-	-	307,614)	(615,228)	-
§ 447.203(b)(1) (Rate transparency) (Table 36)	23,453	-	-	-	23,453	39,195	7,712
§ 447.203(b)(2) (Rate analysis) (Table 37)	87,103	-	-	-	87,103	-	174,206
§ 447.203(b)(6) (advisory group) (Table 38)	145,386	-	-	-	145,386	267,934	22,837
§ 447.203(c)(1) (initial State analysis) (Table 40)	40,678	-	-	-	40,678	-	81,356
§ 447.203(c)(2) (additional State analysis) (Table 40)	92,716	-	-	-	92,716	-	185,432

3. Transfers

Transfers are payments between persons or groups that do not directly affect the total resources available to society. They are a benefit to recipients and a cost to payers, with zero net effects. Because this rule proposes changes to requirements to State agencies without changes to payments from Federal to State governments, the transfer impact is null, and cost impacts are reflected in the other sections of this rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. There is uncertainty involved with accurately quantifying the number of entities that will review the rule. However, for the purposes of this final rule we assume that on average, each of the 51 affected State Medicaid agencies will have one contractor per State review this final rule. This average assumes that some State Medicaid agencies may use the same contractor, others may use multiple contractors to address the various provisions within this final rule, and some State Medicaid agencies may perform the review in-house. We also assume that each affected managed care plan (estimated in the COI section to be 161 managed care plans) will review the final rule. Lastly, we assume that an average of two advocacy or interest group representatives from each State will review this final rule. In total, we are estimating that 314 entities (51 State Contractors + 161 Managed Care Plans + 102 Advocacy and Interest Groups) will review this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We did not receive public comment on this issue.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We solicited comments on this assumption.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

Using the wage information from the Bureau of Labor Statistics, https://www.bls.gov/oes/current/oes_nat.htm, we are considering medical and health service managers (Code 11-9111), as including the 51 State Contractors, 161 Managed Care Plans and 102 Advocacy and Interest Groups identified in this final rule, and we estimate that the cost of reviewing this rule is \$123.06 per hour, including fringe benefits and other indirect costs. Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 6.67 hours for each individual to review half of this final rule ($[200,000 \text{ words} \times 0.5] / 250 \text{ words per minute} / 60 \text{ minutes per hour}$). For each entity that reviews the rule, the estimated cost is \$820.40 (6.67 hours x \$123.06). Therefore, we estimate that the total one-time cost of reviewing this regulation is \$257,605.60 (\$820.40 per individual review x 314 reviewers).

D. Alternatives Considered

1. Medicaid Advisory Committee (MAC)

In determining the best way to promote beneficiary and interested parties' voices in State Medicaid program decision making and administration, we considered several ways of revising the MCAC structure and administration. We considered setting minimum benchmarks for each category of all types of MAC members, but we viewed it as too restrictive. We ultimately concluded that only setting minimum benchmarks (at least 25 percent) for beneficiary representation on the MAC and requiring representation from the other MAC categories would give States maximum flexibility in determining the exact composition of their MAC. However, we understand that some States may want us to set specific thresholds for each MAC category rather than determine those categories on their own.

We also considered having not having a separate BAC, but we ultimately determined that requiring States to establish a separate BAC assures that there is a dedicated forum for States to receive beneficiary input outside of the MAC. In the MAC setting, a beneficiary might not feel as comfortable speaking up among other Medicaid program interested parties. The BAC also

provides an opportunity for beneficiaries to focus on the issues that are most important to them, and bring those issues to the MAC.

Finally, we also considered setting specific topics for the MAC to provide feedback. However, due to the range of issues specific to each State's Medicaid program, we determined it was most conducive to allow States work with their MAC to identify which topics and priority issues would benefit from interested parties' input.

2. Home and Community-Based Services (HCBS)

a. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

We considered whether to codify the existing 86 percent performance level that was outlined in the 2014 guidance for both person-centered service plans and incident management systems. We did not choose this alternative due to feedback from States and other interested parties of the importance of these requirements, as well as concerns that an 86 percent performance level may not be sufficient to demonstrate that a State has met the requirements.

We considered whether to apply these requirements to section 1905(a) "medical assistance" State Plan personal care, home health, and case management services. We decided against this alternative based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for HCBS delivered under sections 1915(c), (i), (j), and (k) of the Act and because of differences between the requirements of those authorities and section 1905(a) State Plan benefits.

Finally, we considered allowing a good cause exception to the minimum performance level reporting requirements to both the person-centered service plan and the incident management system. We decided against this alternative because the 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Furthermore, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

b. HCBS Payment Adequacy and Payment Adequacy Reporting

We considered several alternatives to this final rule. We considered whether the requirements at § 441.302(k) relating to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with mental illness. As discussed in section II.B.5, we decided against these alternatives because the services (homemaker, home health aide, and personal care) are those for which the vast majority of payment should be comprised of compensation for direct care workers and for which there will be low facility or other indirect costs. We also did not include other services for which the percentage might be variable due to the diversity of services included or for which worker compensation will be reasonably expected to comprise only a small percentage of the payment.

As an alternative to the payment adequacy reporting requirement finalized at § 441.311(e), we considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to collect data from States regarding the percent of Medicaid payments is spent on compensation to direct care workers. We determined, upon reviewing public comment, that collecting the data is necessary to promote transparency and inform future policymaking. We considered whether to require reporting at the delivery system, HCBS waiver program, or population level but decided against additional levels of reporting because it will increase reporting burden for States without providing additional information necessary for demonstrating that Medicaid payments are being allocated efficiently in accordance with section 1902(a)(30)(A) of the Act.

We considered whether to apply both § 441.302(k) and the reporting requirements finalized at § 441.311 to section 1905(a) “medical assistance” State Plan personal care and home health services, but decided not to, largely due to concerns that the statutory and regulatory requirements for section 1905(a) services are different from the statutory and regulatory

requirements for section 1915 services; these differences will require additional consideration and rulemaking should the requirements be applied to section 1905(a) services. States also provided feedback that, for the purposes of § 441.311, they do not have the same data collection and reporting capabilities for these services as they do for sections 1915(c), (i), (j), and (k) HCBS.

c. Supporting documentation requirements

No alternatives were considered.

d. HCBS Quality Measure Set Reporting

We considered giving States the flexibility to choose which measures they will stratify and by what factors but decided against this alternative as discussed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule (see 87 FR 51313). We believe that consistent measurement of differences in health outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.⁴¹⁹

Consistency could not be achieved if each State made its own decisions about which data, it would stratify and by what factors.

3. Payment Rate Transparency

In developing this final rule, we considered multiple alternatives. We considered not proposing this rule and maintaining the status quo under current regulations at § 447.203 and 204. However, as noted throughout the Background and Provisions sections of this rule, since the 2011 proposed rule, we have received concerns from interested parties, including State agencies, about the administrative burden of completing AMRPs and questioning whether they are the most efficient way to determine access to care. These comments expressed particular concern about the AMRPs' value when they are required to accompany a proposed nominal rate reduction or restructuring, or where proposed rate changes are made via application of a

⁴¹⁹ Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. *Health Aff (Millwood)*. 2008;27(2):568-573.

previously approved rate methodology. At the same time, and as we have discussed, in *Armstrong v. Exceptional Child Care, Inc.*, 575 U.S. 320 (2015), the Supreme Court held that Medicaid providers and beneficiaries do not have private right of action against States to challenge State-determined Medicaid payment rates in Federal courts. This decision made our administrative review of SPAs proposing to reduce or restructure payment rates all the more important. For both of these reasons, this rule includes requirements that will create an alternative process that both reduces the administrative burden on States and standardizes and strengthens our review of payment rate reductions or payment restructurings to ensure compliance with section 1902(a)(30)(A) of the Act.

We considered, but did not propose, adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. Although such processes could further our goals of ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act, we concluded similar effects can be achieved through methods that did not require the significant amount of Federal effort that will be necessary to develop either or both of these processes. Additionally, a complaint-driven process will not necessarily ensure a balanced review of State-proposed payment rate or payment structure changes, and it is possible that a large volume of complaints could be submitted with the intended or unintended effect of hampering State Medicaid program operations. Therefore, the impact of adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns may be negligible given existing processes. Instead, we believe that relying on existing processes that States are already engaged in, such as the ongoing provider and beneficiary feedback channels under paragraph (b)(7) in § 447.203 and the public process requirement for States submitting a SPA that are required to reduce or restructure Medicaid service payments in § 447.204, will be more effective than creating a new process. While we are relying on existing public feedback channels and processes that States are already engaged in, we solicited public

comment regarding our alternative consideration to adopting a complaint driven process or developing a Federal review process for assessing access to care concerns.

We also considered numerous variations of the individual provisions of the final rule. We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type, calculate an average Medicaid payment rate of all providers for each E/M CPT code subject to the comparative payment rate analysis. We also considered, but did not propose, different points of comparison other than Medicare under the comparative payment rate analysis proposed under § 447.203(b)(2) or using a peer payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate under the comparative payment rate analysis proposed under § 447.203(b)(2) and (3). We considered, but did not propose, varying timeframes for the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered not proposing the payment rate transparency aspect of this rule proposed under § 447.203(b)(1), leaving the comparative payment rate analysis to replace the AMRP process as proposed under § 447.203(b)(2). With regard to the proposal in § 447.203(c), we considered, but did not propose, establishing alternative circumstances from those described in the 2017 SMDL for identifying nominal payment rate adjustments, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring, using measures that are different from the proposed measures that would be reflected in the forthcoming template, allowing States to use their own unstructured data for

States that fail to meet all three criteria in § 447.203(c)(1), and CMS producing and publishing the comparative payment rate analysis proposed in § 447.203(b).

We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). Maintaining the benefits in previous § 447.203(b)(5)(ii)(A) through (H) might have simplified the transition from the AMRP process to the payment rate transparency and comparative payment rate analysis requirements. However, our experience implementing the 2015 final rule with comment period, as well as interested parties' and States' feedback about the AMRP process, encouraged us to review and reconsider the current list of benefits subject to the AMRP process under current regulations § 447.203(b)(5)(ii)(A) through (H) to determine where we could decrease the level of effort required from States while still allowing ourselves an opportunity to review for access concerns. During our review of the current list of benefits under § 447.203(b)(5)(ii)(A) through (H), we considered, but did not propose, requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis. However, when considering the existing burden of the AMRP process under current § 447.203(b), we believed that expanding the list of benefits to include under proposed § 447.203(b) and (c) would not support our goal to develop a new access strategy that aims to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we solicited public comment on primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i). Additionally, we solicited public comment regarding our alternative consideration to propose maintaining the benefits outlined in the current

§ 447.203(b)(5)(ii)(A) through (H) or propose requiring all mandatory Medicaid benefit categories.

We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis. Rather than proposing States distinguish their Medicaid payment rates by each provider type in the comparative payment rate analysis, we considered proposing States calculate an average Medicaid payment rate of all providers for each E/M CPT code. This consideration would have simplified the comparative payment rate analysis because States would include a single, average Medicaid payment rate amount and only need to separately analyze their Medicaid payment rates for services delivered to pediatric and adult populations, if they varied. However, calculating an average for the Medicaid payment rate has limitations, including sensitivity to extreme values and inconsistent characterizations of the payment rate between Medicaid and Medicare. In this rule, we propose to characterize the Medicare payment rate as the non-facility payment rate listed on the Medicare PFS for the E/M CPT/HCPCS codes subject to the comparative payment rate analysis. If we were to propose the Medicaid payment rate be calculated as an average Medicaid payment rate of all provider types for the same E/M CPT/HCPCS code, then States' calculated average Medicaid payment rate could include a wide variety of provider types, from a single payment rate for physicians to an average of three payment rates for physicians, physician assistants, and nurse practitioners. This wide variation in how the Medicaid payment rate is calculated among States would provide a less meaningful comparative payment rate analysis to Medicare. The extremes and outliers that would be diluted by using an average are not necessarily the same for both Medicaid and Medicare, so even if both sides of the comparison used an average, we would not be able to look more closely at specific large differences between the respective rates. As previously noted in section II. of this final rule, we solicited public comment on the proposed characterization of the Medicaid payment rate, which accounts for variation in payment rates for

pediatric and adult populations and distinguishes payment rates by provider type, in the comparative payment rate analysis. Additionally, we solicited public comment regarding our alternative consideration to propose requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis.

We considered, but did not propose, requiring States to use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer, such as pediatric dental services or HCBS. The impact of requiring a different point of comparison, other than Medicare, would have carried forward the current regulation requiring States to “include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, provider payment rates in Medicaid managed care) and private health insurer payment rates within geographic areas of the State” in their AMRPs. As previously discussed in this rule, FFS States expressed concerns following the 2015 final rule with comment period that private payer payment rates were proprietary information and not available to them, therefore, the challenges to comply with current regulations would be carried forward into the proposed rule. Therefore, we also considered, but did not propose, using various payment rate benchmarking approaches for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. As previously noted in section II. of this final rule, we considered benchmarks based on national Medicaid payment averages for certain services included within the LTSS benefit category, benchmarks that use average daily rates for certain HCBS that can be compared to other State Medicaid programs, and benchmarks that use payment data specific to the State’s Medicaid program for similarly situated services so that the service payments may be benchmarked to national average. Notwithstanding the previously described limitations of the alternative considered for situations where differences between Medicaid and Medicare coverage and payment exists, we solicited public comment regarding our alternative consideration to propose States use a different point of comparison,

other than Medicare, for certain services where Medicare is not a consistent or primary payer or States use a payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. Specifically, we solicited public comment on the feasibility and burden on States to implement these alternatives considered for the proposed comparative payment rate analysis. For any comparison to other State Medicaid programs or to a national benchmark, we also solicited public comment on the appropriate role for such a comparison in the context of the statutory requirement to consider beneficiary access relative to the general population in the geographic area.

We considered, but did not propose, various timeframes for the comparative payment rate analysis, including annual (every year), triennial (every 3 years), or quinquennial (every 5 years) updates after the initial effective date of January 1, 2026. As noted in section II. of this final rule, we did not propose an annual timeframe as we believed that an annual update requirement was too frequent due to many States' biennial legislative sessions that provide the Medicaid agency with authority to make Medicaid payment rate changes as well as create more or maintain a similar level of administrative burden of the AMRPs. While some States do have annual legislative sessions and may have annual Medicaid payment rate changes, we believed that proposing annual updates solely for the purpose of capturing payment rate changes in States that with annual legislative sessions would be overly burdensome and duplicative for States with biennial legislative sessions who do not have new, updated Medicaid payment rates to update in their comparative payment rate analysis. Therefore, for numerous States with biennial legislative sessions, the resulting analysis would likely not vary significantly from year to year.

Additionally, the comparative payment rate analysis proposes to use the most recently published Medicare payment rates and we are cognizant that Medicare payment rate updates often occur on a quarterly basis. While Medicare often increases rates by the market basket inflation amount, as

well as through rulemaking, it does not always result in payment increases for providers.^{420,421}

We also considered, but did not propose, maintaining the triennial (every 3 years) timeframe currently in regulation, because we thought it necessary to make significant changes to the non-SPA-related reported in § 447.203(b) that would represent a significant departure from the initial AMRP process in the 2015 final rule with comment in the current § 447.203(b)(1) and this new proposed approach did not lend itself to the triennial timeframe of the current AMRP process. Lastly, we considered, but did not propose, the comparative payment rate analysis be published on a quinquennial basis (every 5 years), because this timeframe was too infrequent for the comparative payment rate analysis to provide meaningful, actionable information. As previously noted in section II. of this rule, we are solicited public comment on the proposed timeframe for the initial publication and biennial update requirements of the comparative payment rate analysis as proposed in § 447.203(b)(4). Additionally, we solicited public comment regarding our alternative consideration to propose an annual, triennial, or quinquennial timeframe for the updating the comparative payment rate analysis after the initial effective date.

We considered, but did not propose, requiring the comparative payment rate analysis be submitted directly to us, as this would not achieve the public transparency goal of the proposed rule. As proposed in § 447.203(b)(3), we are requiring States develop and publish their Medicaid comparative payment rate analysis on the State’s website in an accessible and easily understandable format. This proposal is methodologically similar to the current regulation, which requires AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance. As previously noted in section II. of this rule,

⁴²⁰ Although “market basket” technically describes the mix of goods and services used in providing health care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term “market basket” as used in this document refers to the various CMS input price indexes. A CMS market basket is described as a fixed-weight, Laspeyres-type index because it measures the change in price, over time, of the same mix of goods and services purchased in the base period. FAQ – Medicare Market Basket Definitions and General Information, updated May 2022. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf> Accessed January 4, 2023.

⁴²¹ Medicare Unit Cost Increases Reported as of April 2022. <https://www.cms.gov/files/document/ffs-trends-2021-2023-april-2022.pdf>. Accessed January 4, 2023.

we solicited public comment on the proposed requirement for States to publish their Medicaid FFS payment rates for all services and comparative payment rate analysis and payment rate disclosure information on the State's website under the proposed § 447.203(b)(1) and (3), respectively. Additionally, we solicited public comment regarding our alternative consideration to propose requiring the comparative payment rate analysis be submitted directly to us and not publicly published.

We considered, but did not propose, that we produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates. Shifting responsibility for this analysis would remove some burden from States and allow us to do a full cross-comparison of State Medicaid payment rates to Medicare payment rates, while ensuring a consistent rate analysis across States. However, this approach would rely on T-MSIS data, which would increase the lag in available data due to the need for CMS to prepare it, and introduce uncertainty into the results due to ongoing variation in State T-MSIS data quality and completeness. Although our proposed approach still relies on State-supplied data, they are able to perform the comparisons on their own regardless of the readiness and compliance of any other State. Furthermore, we would need to validate its results with States and work through any discrepancies. Ultimately, we determined the increased lag time and uncertainty in results would diminish the utility of the rate analyses proposed in § 447.203(b), if performed by us instead of the States, to support our oversight of State compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we solicited public comment on our proposal to require States to develop and publish a comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(2) and (3). Additionally, we solicited public comment regarding our alternative consideration to propose that we produce and publish the comparative

payment rate analysis and payment rate disclosure proposed in § 447.203(b)(2) and (3) for all States.

We considered, but did not propose, establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring. We previously outlined in SMDL #17-004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This final rule will not codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. We considered, but did not propose, setting a different percentage for the criteria that State Medicaid rates for each benefit category affected by the reductions or restructurings must, in the aggregate, be at or above 80 percent of the most recent comparable Medicare payment rates after the proposed reduction or restructuring as a threshold. We considered setting the threshold at 100 percent of Medicare to remain consistent with the 2017 SMDL. However, after conducting a literature review, we determined that 80 percent of the most recently published Medicare payment rates is currently the most reliable benchmark of whether a rate reduction or restructuring is likely to diminish access to care. We also considered, but did not propose, setting a different percentage for the criteria that proposed reductions or restructurings result in no more than 4 percent reduction of overall FFS Medicaid expenditures for a benefit category. We considered a variety of percentages, but determined that codifying the 4 percent threshold from the 2017 SMDL and proposed in the 2018 proposed rule⁴²² was the best option based on our experience implementing this established

⁴²² 83 FR 12696 at 12705.

policy after the publication of the 2017 SMDL. Additionally, we received a significant number of comments in the 2018 proposed rule from State Medicaid agencies that signaled strong support for this percentage threshold as a meaningful threshold for future rate changes.^{423 424 425} Lastly, we considered, but did not propose, defining what is meant by “significant” access concerns received through the public process described in § 447.204 when a State proposes a rate reduction or restructuring. As proposed, we expect State Medicaid agencies to make reasonable determinations about which access concerns are significant when raised through the public process, and as part of our SPA review, may request additional information from the State to better understand any access concerns that have been raised through public processes and whether they are significant. Based on our experience implementing the policies outlined in the 2017 SMDL and a literature review of relevant research about payment rate sufficiency, we proposed criteria for States proposing rate reductions or restructurings that would reduce the SPA submission requirements when those criteria are met. Additionally, each of these thresholds is one of a three-part test where States must meet all three, or else it will trigger a requirement for additional State analysis of the rate reduction or restructuring. As previously noted in section II. of this rule, we solicited public comment on the streamlined criteria proposed in § 447.203(c)(1). Additionally, we solicited public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring regardless of the remaining criteria. This requirement would minimize

⁴²³ Connecticut Department of Social Services, Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0021/attachment_1.pdf.

⁴²⁴ California Department of Health Care Services, Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0090/attachment_1.pdf.

⁴²⁵ Florida Agency for Health Care Administration, Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0083/attachment_1.pdf.

administrative burden on States by not requiring States submit all items in § 447.203(c)(2) and establish a baseline for comparison if future rate reductions or restructurings are proposed that may lower the State's payment rates below 80 percent of the most recent Medicare payment rates. However, we determined that, while we believe 80 percent to be an effective threshold point, we did not want that to serve as the only trigger for additional analysis. As proposed, only States that do not meet all of the proposed requirements in § 447.203(c)(1) will have to submit the required data outlined in § 447.203(c)(2). As previously noted in section II. of this rule, we solicited public comment on our proposal to require all three criteria described in § 447.203(c)(1)(i) through (iii) for assessing the effect of a proposed payment rate reduction or payment restructuring on access to care. Additionally, we solicited public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1), thereby eliminating the need for us to develop a template for States proposing rate reductions or restructurings. While this would reduce administrative burden on us and provide States with flexibility in determining relevant data for complying with statutory and regulatory requirements, we received feedback after the 2015 final rule with comment period that States found developing an AMRP from scratch with minimal Federal guidelines a challenging task and other interested parties noted that States had too much discretion in documenting sufficient access to care. Therefore, we proposed developing a template to support State analyses of rate reduction or restructuring SPAs that fail to meet the criteria in § 447.203(c)(1). As noted elsewhere in the preamble, we are releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), alongside this final rule. We also anticipate working directly with States through the SPA review process to ensure compliance

with section 1902(a)(30)(A) of the Act. Additionally, we solicited public comment regarding our alternative consideration to propose allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1).

After careful consideration, we ultimately determined that the requirements in proposed § 447.203(b) and (c) would strike a more optimal balance between alleviating State and Federal administrative burden, while ensuring a transparent, data-driven, and consistent approach to States' implementation and our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act.

We considered finalizing the payment rate transparency provisions under 447.203(b)(1) as proposed, but in response to commenter concerns about the requirement to breakdown bundled payment rates into constituent services and rates, we added regulatory language to provide States with flexibility in complying with the payment rate transparency publication requirements when individual rates for constituent services within a State's bundle payment rate do not exist. Specifically, we added the following language: "unless this information is not reasonably available" to the requirement that "in the case of a bundled or similar payment methodology" States must "identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology." We also clarified in this final rule through a previous comment response that facility payment rates (for example, provider-specific rates and per diem rates) are not considered to be bundled payment rates and are not subject to the payment rate transparency provisions. We believe this additional regulatory language and clarification will reduce administrative burden on States by narrowing the scope of bundled payment rates subject to the payment rate transparency requirements. While we still believe this requirement is necessary to ensure maximum transparency of payment rates in the case of bundled fee schedule payment rates, it is also necessary to account for circumstances where a State does not have information available to comply with this regulatory requirement.

We considered finalizing the payment rate transparency provisions under 447.203(b)(1) as proposed, but in response to commenter concerns about requiring States with prospective effective dates to publish rates that are not yet in effect, we added regulatory language to address this circumstance. Specifically, the regulation now states that the agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current, where any necessary update must be made no later than either 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or 1 month following the effective date of the approved amendment, whichever date occurs latest. If we finalized the regulatory language as proposed, then States would be required to update their payment rate transparency publications with payment rates that are not yet in effect, and this would not align with our transparency efforts to ensure a States' payment rate transparency publication is as current as possible, and accurate once published.

We considered finalizing the payment rate transparency provisions under § 447.203(b)(1) with a requirement to organize the payment rate transparency publication by CPT/HCPCS code, similar to the comparative payment rate analysis, but in response to commenter concerns about administrative burden on States to comply with the provisions as proposed, we did not require the payment rate transparency publication to be organized in this manner. While we still require both the payment rate transparency publication and comparative payment rate analysis to be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service, requiring the publication to be organized by CPT/HCPCS code would create substantial burden for States that do not current organize their payment rates in this manner as all fee schedule payment rates are subject to this provision. By not requiring the payment rate transparency publication to be organized a particular way, we are providing States with the flexibility to use existing fee schedule publications for compliance with the regulations finalized in this rule.

We considered, but did not finalize, an increase to the 80 percent of Medicare threshold in § 447.203(c)(1)(i) to 100 percent of Medicare as suggested by some of the commenters. Taking such an action would have increased the threshold for States to qualify for the streamlined review process and increased administrative burden on the States. We ultimately decided not to pursue this alternative because this threshold was not intended to provide absolute assurance that a provider would participate in the Medicaid program. Instead, we are using 80 percent as a threshold to determine the level of analysis and information a State must provide to CMS to support consistency with section 1902(a)(30)(A) of the Act and allow CMS to focus its review efforts on proposals at the highest risk of access concerns. We also note that the 80 percent threshold was just one of three criteria that must be met for a streamlined review. Our stated intention in this rule was that we were intending this to provide States with relief from the more burdensome AMRP process defined in the 2015 final rule with comment period, and establishing a higher threshold would not fit within that stated purpose.

We received public comments on several of these alternatives, but many of those comments blended with discussion of the relevant provisions, so in general our responses to those comments are contained in section II.C. However, we did receive some comments on alternatives not already addressed in this final rule.

Comment: One commenter responded to our decision not to propose adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. That commenter stated that CMS' reliance on existing State processes, such as the ongoing provider and beneficiary feedback channels and the public process requirement for States submitting a SPA that proposed to reduce or restructure Medicaid services would be acceptable if the existing processes are responsive and delivered timely action when concerns are raised.

Response: We agree with the commenter regarding existing processes being responsive and timely. As described in the proposed rule, these processes must meet requirements under

newly finalized § 447.203(c)(4) (which includes existing requirements from the 2015 final rule with comment period that was relocated from § 447.203(b)(7)), as well as § 447.204 (which includes existing requirements from the 2015 final rule with comment period with confirming changes to align with this final rule). These existing regulatory requirements require States have ongoing mechanisms for beneficiary and provider input on access to care in which they promptly respond to public input and maintain a record the public input, as well as how the State responded. While this is a general requirement for ensuring States have a method for collecting access to care issues from the public, these requirements also specifically apply to States proposing a rate reduction or restructuring.

Comment: One commenter agreed with CMS’ decision to exclude outpatient drugs from the proposed comparative payment rate analysis under § 447.203(b)(2) noting that, in addition to the reasons CMS outlined in the proposed rule, the cost of outpatient drugs can change weekly and there are anticipated cost differences compared to other payers, such as Medicare or States. The commenter recommended that, if CMS decides to subject outpatient drugs to the comparative payment rate analysis, then CMS should develop a unique methodology for States to follow in making the comparison to another payer.

Response: We appreciate the commenter’s support for our decision, as well as their recommendation for how we could subject outpatient drugs to the comparative payment rate analysis if we did end up deciding to include them. We are not changing the services subject to the analysis in this final rule, although we note we have updated “outpatient behavioral health services” to “outpatient mental health and substance use disorder services.”

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 48 showing the classification of the impact associated with the provisions of

this final rule. Note, Table 47 shown previously in this final rule provides a summary of the one-time and annual costs estimates.

TABLE 48: Accounting Table

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Regulatory Review Costs				
Annualized Monetized (\$million/year)	.112	2023	7%	2024 - 2028
	.117	2023	3%	2024 - 2028
Costs to States				
Annualized Monetized (\$million/year)	72.12	2023	7%	2024 - 2028
	75.22	2023	3%	2024 - 2028
Costs to Beneficiaries				
Annualized Monetized (\$million/year)	0.47	2023	7%	2024 - 2028
	0.49	2023	3%	2024 - 2028
Costs to Providers				
Annualized Monetized (\$million/year)	102.05	2023	7%	2024 - 2028
	106.44	2023	3%	2024 - 2028
Costs to Managed Care Plans				
Annualized Monetized (\$million/year)	6.84	2023	7%	2024 - 2028
	7.13	2023	3%	2024 - 2028

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that *almost all* of Home Health Care Services, Services for the Elderly and Persons with Disabilities, and Direct Health and Medical Insurance Carriers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$9.0 million to \$47 million in any 1 year).

For purposes of the RFA, approximately 95 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards with total revenues of \$47 million or less in any 1 year.

According to the SBA's website at <http://www.sba.gov/content/small-business-size-standards> HCBS Provider Costs and Managed care Plan fall in the North American Industrial

Classification System 621610 Home Health Care Services, 624120 Services for the Elderly and Persons with Disabilities, and 524114 Direct Health and Medical Insurance Carriers.

TABLE 49: HCBS Providers Costs and Managed Care Plan Size Standards

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/ Small Entity Threshold	Total Small Businesses
621610	Home Health Care Services	\$19 Million	22,840
624120	Services for the Elderly and Persons with Disabilities	\$15 Million	26,051
524114	Direct Health and Medical Insurance Carriers	\$47 Million	455

Source: 2017 Statistics of U.S. Businesses

TABLE 50: NAICS 62160 Home Health Care Services (\$19 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	22,840	100%	\$ 5,320,704.31
<\$100K	5,861	26%	\$ 35,948.98
\$100K - \$499K	5,687	25%	\$ 256,725.47
\$500 - \$999K	3,342	15%	\$ 414,742.71
\$1M - \$2.49M	4,434	19%	\$ 1,201,189.90
\$2.5M - \$4.9M	1,951	9%	\$ 1,135,879.03
\$5M - \$7.5M	672	3%	\$ 667,476.88
\$7.6M - \$9.9M	356	2%	\$ 496,663.20
\$10M - \$14.9M	346	2%	\$ 642,844.22
\$15M - \$19.9M	191	1%	\$ 469,233.92
LARGE FIRMS			
Receipts > \$20M	961	N/A	\$ 6,451,412.39 (for firms > \$100M)

Source: 2017 Statistics of U.S. Businesses

TABLE 51: NAICS 624120 Services for the Elderly and Persons with Disabilities (\$15 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	26,051	100%	\$ 3,117,267.70
<\$100K	8,293	32%	\$ 31,953.45
\$100K - \$499K	6,864	26%	\$ 215,283.61
\$500 - \$999K	3,449	13%	\$ 298,760.76
\$1M - \$2.49M	4,093	16%	\$ 764,108.16
\$2.5M - \$4.9M	1,827	7%	\$ 705,634.63
\$5M - \$7.5M	695	3%	\$ 404,539.85
\$7.6M - \$9.9M	401	2%	\$ 295,453.88
\$10M - \$14.9M	429	2%	\$ 401,533.34
LARGE FIRMS			
Receipts > \$15M	1,211	N/A	\$57,136,066.67 (for firms > \$100M)

Source: 2017 Statistics of U.S. Businesses

TABLE F52: NAICS 524114 Direct Health and Medical Insurance Carriers (\$47 Million Size Standard)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Avg. Revenue
SMALL FIRMS	455	100%	\$25,087,240.51

<\$100K	79	17%	\$ 52,101.27
\$100K - \$499K	170	37%	\$ 542,278.48
\$500 - \$999K	42	9%	\$ 388,329.11
\$1M - \$2.49M	48	11%	\$ 946,037.97
\$2.5M - \$4.9M	31	7%	\$ 1,371,468.35
\$5M - \$7.5M	12	3%	\$ 939,797.47
\$7.6M - \$9.9M	10	2%	\$ 1,126,303.80
\$10M - \$14.9M	14	3%	\$ 2,033,645.57
\$15M - \$19.9M	13	3%	\$ 2,802,481.01
\$20M - \$24.9M	5	1%	\$ 1,389,189.87
\$25M - \$29.9M	4	1%	\$ 1,523,012.66
\$30M - \$34.9M	9	2%	\$ 3,417,797.47
\$35M - \$39.9M	6	1%	\$ 2,599,443.04
\$40M - \$49.9M	12	3%	\$ 5,955,354.43
LARGE FIRMS			
Receipts > 50M	290	N/A	\$ 3,244,413,424.12 (for firms > \$100M)

Tables 50, 51, and 52 aid in showing the distribution of firms and revenues at their 6 digits NAICS code level. These tables aim to provide an understanding of the disproportionate impacts among firms, between small and large firms.

Individuals and States are not included in the definition of a small entity. This rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. All the industries combined, according to the 2017 Economic Census, earned approximately \$46,771,961,000.00. Hence, all the costs combined, amounts to about 1 percent.

TABLE 53: NAICS Classification of Services, the Distribution of Costs, Annualized Cost per Industry, Average Annual Revenue for Small Firms, and Revenue Test

Services	NAICS	Percentage of Costs	Annualized Cost* per Industry	Avg. Annual Revenue for Small Firms	Revenue Test
Managed Care Plans	Direct Health and Medical Insurance Carriers (524114)	100 Percent	\$370,989,000	\$5,320,704.31	1.4%
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent	\$248,562,630.00	\$3,117,267.70	1.3%
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent	\$137,265,930.00	\$25,087,240.51	18%

*Annualized Cost per Industry was determined from the Accounting Table 7.

Therefore, as its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent.

According to Table 12, for Direct Health and Medical Insurance Carriers (524114) and Elderly and Persons with Disabilities (624120), we do not believe that the 3 to 5 percent

threshold will be reached by the requirements in this final rule. However, Home Health Care Services (621610) has a substantial effect on its small businesses.

Therefore, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities in the Direct Health and Medical Insurance Carriers (524114) and Elderly and Persons with Disabilities (624120) industries. However, the Secretary cannot certify that this final rule will not have a significant economic impact on the Home Health Care Services (621610) industry.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule will not have a significant impact on the operations of small rural hospitals since small hospitals are not affected by the proposed rule. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately \$177 million. This final rule will impose a mandate that will result in the expenditure by the private sector, of more than \$177 million in at least 1 year.

Several of the provisions in this final rule address gaps in existing regulations. In these cases, the costs for States to implement the changes to existing processes will likely be minimal. For the remaining areas of the rule, we have sought to minimize burden whenever possible, while still achieving the goals of this rulemaking, as reflected in the burden analyses and estimates described in sections III. and IV. of this final rule. We further note that, as reflected in

those sections, States would be able to claim administrative match for the work required to implement the proposals.

We have described the projected paperwork costs to providers, as well as to States, the Federal Government, and managed care plans (as applicable) in the Collection of Information section (section III. of this final rule.) We note that the requirements finalized at § 441.302(k) regarding the HCBS payment adequacy requirements represent the biggest impact on small entities. We have not calculated an additional financial impact on providers beyond what is reflected in the Collection of Information (in section III.) and the Regulatory Impact Analysis (section (this section, section IV. of the final rule.) The requirements finalized at § 441.302(k) may require that a number of HCBS providers ensure that they allocate more of their Medicaid payments to direct care workers than they had prior to the implementation of § 441.302(k); this does not reflect a change in the Medicaid payments. The underlying assumption of this requirement is that providers are capable of allocating 80 percent their Medicaid payments to direct care workers by ensuring that payments are allocated efficiently and that overhead is kept to a minimum. Additionally, as discussed in II.B.5. of this final rule, we have provided States with several flexibilities for certain providers that would be unable to operate successfully under this requirement. While we received anecdotal data from public commenters regarding current Medicaid rates, workforce shortages, and survey responses from providers regarding their reaction to the proposal in the proposed rule, we did not receive data (nor do we have other sources of data) on which to estimate additional costs associated with § 441.302(k) aside from what is presented in the Collection of Information and Regulatory Impact Analysis sections above.

H. Federalism

EO 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose

substantial direct costs on State or local governments, preempt State law, or otherwise have Federalism implications. As mentioned in the previous section of this rule, the costs to States by our estimate do not rise to the level of specified thresholds for significant burden to States. In addition, many proposals amend existing requirements or further requirements that already exist in statute, and as such would not create any new conflict with State law.

I. Conclusion

The policies in this final rule, will enable us to implement enhanced access to health care services for Medicaid beneficiaries across FFS, managed care, and HCBS delivery systems.

The analysis in section IV. of this final rule, together with the rest of this preamble, provides a regulatory impact analysis. In accordance with the provisions of EO 12866, this final rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 11, 2024.

List of Subjects

42 CFR Part 431

Administrative practice and procedure, Consumer protection, Grant programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirement.

42 CFR Part 438

Administrative practice and procedure, Grant programs-health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements.

42 CFR Part 441

Administrative practice and procedure, Consumer protection, Grant programs-health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs- health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

2. Section 431.12 is revised to read as follows:

§ 431.12 Medicaid Advisory Committee and Beneficiary Advisory Council.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State Plan requirements for establishment and ongoing operation of a public Medicaid Advisory Committee (MAC) with a dedicated Beneficiary Advisory Council (BAC) comprised of current and former Medicaid beneficiaries, their family members, and caregivers, to advise the State Medicaid agency on matters of concern related to policy development, and matters related to the effective administration of the Medicaid program.

(b) *State plan requirement.* The State plan must provide for a MAC and a BAC that will advise the director of the single State Agency for the Medicaid program on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(c) *Selection of members.* The Director of the single State Agency for the Medicaid program must select members for the MAC and BAC for a term of length determined by the State, which may not be followed immediately by a consecutive term for the same member, on a rotating and continuous basis. The State must create a process for recruitment and selection of members and publish this information on the State's website as specified in paragraph (f).

(d) *MAC membership and composition.* The membership of the MAC must be composed of the following percentage and representative categories of interested parties in the State:

(1) For the period from July 9, 2024 through July 9, 2025, 10 percent of the MAC members must come from the BAC; for the period from July 10, 2025 through July 9, 2026, 20 percent of MAC members must come from the BAC; and thereafter, 25 percent of MAC members must come from the BAC.

(2) The remaining committee members must include representation of at least one from each of the following categories:

(A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries.

(B) Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care. This includes providers or administrators of primary care, specialty care, and long-term care.

(C) As applicable, participating Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2, or a health plan association representing more than one such plans; and

(D) Other State agencies that serve Medicaid beneficiaries (for example, foster care agency, mental health agency, health department, State agencies delegated to conduct eligibility determinations for Medicaid, State Unit on Aging), as ex-officio, non-voting members.

(e) *Beneficiary Advisory Council.* The State must form and support a BAC, which can be an existing beneficiary group, that is comprised of: individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members and paid or unpaid caregivers of those enrolled in Medicaid), to advise the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.

(1) The MAC members described in paragraph (d)(1) of this section must also be members of the BAC.

(2) The BAC must meet separately from the MAC, on a regular basis, and in advance of each MAC meeting to ensure BAC member preparation for each MAC meeting.

(f) *MAC and BAC administration.* The State agency must create standardized processes and practices for the administration of the MAC and the BAC that are available for public review on the State website. The State agency must –

(1) Develop and publish, by posting publicly on its website, bylaws for governance of the MAC and BAC along with a current list of members. States will also post publicly the past meeting minutes of the MAC and BAC meetings, including a list of meeting attendees. States will give BAC members the option to include their names in the membership list and meeting minutes that will be posted publicly.

(2) Develop and publish by posting publicly on its website a process for MAC and BAC member recruitment and selection along with a process for selection of MAC and BAC leadership;

(3) Develop, publish by posting publicly on its website, and implement a regular meeting schedule for the MAC and BAC; the MAC and BAC must each meet at least once per quarter and hold off-cycle meetings as needed. Each MAC and BAC meeting agenda must include a time for members and the public (if applicable) to disclose conflicts of interest.

(4) Make at least two MAC meetings per year open to the public and those meetings must include a dedicated time during the meeting for the public to make comments. BAC meetings are not required to be open to the public, unless the State's BAC members decide otherwise. The public must be adequately notified of the date, location, and time of each public MAC meeting and any public BAC meeting at least 30 calendar days in advance of the date of the meeting.

(5) Offer a rotating, variety of meeting attendance options. These meeting options are: all in-person attendance, all virtual attendance, and hybrid (in person and virtual) attendance options. Regardless of which attendance type of meeting it is, States are required to always

have, at a minimum, telephone dial-in option at the MAC and BAC meetings for its members. If the MAC or BAC meeting is deemed open to the public, the State must offer at a minimum a telephone dial-in option for members of the public;

(6) Ensure that the meeting times and locations for MAC and BAC meetings are selected to maximize member attendance and may vary by meeting; and

(7) Facilitate participation of beneficiaries by ensuring that that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, and communications with individuals with disabilities are as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 80, 84 and 92, respectively.

(g) *MAC and BAC participation and scope.* The MAC and BAC participants must have the opportunity to advise the director of the single State Agency for the Medicaid program on matters related to policy development and matters related to the effective administration of the Medicaid program. At a minimum, the MAC and BAC must determine, in collaboration with the State, which topics to provide advice on related to -

(1) Additions and changes to services;

(2) Coordination of care;

(3) Quality of services;

(4) Eligibility, enrollment, and renewal processes;

(5) Beneficiary and provider communications by State Medicaid agency and Medicaid MCOs, PIHPs, PAHPs, PCCM entities or PCCMs as defined in § 438.2;

(6) Cultural competency, language access, health equity, and disparities and biases in the Medicaid program;

(7) Access to services; and

(8) Other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as determined by the MAC, BAC, or State.

(h) *State agency staff assistance, participation, and financial help.* The single State Agency for the Medicaid program must provide staff to support planning and execution of the MAC and the BAC to include -

(1) Recruitment of MAC and BAC members;

(2) Planning and execution of all MAC and BAC meetings and the production of meeting minutes that include actions taken or anticipated actions by the State in response to interested parties' feedback provided during the meeting. The minutes are to be posted on the State's website within 30 calendar days following each meeting. Additionally, the State must produce and post on its website an annual report as specified in paragraph (i) of this section; and

(3) The provision of appropriate support and preparation (providing research or other information needed) to the MAC and BAC members who are Medicaid beneficiaries to ensure meaningful participation. These tasks include –

(i) Providing staff whose responsibilities are to facilitate MAC and BAC member engagement;

(ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAC; and

(iii) Attendance by at least one staff member from the single State Agency for the Medicaid program's executive staff at all MAC and BAC meetings.

(i) *Annual report.* The MAC, with support from the State, must submit an annual report describing its activities, topics discussed, and recommendations. The State must review the report and include responses to the recommended actions. The State agency must then –

(1) Provide MAC members with final review of the report;

(2) Ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAC, as well as the State's responses to the recommendations; and

(3) Post the report to the State's website. States have 2 years from [insert the effective date of the final rule] to finalize the first annual MAC report. After the report has been finalized, States will have 30 days to post the annual report.

(j) *Federal financial participation*. FFP is available at 50 percent of expenditures for the MAC and BAC activities.

(k) *Applicability dates*. Except as noted in paragraphs (d)(1) and (i)(3) of this section, the requirements in paragraphs (a) through (j) of this section are applicable July 9, 2025.

3. Section 431.408 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 431.408 State public notice process.

(a) * * *

(3) * * *

(i) The Medicaid Advisory Committee and Beneficiary Advisory Council that operate in accordance with § 431.12 of this subpart; or

* * * * *

PART 438—MANAGED CARE

4. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

5. Section 438.72 is added to subpart B to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

(a) [Reserved]

(b) *Services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities*. The State must comply with the requirements at §§ 441.301(c)(1) through

(3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

PART 441— SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

6. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

7. Section 441.301 is amended by revising paragraphs (c)(1) introductory text and (c)(3), and adding paragraph (c)(7) to read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(c) * * *

(1) *Person-centered planning process.* The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term "individual" is used throughout § 441.301(c)(1) through (3), it includes the individual's authorized representative if applicable. In addition, the person-centered planning process:

* * * * *

(3) *Review of the person-centered service plan--(i) Requirement.* The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(3), that it ensures the following minimum performance levels are met:

(A) Complete a reassessment of functional need at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days; and

(B) Review, and revise as appropriate, the person-centered service plan, based upon the reassessment of functional need, at least every 12 months, for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days.

(iii) *Applicability date.* States must comply with the performance levels described in paragraph (c)(3)(ii) of this section beginning 3 years after [insert the effective date of this final rule]; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after [insert the effective date of this final rule].

* * * * *

(7) *Grievance system*--(i) *Purpose.* The State must establish a procedure under which a beneficiary may file a grievance related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. The State may have activities described in paragraph (c)(7) of this section performed by contractors or other government entities, provided, however, that the State retains responsibility for ensuring performance of and compliance with these provisions.

(ii) *Definitions.* As used in this section:

Grievance means an expression of dissatisfaction or complaint related to the State's or a provider's performance of the activities described in paragraphs (c)(1) through (6) of this section, regardless of whether remedial action is requested.

Grievance system means the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

(iii) *General requirements.* (A) The beneficiary or a beneficiary's authorized representative, if applicable, may file a grievance. All references to beneficiary include the role of the beneficiary's representative, if applicable.

(1) Another individual or entity may file a grievance on behalf of the beneficiary, or provide the beneficiary with assistance or representation throughout the grievance process, with the written consent of the beneficiary or authorized representative.

(2) A provider cannot file a grievance that would violate the State's conflict of interest guidelines, as required in § 441.540(a)(5).

(B) The State must:

(1) Base its grievance processes on written policies and procedures that, at a minimum, meet the conditions set forth in this paragraph (c)(7);

(2) Provide beneficiaries reasonable assistance in ensuring grievances are appropriately filed with the grievance system, completing forms and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and providing meaningful access to individuals with Limited English Proficiency, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services where necessary to ensure effective communication, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability;

(3) Ensure that punitive or retaliatory action is neither threatened nor taken against an individual filing a grievance or who has had a grievance filed on their behalf;

(4) Accept grievances and requests for extension of timeframes from the beneficiary;

(5) Provide to the beneficiary the notices and information required under this subsection, including information on their rights under the grievance system and on how to file grievances, and ensure that such information is accessible for individuals with disabilities and individuals with Limited English Proficiency in accordance with § 435.905(b);

(6) Review any grievance resolution with which the beneficiary is dissatisfied; and

(7) Provide information about the grievance system to all providers and subcontractors approved to deliver services.

(C) The process for handling grievances must:

(1) Allow the beneficiary to file a grievance with the State either orally or in writing;

(2) Acknowledge receipt of each grievance;

(3) Ensure that the individuals who make decisions on grievances are individuals:

(i) Who were neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual;

(ii) Who are individuals who have the appropriate clinical and non-clinical expertise, as determined by the State; and

(iii) Who consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State;

(4) Provide the beneficiary a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance. The State must inform the beneficiary of the limited time available for this sufficiently in advance of the resolution timeframe for grievances as specified in paragraph (c)(7)(v) of this section;

(5) Provide the beneficiary their case file, including medical records in compliance with the HIPAA Privacy Rule (45 CFR part 160 and part 164 subparts A and E), other documents and records, and any new or additional evidence considered, relied upon, or generated by the State related to the grievance. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for grievances as specified in paragraph (c)(7)(v) of this section; and

(6) Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.

(iv) *Filing timeframes.* A beneficiary may file a grievance at any time.

(v) *Resolution and notification—(A) Basic rule.* The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(B) *Resolution timeframes.* For resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.

(C) *Extension of timeframes.* The States may extend the timeframe from that in paragraph (c)(7)(v)(B) of this section by up to 14 calendar days if –

(1) The beneficiary requests the extension; or

(2) The State documents that there is need for additional information and how the delay is in the beneficiary's interest.

(D) *Requirements following extension.* If the State extends the timeframe not at the request of the beneficiary, it must complete all of the following:

(1) Make reasonable efforts to give the beneficiary prompt oral notice of the delay;

(2) Within 2 calendar days of determining a need for a delay, but no later than the timeframes in paragraph (c)(7)(v)(B) of this section, give the beneficiary written notice of the reason for the decision to extend the timeframe; and

(3) Resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires.

(vi) *Format of notice.* The State must establish a method to notify a beneficiary of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 435.905(b) of this chapter.

(vii) *Recordkeeping.* (A) The State must maintain records of grievances and must review the information as part of its ongoing monitoring procedures.

(B) The record of each grievance must contain, at a minimum, all of the following information:

- (1) A general description of the reason for the grievance;
- (2) The date received;
- (3) The date of each review or, if applicable, review meeting;
- (4) Resolution of the grievance, as applicable;
- (5) Date of resolution, if applicable; and
- (6) Name of the beneficiary for whom the grievance was filed.

(C) The record must be accurately maintained in a manner available upon request to CMS.

(viii) *Applicability date.* States must comply with the requirement at paragraph (c)(7) of this section beginning 2 years after [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

8. Section 441.302 is amended by--

- a. Adding paragraph (a)(6);
- b. Revising paragraph (h); and
- c. Adding paragraph (k).

The additions and revision read as follows:

§ 441.302 State assurances.

* * * * *

(a) * * *

(6) Assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents.

(i) *Requirements.* The State must:

(A) Define critical incident to include, at a minimum—

(1) Verbal, physical, sexual, psychological, or emotional abuse;

(2) Neglect;

(3) *Exploitation* including financial exploitation;

(4) Misuse or unauthorized use of restrictive interventions or seclusion;

(5) A medication error resulting in a telephone call to, or a consultation with, a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or

(6) An unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect;

(B) Use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, that, at a minimum, enables —

(1) Electronic critical incident data collection;

(2) Tracking (including of the status and resolution of investigations); and

(3) Trending;

(C) Require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan;

(D) Use claims data, Medicaid fraud control unit data, and data from other State agencies, such as Adult Protective Services or Child Protective Services, to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan, or occur as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the beneficiary's person-centered service plan;

(E) Ensure that there is information sharing on the status and resolution of investigations, such as through the use of information sharing agreements, between the State and the entity or entities responsible in the State for investigating critical incidents as defined in paragraph (a)(6)(i)(A) of this section if the State refers critical incidents to other entities for investigation;

(F) Separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes; and

(G) Demonstrate that it meets the requirements in paragraph (a)(6) of this section through the reporting requirement at § 441.311(b)(1).

(ii) *Minimum performance at the State level.* The State must demonstrate, through the reporting requirements at § 441.311(b)(2), that it meets the following minimum performance levels:

(A) Initiate an investigation, within State-specified timeframes, for no less than 90 percent of critical incidents;

(B) Complete an investigation and determine the resolution of the investigation, within State-specified timeframes, for no less than 90 percent of critical incidents; and

(C) Ensure that corrective action has been completed within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.

(iii) *Applicability date.* States must comply with the requirements in paragraph (a)(6) of this section beginning 3 years after [insert the effective date of this final rule]; except for the requirement at paragraph (a)(6)(i)(B) of this section, with which the State must comply beginning 5 years after [insert the effective date of this final rule]; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after 3 years after [insert the effective date of this final rule], except for the requirement at paragraph

(a)(6)(i)(B) of this section, with which the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after 5 years after [insert the effective date of this final rule].

* * * * *

(h) *Reporting.* Assurance that the agency will provide CMS with information on the waiver's impact, including the data and information as required in § 441.311.

* * * * *

(k) *HCBS payment adequacy.* Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans.

(1) *Definitions.* As used in this paragraph--

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.*, 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

(iii) *Excluded costs* means costs that are not included in the calculation of the percentage of Medicaid payments to providers that is spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Costs of personal protective equipment for direct care workers.

(2) *Requirement.* (i) Except as provided in paragraph (k)(2)(ii) of this section, the State must demonstrate annually, through the reporting requirements at paragraph (k)(6) of this section and § 441.311(e), that it meets the minimum performance levels in paragraph (k)(3) of this section for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), that are delivered by direct care workers and authorized under section 1915(c) of the Act.

(ii) *Treatment of certain payment data under self-directed services delivery models.* If the State provides that homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the

State does not include such payment data in its calculation of the State's compliance with the minimum performance levels at paragraph (k)(3) of this section.

(3) *Minimum performance at the provider level.* Except as provided in paragraphs (k)(5) and (7) of this section, the State must meet the following minimum performance level as applicable, calculated as the percentage of total payment (not including excluded costs) to a provider for furnishing homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4), represented by the provider's total compensation to direct care workers:

(i) Except as provided in paragraph (k)(3)(ii) of this section, the State must ensure that each provider spends 80 percent of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

(ii) At the State's option, for providers determined by the State to meet its State-defined small provider criteria in paragraph (k)(4)(i) of this section, the State must ensure that each provider spends the percentage set by the State in accordance with paragraph (k)(4)(ii) of this section of total payments the provider receives for services it furnishes as described in paragraph (k)(3) of this section on total compensation for direct care workers who furnish those services.

(4) *Small provider minimum performance level--(i) Small provider criteria.* The State may develop reasonable, objective criteria through a transparent process to identify small providers that the State would require to meet the minimum performance requirement at paragraph (k)(3)(ii) of this section. The transparent process for developing criteria to identify providers that qualify for the minimum performance requirement in paragraph (k)(3)(ii) of this section must include public notice and opportunities for comment from interested parties.

(ii) *Small provider minimum performance level.* The State must set the percentage for a small provider to meet the minimum performance level at paragraph (k)(3)(ii) of this section

based on reasonable, objective criteria it develops through a transparent process that includes public notice and opportunities for comment from interested parties.

(5) *Hardship exemption.* The State may develop reasonable, objective criteria through a transparent process to exempt from the minimum performance requirement at paragraph (k)(3) of this section a reasonable number of providers determined by the State to be facing extraordinary circumstances that prevent their compliance with paragraph (k)(3) of this section. The State must develop these criteria through a transparent process that includes public notice and opportunities for comment from interested parties. If a provider meets the State's hardship exemption criteria, then the State does not include that provider in its calculation of the State's compliance with the minimum performance level at paragraph (k)(3) of this section.

(6) Reporting on small provider minimum performance level and hardship exemption.

(i) States that establish a small provider minimum performance level under paragraph (k)(4) of this section must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS:

(A) The State's small provider criteria developed in accordance with paragraph (k)(4)(i) of this section;

(B) The State's small provider minimum performance level developed in accordance with paragraph (k)(4)(ii) of this section;

(C) The percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for the small provider minimum performance level at paragraph (k)(4) of this section; and

(D) A plan, subject to CMS review and approval, for small providers to meet the minimum performance requirement at paragraph (k)(3)(i) of this section within a reasonable period of time.

(ii) States that provide a hardship exemption in accordance with paragraph (k)(5) of this section must report to CMS annually the following information, in the form and manner, and at a time, specified by CMS:

(A) The State's hardship criteria developed in accordance with paragraph (k)(5) of this section;

(B) The percentage of providers of services set forth at § 440.180(b)(2) through (4) that qualify for a hardship exemption as provided in paragraph (k)(5) of this section; and

(C) A plan, subject to CMS review and approval, for reducing the number of providers that qualify for a hardship exemption within a reasonable period of time.

(iii) CMS may waive the reporting requirements in paragraphs (k)(6)(i)(D) or (k)(6)(ii)(C) of this section, as applicable, if the State demonstrates it has applied the small provider minimum performance level at paragraph (k)(4)(ii) of this section or the hardship exemption at paragraph (k)(5) of this section to less than 10 percent of the State's providers.

(7) *Exemption for the Indian Health Service and Tribal health programs subject to 25 U.S.C. 1641.* The Indian Health Service and Tribal health programs subject to the requirements at 25 U.S.C. 1641 are exempt from the requirements at paragraph (k) of this section.

(8) *Applicability date.* States must comply with the requirements set forth in paragraph (k) of this section beginning 6 years after [insert the effective date of this final rule]; and in the case of the State that implements a managed care delivery system under the authority of section 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes homemaker, home health aide, or personal care services, as set forth at § 440.180(b)(2) through (4) in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 6 years after [insert the effective date of this final rule].

9. Section 441.303 is amended by revising paragraph (f)(6) to read as follows:

§ 441.303 Supporting documentation required.

* * * * *

(f) * * *

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment. If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

* * * * *

10. Section 441.311 is added to subpart G to read as follows:

§ 441.311 Reporting requirements.

(a) *Basis and scope.* Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interests of Medicaid beneficiaries. This section describes the reporting requirements for States for section 1915(c) waiver programs, under the authority at section 1902(a)(6) and (a)(19) of the Act.

(b) *Compliance reporting--(1) Incident management system.* As described in § 441.302(a)(6)--

(i) The State must report, every 24 months, in the form and manner, and at a time, specified by CMS, on the results of an incident management system assessment to demonstrate that it meets the requirements in § 441.302(a)(6).

(ii) CMS may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).

(2) *Critical incidents.* The State must report to CMS annually on the following information regarding critical incidents as defined in § 441.302(a)(6)(i)(A), in the form and manner, and at a time, specified by CMS:

(i) Number and percent of critical incidents for which an investigation was initiated within State-specified timeframes;

(ii) Number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes;

(iii) Number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes.

(3) *Person-centered planning.* To demonstrate that the State meets the requirements at § 441.301(c)(3)(ii) regarding person-centered planning (as described in § 441.301(c)(1) through (3)), the State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS -

(i) Percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(ii) Percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(4) Annually, the State will provide CMS with information on the waiver's impact on the type, amount, and cost of services provided under the State plan, in the form and manner, and at a time, specified by CMS.

(c) *Reporting on the Home and Community-Based Services Quality Measure Set*, as described in § 441.312.

(1) *General rules.* The State—

(i) Must report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the measure set described in § 441.312(d), on all measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) of this subpart.

(ii) May report on all other measures in the Home and Community-Based Services Quality Measure Set that are not described in § 441.312(d)(1)(ii) and (iii) of this subpart.

(iii) Must establish, subject to CMS review and approval, State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(iv) May establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are not identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.

(2) Measures identified per § 441.312(d)(1)(iii) of this subpart will be reported by the Secretary on behalf of the State.

(3) In reporting on Home and Community-Based Services Quality Measure Set measures, the State may, but is not required to:

(i) Report on the measures identified by the Secretary pursuant to § 441.312(c) of this subpart for which reporting will be, but is not yet required (that is, reporting has not yet been phased-in).

(ii) Report on the populations identified by the Secretary pursuant to § 441.312(c) of this subpart for whom reporting will be, but is not yet required.

(d) *Access reporting.* The State must report to CMS annually on the following, in the form and manner, and at a time, specified by CMS:

(1) *Waiver waiting lists.* (i) A description of how the State maintains the list of individuals who are waiting to enroll in the waiver program, if the State has a limit on the size of the waiver program, as described in § 441.303(f)(6), and maintains a list of individuals who are waiting to enroll in the waiver program. This description must include, but is not limited to:

(A) Information on whether the State screens individuals on the list for eligibility for the waiver program;

(B) Whether the State periodically re-screens individuals on the list for eligibility; and

(C) The frequency of re-screening, if applicable.

(ii) Number of people on the list of individuals who are waiting to enroll in the waiver program, if applicable.

(iii) Average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list of individuals waiting to enroll in the waiver program, if applicable.

(2) *Access to homemaker, home health aide, personal care, and habilitation services.* (i) Average amount of time from when homemaker services, home health aide services, personal care services, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), are initially approved to when services began, for individuals newly receiving services within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(ii) Percent of authorized hours for homemaker services, home health aide services, personal care services, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that are provided within the past 12 months. The State may report this metric using statistically valid random sampling of beneficiaries.

(e) *Payment adequacy--(1) Definitions.* As used in this paragraph (e)-

(i) *Compensation* means:

(A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.*, 29 CFR parts 531 and 778);

(B) Benefits (such as health and dental benefits, life and disability insurance, paid leave, retirement, and tuition reimbursement); and

(C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.

(ii) *Direct care worker* means any of the following individuals who may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed services delivery model:

(A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid beneficiaries receiving home and community-based services available under this subpart;

(B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;

(C) A direct support professional;

(D) A personal care attendant;

(E) A home health aide; or

(F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid beneficiaries receiving home and community-based services available under this subpart, including nurses and other staff providing clinical supervision.

(iii) *Excluded costs* means costs that are not included in the calculation of the percentage of Medicaid payments to providers that are spent on compensation for direct care workers. Such costs are limited to:

(A) Costs of required trainings for direct care workers (such as costs for qualified trainers and training materials);

(B) Travel costs for direct care workers (such as mileage reimbursement or public transportation subsidies); and

(C) Cost of personal protective equipment for direct care workers.

(2) *Payment adequacy reporting.* (i) Except as provided in paragraphs (e)(2)(ii) and (e)(4) of this section, the State must report to CMS annually on the percentage of total payments (not including excluded costs) for furnishing homemaker services, home health aide services, personal care, and habilitation services, as set forth in § 440.180(b)(2) through (4) and (6), that is spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed and services delivered in a provider-operated physical location for which facility-related costs are included in the payment rate.

(ii) If *the* State provides that homemaker, home *health* aide, personal care services, or habilitation services, as set forth at § 440.180(b)(2) through (4) and (6), may be furnished under a self-directed services delivery model in which the beneficiary directing the services sets the direct care worker's payment rate, then the State must exclude such payment data from the reporting required in paragraph (e) of this section.

(3) *Payment adequacy reporting readiness.* One year prior to the applicability date for paragraph (e)(2)(i) of this section, the State must report on its readiness to comply with the reporting requirement in (e)(2)(i) of this section.

(4) *Exclusion of data from the Indian Health Service and Tribal health programs that are subject to 25 U.S.C. 1641.* States must exclude the Indian Health Service and Tribal health

programs subject to the requirements at 25 U.S.C. 1641 from the reporting required in paragraph (e) of this section, and not require submission of data by, or include any data from, the Indian Health Service or Tribal health programs subject to the requirements at 25 U.S.C. 1641 for the State's reporting required under paragraph (e)(2) of this section.

(f) *Applicability dates.* (1) The State must comply with the reporting requirements at paragraphs (b) and (d) of this section beginning 3 years after [insert the effective date of this final rule]; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after [insert the effective date of this final rule].

(2) The State must comply with the reporting requirements at paragraphs (c) and (e) of this section beginning 4 years after [insert the effective date of this final rule]; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP or PAHP beginning on or after the date that is 4 years after [insert the effective date of this final rule].

11. Section 441.312 is added to subpart G to read as follows:

§ 441.312 Home and community-based services quality measure set.

(a) *Basis and scope.* Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. This section describes the Home and Community-Based Services Quality Measure Set, which States

are required to use in section 1915(c) waiver programs to promote public transparency related to the administration of Medicaid-covered HCBS, under the authority at sections 1102(a) and 1902(a)(6) of the Act.

(b) *Definitions.* As used in this subpart—

(1) *Attribution rules* means the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Home and Community-Based Services Quality Measure Set.

(2) *Home and Community-Based Services Quality Measure Set* means the Home and Community-Based Services Quality Measures for Medicaid established and updated by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section.

(c) *Responsibilities of the Secretary.* The Secretary shall—

(1) Identify, and update no more frequently than every other year, beginning no later than December 31, 2026, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section.

(2) Make technical updates and corrections to the Home and Community-Based Services Quality Measure Set annually as appropriate.

(3) Consult at least every other year with States and other interested parties identified in paragraph (g) of this section to—

(i) Establish priorities for the development and advancement of the Home and Community-Based Services Quality Measure Set;

(ii) Identify newly developed or other measures which should be added including to address any gaps in the measures included in the Home and Community-Based Services Quality Measure Set;

(iii) Identify measures which should be removed as they no longer strengthen the Home and Community-Based Services Quality Measure Set; and

(iv) Ensure that all measures included in the Home and Community-Based Quality Measure Set reflect an evidenced-based process including testing, validation, and consensus among interested parties; are meaningful for States; and are feasible for State-level, program-level, or provider-level reporting as appropriate.

(4) In consultation with States, develop and update, no more frequently than every other year, the Home and Community-Based Services Quality Measure Set Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.

(d) *Process for developing and updating the HCBS Quality Measure Set.* The process for developing and updating the Home and Community-Based Services Quality Measure Set Quality Measure Set will address all of the following:

(1) Identification of all measures in the Home and Community-Based Services Quality Measure Set, including:

(i) Measures newly added and measures removed from the prior version of the Home and Community-Based Services Quality Measure Set;

(ii) The specific measures for which reporting is mandatory;

(iii) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and

(iv) The measures, if any, for which the Secretary will provide States with additional time to report, as well as how much additional time the Secretary will provide, in accordance with paragraph (c) of this section.

(2) Technical information to States on how to collect and calculate the data on the Home and Community-Based Services Quality Measure Set.

(3) Standardized format and reporting schedule for reporting measure data required under this section.

(4) Procedures that State agencies must follow in reporting measure data required under this section.

(5) Identification of the populations for which States must report the measures identified by the Secretary under paragraph (e) of this section, which may include, but is not limited to beneficiaries—

(i) Receiving services through specified delivery systems, such as those enrolled in a MCO, PIHP, or PAHP as defined in § 438.2 or receiving services on a fee-for-service basis;

(ii) Who are dually eligible for Medicare and Medicaid, including beneficiaries whose medical assistance is limited to payment of Medicare premiums or cost sharing;

(iii) Who are older adults;

(iv) Who have physical disabilities;

(v) Who have intellectual and development disabilities;

(vi) Who have serious mental illness; and

(vii) Who have other health conditions.

(6) Technical information on attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, as described in paragraph (d)(5) of this section, during the reporting period.

(7) The subset of measures among the measures in the Home and Community-Based Services Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with paragraphs (b)(2) and (g) of this section.

(8) Describe how to establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set.

(e) *Phasing in of certain reporting.* As part of the process that allows for developing and updating the Home and Community-Based Services Quality Measure Set described in paragraph (d) of this section, the Secretary may provide that mandatory State reporting for certain measures

and reporting for certain populations of beneficiaries will be phased in over a specified period of time, taking into account the level of complexity required for such State reporting.

(f) *Selection of measures for stratification.* In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (d)(7) of this section, the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary will require stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 4 years after [insert the effective date of this final rule], 50 percent of such measures by 6 years after [insert the effective date of this final rule], and 100 percent of measures by 8 years after [insert the effective date of this final rule].

(g) *Consultation with interested parties.* For purposes of paragraph (c)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:

(1) State Medicaid Agencies and agencies that administer Medicaid-covered home and community-based services.

(2) Health care and home and community-based services professionals, including members of the allied health professions who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs.

(3) Health care and home and community-based services professionals (including members of the allied health professions), providers, and direct care workers who provide services to older adults, children and adults with disabilities, and individuals with complex medical and behavioral health care needs who live in urban and rural medically underserved

communities or who are members of distinct population sub-groups at heightened risk for poor outcomes.

(4) Providers of home and community-based services.

(5) Direct care workers and national organizations representing direct care workers.

(6) Consumers and national organizations representing older adults, children and adults with disabilities, and individuals with complex medical needs.

(7) National organizations and individuals with expertise in home and community-based services quality measurement.

(8) Voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care.

(9) Measure development experts.

(10) Such other interested parties as the Secretary may determine appropriate.

12. Section 441.313 is added to subpart G to read as follows:

§ 441.313 Website transparency.

(a) The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311.

The State must:

(1) Include all content on one website, either directly or by linking to websites of individual MCO's, PIHP's, or PAHP's, as defined in § 438.2 of this chapter;

(2) Include clear and easy to understand labels on documents and links;

(3) Verify no less than quarterly, the accurate function of the website and the timeliness of the information and links; and

(4) Include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-

English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

(b) CMS must report on its website the results of the reporting requirements specified at §§ 441.302(k)(6) and 441.311 that the State reports to CMS.

(c) The State must comply with these requirements beginning 3 years after [insert the effective date of this final rule]; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first rating period for contracts with the MCO, PIHP, or PAHP beginning on or after the date that is 3 years after [insert the effective date of this final rule].

13. Section 441.450 is amended in paragraph (c) by revising the definition of "Service plan" to read as follows:

§ 441.450 Basis, scope, and definitions.

* * * * *

(c) * * *

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to live in the community. The service plan is developed based on the assessment of need using a person-centered and directed process. The service plan supports the participant's engagement in community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends, and professionals, as desired or required by the participant, will be involved in the service-planning process. Service plans must meet the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

* * * * *

14. Section 441.464 is amended by–

- a. Adding paragraph (d)(5);
- b. Redesignating paragraphs (e) and (f) as paragraphs (g) and (h); and
- c. Adding new paragraphs (e) and (f).

The revisions and additions read as follows:

§ 441.464 State assurances.

* * * * *

(d) * * *

(5) Implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

(e) *Incident management system.* The State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents and adheres to requirements of § 441.302(a)(6), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

(f) *Payment rates.* *Payment rates* are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries’ person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

* * * * *

15. Section 441.474 is amended by adding paragraph (c) to read as follows:

§ 441.474 Quality assurance and improvement plan.

* * * * *

(c) The quality assurance and improvement plan must comply with all components of §§ 441.302(k)(6), 441.311 and 441.312 and related reporting requirements relevant to the State’s

self-directed PAS program, except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

16. Section 441.486 is added to subpart J to read as follows:

§ 441.486 Website transparency.

For States subject to the requirements of subpart J, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(j) of the Act.

17. Section 441.540 is amended by revising paragraph (c) to read as follows:

§ 441.540 Person-centered service plan.

* * * * *

(c) *Reviewing the person-centered service plan.* The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

18. Section 441.555 is amended by adding paragraph (e) to read as follows:

§ 441.555 Support system.

* * * * *

(e) Implement and maintain a grievance process, in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

19. Section 441.570 is amended by adding paragraphs (e) and (f) to read as follows:

§ 441.570 State assurances.

* * * * *

(e) An incident management system in accordance with § 441.302(a)(6) is implemented, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

(f) Payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

20. Section 441.580 is amended by redesignating paragraph (i) as (j), and adding a new paragraph (i) to read as follows:

§ 441.580 Data collection.

* * * * *

(i) Data and information as required in §§ 441.302(k)(6) and 441.311, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

* * * * *

21. Section 441.585 is amended by adding paragraph (d) to read as follows:

§ 441.585 Quality assurance system.

* * * * *

(d) The State must implement the Home and Community-Based Services Quality Measure Set in accordance with § 441.312, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act

22. Section 441.595 is added to subpart K to read as follows-

§ 441.595 Website transparency.

For States subject to the requirements of subpart K, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(k) of the Act.

23. Section 441.725 is amended by revising paragraph (c) to read as follows:

§ 441.725 Person-centered service plan.

* * * * *

(c) Reviewing the person-centered service plan. The State must ensure that the person-centered service plan for every individual is reviewed, and revised as appropriate, based upon the reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

24. Section 441.745 is amended by—

- a. Revising paragraph (a)(1)(iii) and adding (a)(1)(iv) through (vii);
- b. Revising paragraph (b)(1)(i); and
- c. Adding paragraph (b)(1)(v).

The revision and additions read as follows:

§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.

* * * * *

(a) * * *

(1) * * *

(iii) *Grievances*. A State must implement and maintain a grievance process in accordance with § 441.301(c)(7), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(iv) *Appeals*. A State must provide individuals with advance notice of and the right to appeal terminations, suspensions, or reductions of Medicaid eligibility or covered services as described in part 431, subpart E, of this chapter.

(v) A State must implement an incident management system in accordance with § 441.302(a)(6), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(vi) A State must assure payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in beneficiaries' person-centered service plans, in accordance with § 441.302(k), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

(vii) A State must assure the submission of data and information as required in § 441.302(k)(6) and § 441.311, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * *

(b) * *

(1) * *

(i) Incorporate a continuous quality improvement process that includes monitoring, remediation, and quality improvement, including recognizing and reporting critical incidents, as defined in § 441.302(a)(6)(i)(A), except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * *

(v) Implementation of the Home and Community-Based Services Quality Measure Set in accordance with § 441.312, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

* * * *

25. Section 441.750 is added to subpart M to read as follows-

§ 441.750 Website transparency.

For States subject to the requirements of subpart M, the State must operate a website consistent with § 441.313, except that the references to section 1915(c) of the Act are instead references to section 1915(i) of the Act.

PART 447 PAYMENT FOR SERVICES

26. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1396r-8, and Pub. L. 111–148.

27. Section 447.203 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 447.203 Documentation of access to care and service payment rates.

* * * * *

(b)(1) *Payment rate transparency.* The State agency is required to publish all Medicaid fee-for-service fee schedule payment rates on a website that is accessible to the general public.

(i) For purposes of this paragraph (b)(1), the payment rates that the State agency is required to publish are Medicaid fee-for-service fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system.

(ii) The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency’s website.

(iii) Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for a given service.

(iv) In the case of a bundled payment methodology, the State must publish the Medicaid fee-for-service bundled payment rate and, where the bundled payment rate is based on fee schedule payment rates for each constituent service, must identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State’s methodology.

(v) If the rates vary, the State must separately identify the Medicaid fee-for-service payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(vi) The initial publication of the Medicaid fee-for-service payment rates shall occur no later than July 1, 2026 and include approved Medicaid fee-for-service payment rates in effect as

of July 1, 2026. The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the latter of the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology, or the effective date of the approved amendment. In the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State will ensure that its payment rate transparency publication is updated no later than 1 month after the effective date of the most recent update to the payment rate.

(2) *Comparative payment rate analysis and payment rate disclosure.* The State agency is required to develop and publish a comparative payment rate analysis of Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraphs (b)(2)(i) through (iii) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The State agency is further required to develop and publish a payment rate disclosure of the average hourly Medicaid fee-for-service fee schedule payment rates for each of the categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable.

(i) Primary care services.

(ii) Obstetrical and gynecological services.

(iii) Outpatient mental health and substance use disorder services.

(iv) Personal care, home health aide, homemaker, and habilitation services, as specified in § 440.180(b)(2) through (4) and (6), provided by individual providers and provider agencies.

(3) *Comparative payment rate analysis and payment rate disclosure requirements.* The State agency must develop and publish, consistent with the publication requirements described in paragraphs (b)(1) through (b)(1)(ii) of this section, a comparative payment rate analysis and a payment rate disclosure.

(i) For the categories of services described in paragraph (b)(2)(i) through (iii) of this section, the comparative payment rate analysis must compare the State agency's Medicaid fee-for-service fee schedule payment rates to the most recently published Medicare payment rates effective for the same time period for the evaluation and management (E/M) codes applicable to the category of service. The State must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS, and the analysis must meet the following requirements:

(A) The State must organize the analysis by category of service as described in paragraphs (b)(2)(i) through (iii) of this section.

(B) The analysis must clearly identify the base Medicaid fee-for-service fee schedule payment rates for each E/M CPT/HCPCS code identified by CMS under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

(C) The analysis must clearly identify the Medicare non-facility payment rates as established in the annual Medicare Physician Fee Schedule final rule effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the base Medicaid fee-for-service fee schedule payment rates, that correspond to the base Medicaid fee-for-service fee schedule payment rates identified under paragraph (b)(3)(i)(B) of this section, including separate identification of the payment rates by provider type.

(D) The analysis must specify the base Medicaid fee-for-service fee schedule payment rate identified under paragraph (b)(3)(i)(B) of this section as a percentage of the Medicare non-

facility payment rate as established in the annual Medicare Physician Fee Schedule final rule identified under paragraph (b)(3)(i)(C) of this section for each of the services for which the base Medicaid fee-for-service fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(E) The analysis must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the base Medicaid fee-for-service fee schedule payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

(ii) For each category of services specified in paragraph (b)(2)(iv) of this section, the State agency is required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly Medicaid fee-for-service fee schedule payment rates, separately identified for payments made to individual providers and provider agencies, if the rates vary. The payment rate disclosure must meet the following requirements:

(A) The State must organize the payment rate disclosure by category of service as specified in paragraph (b)(2)(iv) of this section.

(B) The disclosure must identify the average hourly Medicaid fee-for-service fee schedule payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly Medicaid fee-for-service fee schedule payment rates for payments made to individual providers and provider agencies, by population (pediatric and adult), provider type, geographical location, and whether the payment rate includes facility-related costs, as applicable.

(C) The disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly Medicaid fee-for-service fee schedule payment rates are published pursuant to paragraph (b)(3)(ii)(B) of this section.

(4) *Comparative payment rate analysis and payment rate disclosure timeframe.* The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid fee-for-service fee schedule payment rates in effect as of July 1, 2025 as required under paragraphs (b)(2) and (b)(3) of this section, by no later than July 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than July 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure must be published consistent with the publication requirements described in paragraphs (b)(1) introductory text, (b)(1)(i) and (b)(1)(ii) of this section.

(5) *Compliance with payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements.* If a State fails to comply with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of this section, including requirements for the time and manner of publication, future grant awards may be reduced under the procedures set forth at 42 CFR part 430, subparts C and D by the amount of FFP CMS estimates is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of this section for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. Unless otherwise prohibited by law, deferred FFP for those expenditures will be released after the State has fully complied with all applicable requirements.

(6) *Interested parties advisory group for rates paid for certain services.* (i) The State agency must establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, 1915(c) waiver, and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.311(e)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4), and (6).

(ii) The interested parties advisory group must include, at a minimum, direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State.

(iii) The interested parties advisory group will advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4) and (6), to ensure the relevant Medicaid payment rates are sufficient to ensure access to personal care, home health aide, homemaker, and habilitation services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

(iv) The interested parties advisory group shall meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency will ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy reporting information as described in § 441.311(e), and applicable access to care metrics as described in § 441.311(d)(2) for HCBS in order to produce these recommendations. The process by which the State selects interested party advisory group members and convenes its meetings must be made publicly available.

(v) The Medicaid agency must publish the recommendations produced under paragraph (b)(6)(iv) of the interested parties advisory group consistent with the publication requirements described in paragraph (b)(1) through (b)(1)(ii) of this section, within 1 month of when the group provides the recommendation to the agency.

(c)(1) *Initial State analysis for rate reduction or restructuring.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the criteria in

paragraphs (c)(1)(i) through (iii) of this section are met, the State agency must provide written assurance and relevant supporting documentation that the following conditions are met as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act, as part of the State plan amendment submission in a format prescribed by CMS as a condition of approval:

(i) Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

(ii) The proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(iii) The public processes described in paragraph (c)(4) of this section and § 447.204 yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).

(2) *Additional State rate analysis.* For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) of this section are not met, the State must also provide the following to CMS as part of the State

plan amendment submission as a condition of approval, in addition to the information required under paragraph (c)(1) of this section, in a format prescribed by CMS:

(i) A summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

(ii) Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services.

(iii) Information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State must provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of actively participating providers in each geographic area over this period. The State may provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(iv) Information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish). The State must document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State must provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(v) Information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and

service delivery. The State must provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

(vi) A summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2).

(3) Compliance with requirements for State analysis for rate reduction or restructuring.

A State that submits a State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access that fails to provide the information and analysis to support approval as specified in paragraphs (c)(1) and (2) of this section, as applicable, may be subject to State plan amendment disapproval under § 430.15(c) of this chapter. Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed State plan amendment, including any raised by CMS in its review of the proposal and any raised through the public process as specified in paragraph (c)(4) of this section or under § 447.204(a)(2), may be subject to State plan amendment disapproval. If State monitoring of beneficiary access after the payment rate reduction or restructuring takes effect shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, CMS may take a compliance action using the procedures described in § 430.35 of this chapter.

(4) Mechanisms for ongoing beneficiary and provider input. (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanism), consistent with the access requirements and public process described in § 447.204.

(ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.

(iii) States must maintain a record of data on public input and how the State responded to this input. This record will be made available to CMS upon request.

(5) *Addressing access questions and remediation of inadequate access to care.* When access deficiencies are identified, the State must, within 90 days after discovery, submit a corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

(i) The State's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: Increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, providing additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.

(ii) The resulting improvements in access must be measured and sustainable.

(6) *Compliance actions for access deficiencies.* To remedy an access deficiency, CMS may take a compliance action using the procedures described at § 430.35 of this chapter.

28. Section 447.204 is amended by—

a. Revising paragraphs (a)(1) and (b); and

b. Removing paragraph (d).

The revisions read as follows:

§ 447.204 Medicaid provider participation and public process to inform access to care.

(a) * * *

(1) The data collected, and the State analysis performed, under § 447.203(c).

* * * * *

(b) The State must submit to CMS with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.

* * * * *

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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