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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 438, and 457

[CMS-2439-P]

RIN 0938-AU99

Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would advance CMS' efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and Children's Health Insurance Program (CHIP) managed care enrollees. The proposed rule would specifically address standards for timely access to care and States' monitoring and enforcement efforts, reduce burden for some State directed payments and certain quality reporting requirements, add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and specify the scope and nature of ILOS, specify medical loss ratio (MLR) requirements, and establish a quality rating system for Medicaid and CHIP managed care plans.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by **[**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER]**.

ADDRESSES: In commenting, please refer to file code CMS-2439-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2439-P,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2439-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

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Requirements.

Andrew Wilson, (410) 786-8515, Medicaid Managed Care State Directed Payments Medicare Fee Schedules and Appeals Process.

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Joshua Bougie, (410) 786-8117, CHIP.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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Applicability and Complicace Timeframes

CMS proposes that the proposed new requirements would be applicable, and therefore, States required to comply by the effective date of the final rule or as otherwise specified in regulatory text.

I. Medicaid and CHIP Managed Care

A. Background

As of September 2022, the Medicaid program provided essential health care coverage to more than 83 million[1] individuals, and, in 2020, had annual outlays of more than $671 billion. In 2021, the Medicaid program accounted for 17 percent of national health expenditures.[2] The program covers a broad array of health benefits and services critical to underserved populations, including low-income adults, children, parents, pregnant individuals, the elderly, and people with disabilities. For example, Medicaid pays for approximately 42 percent of all births in the U.S.[3] and is the largest payer of long-term services and supports (LTSS)[4], services to treat substance use disorder, and services to prevent and treat the Human Immunodeficiency Virus[5].

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[1] September 2022 Medicaid and CHIP Enrollment Snapshot. Accessed at *https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/september-2022-medicaid-chip-enrollment-trend-snapshot.pdf*.

[2] CMS National Health Expenditure Accounts. National Health Expenditures 2021 Highlights. Accessed at *https://www.cms.gov/files/document/highlights.pdf*.

[3] National Center for Health Statistics. Key Birth Statistics (2020 Data. Final 2022 Data forthcoming). Accessed at *https://www.cdc.gov/nchs/nvss/births.htm*.

[4] Colello, Kirsten J. *Who Pays for Long-Term Services and Supports?* Congressional Research Service. Updated June 15, 2022. Accessed at *https://crsreports.congress.gov/product/pdf/IF/IF10343*.

[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/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/*.

Ensuring beneficiaries can access covered services is a crucial element 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, fee-for-service (FFS) and managed care, including through demonstrations and waiver programs. In 2020, 72 percent[6] of Medicaid beneficiaries were enrolled in comprehensive managed care plans; the remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

With a program as large and complex as Medicaid, to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements, access regulations need to be multi-factorial. 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 early 2022, we released a request for information (RFI)[7] 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

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[6] MACPAC 2022 Analysis of T-MSIS data February 2022. Exhibit 30. Percentage of Medicaid Enrollees in Managed Care by State and Eligibility Group *https://www.macpac.gov/wp-content/uploads/2022/12/EXHIBIT-30.-Percentage-of-Medicaid-Enrollees-in-Managed-Care-by-State-and-Eligibility-Group-FY-2020.pdf*.

[7] 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*.

promoting cultural competency in access to and the quality of services for beneficiaries across all dimensions of health care and using payment rates as a driver to increase provider participation in Medicaid and CHIP programs. Commenters were also interested in opportunities to align approaches for payment regulation and compliance across Medicaid and CHIP delivery systems and services.

As noted above, 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. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, E*nrollment*, and Renewal Processes* (87 FR 54760; hereinafter the "Streamlining Eligibility & Enrollment proposed rule") to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP).

The third dimension, which is the focus of this proposed rule, is access to services and supports. This rule is focused on addressing additional critical elements of access: (1) potential access (for example, provider availability and network adequacy); (2) beneficiary utilization (the use of health care and health services); and (3) beneficiaries' perceptions and experiences with

the care they did or did not receive. These terms and definitions build upon our previous efforts to examine how best to monitor access.[8]

In addition to the three proposed rules (the Streamlining Eligibility & Enrollment proposed rule, this proposed rule on managed care, and Medicaid Program; Ensuring Access to Medicaid Services proposed rule), we are also engaged in non-regulatory activities (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems. As noted earlier, the Streamlining Eligibility & Enrollment proposed rule addresses the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through that proposed rule, we sought to streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals. Through the Ensuring Access to Medicaid Services proposed rule, and this proposed rule involving managed care, we outline additional proposed steps to address the third dimension of the health care access continuum: access to services, while also in this rule addressing quality and financing of services in the managed care context. We seek to address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems.

The use of managed care in Medicaid has grown from 81 percent in 2016 to 84 percent in 2020[9], with 72 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations in 2020. We note that States may implement a Medicaid managed care delivery system using four Federal authorities--sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Social Security Act (the Act); each is described briefly below.

Under section 1915(a) of the Act, States can implement a voluntary managed care

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[8] 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.medicaid.gov/sites/default/files/2019-12/monitoring-plan.pdf*.

[9] *https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html*.

program by executing a contract with organizations that the State has procured using a competitive procurement process. To require beneficiaries to enroll in a managed care program to receive services, a State must obtain approval from CMS under two primary authorities:

- Through a State plan amendment (SPA) that meets standards set forth in section 1932(a) of the Act, States can implement a mandatory managed care delivery system. This authority does not allow States to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible beneficiaries), American Indians/Alaska Natives (except as permitted in section 1932 (a)(2)(C) of the Act), or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the State.
- We may grant a waiver under section 1915(b) of the Act, permitting a State to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a State may operate a section 1915(b) waiver for a 2-year period (certain waivers can be operated for up to 5 years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2- (or 5-) year period.

We may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act that include waivers permitting a State to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, States may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such demonstrations are approvable only if it is determined that the demonstration would promote the objectives of the Medicaid statute and the demonstration is subject to evaluation.

The above authorities all permit States to operate their Medicaid managed care programs without complying with the following standards of Medicaid law outlined in section of 1902 of the Act:

- Statewideness (section 1902(a)(1) of the Act): States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole State;
- Comparability of Services (section 1902(a)(10)(B) of the Act): States may provide different benefits to people enrolled in a managed care delivery system; and
- Freedom of Choice (section 1902(a)(23)(A) of the Act): States may generally require people to receive their Medicaid services only from a managed care plan's network of providers or primary care provider.

States that elect to operate a separate CHIP within a managed care delivery system do not need specific statutory authority to offer benefits through a managed care program. However, sections 2103(f)(3) and 2107(e)(1)(N) and (R) of the Act apply certain provisions of sections 1903 and 1932 of the Act related to Medicaid managed care to separate CHIPs. States that elect a Medicaid expansion CHIPs that operate within a managed care delivery system are subject to all requirements under section 1932 of the Act.

In the May 6, 2016 **Federal Register** (81 FR 27498), we published the "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability" final rule (hereinafter referred to as "the 2016 final rule") that modernized the Medicaid and CHIP managed care regulations to reflect changes in the use of managed care delivery systems. The 2016 final rule aligned many of the rules governing Medicaid and CHIP managed care with those of other major sources of coverage; implemented applicable statutory provisions; strengthened actuarial soundness payment provisions to promote the accountability of managed care program rates; strengthened efforts to reform delivery systems that serve Medicaid and

CHIP beneficiaries; and enhanced policies related to program integrity. The 2016 final rule applied many of the Medicaid managed care rules to separate CHIP, particularly in the areas of access, finance, and quality through cross-references to 42 CFR part 438.

In the January 18, 2017 **Federal Register** (82 FR 5415), we published the "Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems" final rule (hereinafter referred to as "the 2017 final rule"). In the 2016 final rule, we defined pass-through payments at § 438.6(a) as any amount required by the State (and considered in calculating the actuarially sound capitation rate) to be added to the contracted payment rates paid by the MCO, PIHP, or PAHP to hospitals, physicians, or nursing facilities that is not for the following purposes: a specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under § 438.6(c)(1)(i) through (iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; graduate medical education (GME) payments; or Federally-qualified health center (FQHC) or rural health clinic (RHC) wrap around payments. On June 29th, 2016, we also published the CMCS Informational Bulletin (CIB) concerning "The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems." The 2017 final rule codified the information in the CIB as well as gave States the option to eliminate physician and nursing facility payments immediately or phase down these payments over the 5-year transition period if they prefer and specified the maximum amount of pass-through payments permitted annually during the transition periods under Medicaid managed care contract(s) and rate certification(s). That final rule prevented increases in pass-through payments and the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were established in the 2016 final rule.

In the November 13, 2020 **Federal Register** (85 FR 72754), we published the "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care" final rule

(hereinafter referred to as the "2020 final rule") which streamlined the Medicaid and CHIP managed care regulatory framework to relieve regulatory burdens; support State flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. The rule was intended to ensure that the regulatory framework was efficient and feasible for States to implement in a cost-effective manner and ensure that States can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

Since publication of the 2020 final rule, the COVID-19 public health emergency (PHE) challenged States' ability to ensure beneficiaries' access to high-quality care, ensure adequate provider payment during extreme workforce challenges, and provide adequate program monitoring and oversight. On January 28, 2021, Executive Order (EO) 14009, *Strengthening Medicaid and the Affordable Care Act,* was signed and established the policy objective to protect and strengthen Medicaid and the Affordable Care Act (ACA) and to make high-quality health care accessible and affordable for every American, and 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 25, 2022, Executive Order 14070 directed 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. This proposed rule aims to fulfill Executive Orders 14009 and 14070 by helping States to use lessons learned from the PHE and build stronger managed care programs to better meet the needs of the Medicaid and CHIP populations by improving access to and quality of care provided.

In addition, this rule proposes new standards to help States improve their monitoring of access to care by requiring establishment of new standards for appointment wait times, use of secret shopper surveys, use of enrollee experience surveys, and requiring States to submit a managed care plan analysis of payments made by plans to providers, for specific services, to

more closely monitor plans' network adequacy. It also proposes provisions that would reduce burden for States that choose to direct MCOs, PIHPs, or PAHPs in certain ways to use their capitation payments to pay specified providers specified amounts, address impermissible redistribution arrangements related to State directed payments, and add clarity to the requirements related to medical loss ratio calculations. To improve transparency and provide valuable information to enrollees, providers, and CMS, this rule proposes to enhance existing State website requirements for content and ease of use. Lastly, this proposed rule would make quality reporting more transparent and meaningful for driving quality improvement, reduce burden on certain quality reporting requirements, and establish State requirements for implementing a Medicaid and CHIP quality rating system aimed at ensuring monitoring of performance by Medicaid and CHIP managed care plans and empowering beneficiary choice in managed care.

Finally, we believe it is important to acknowledge the role of health equity within this proposed rule. Medicaid and CHIP are the primary source of health care coverage for over one in three people of color in this country. Consistent with Executive Order 13985[10] which calls for advancing equity for underserved populations, we are working to advance health equity across CMS programs consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022-2032[11] and the HHS Equity Action Plan.[12] That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable care and coverage.

A key part of our approach will be to work with States to improve measurement of health disparities through the stratification of State reporting on certain measures to identify potential differences in access, quality, and outcomes based on demographic factors like race, ethnicity,

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[10] Executive Order 13985, *https://www.whitehouse.gov/briefing-room/presidentialactions/2021/01/20/executive-order-advancingracial-equity-and-support-or-underservedcommunities-through-the-federal-government/*.
[11] CMS Framework for Health Equity 2022–2032: *https://www.cms.gov/files/document/cmsframework-health-equity.pdf*.
[12] HHS Equity Action Plan, *https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf*.

age, rural/urban status, disability, language, sex, sexual orientation, and gender identity, as well as social determinants of health.

The "Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting" proposed rule appeared in the August 22, 2022 **Federal Register** (87 FR 51303) (hereinafter referred to as the"Mandatory Medicaid and CHIP Core Set Reporting proposed rule"). In that proposed rule, we proposed that the Secretary would specify, through annual subregulatory guidance, which measures in the Medicaid and CHIP Child Core Set, the behavioral health measures of the Medicaid Adult Core Set, and the Health Home Core Sets, States would be required to stratify, and by which factors, such as race, ethnicity, sex, age, rural/urban status, disability, language or other factors specified by the Secretary. CMS also proposed a phased-in timeline for stratification of measures in these Core Sets. In the Medicaid Program; Ensuring Access to Medicaid Services proposed rule, published elsewhere in the **Federal Register**, we also proposed a similar phased-in timeline and process for mandatory reporting and stratification of the Home and Community-Based Services (HCBS) Quality Measure Set.

Measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity and also align with the CMS Strategic Priorities.[13] In this proposed rule, we establish our intent to align with the stratification factors required for Core Set measure reporting, which we believe would minimize State and health plan burden to report stratified measures. To further reduce burden on States, we would permit States to report, if finalized, the same measurement and stratification methodologies and classifications as those proposed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule and the Ensuring Access to Medicaid Services proposed rule. We believe these measures and methodologies would be appropriate to include in States' Managed Care Program Annual Report (MCPAR) because § 438.66(e)(2)(vii) requires information on and an assessment

[13] CMS Strategic Plan 2022, *https://www.cms.gov/cms-strategic-plan*.

of the operation of each managed care program and an evaluation of managed care plan performance on quality measures. Reporting these measures in MCPAR would minimize State and provider burden while allowing more robust CMS monitoring and oversight of the quality of the health care provided at a managed care plan and program level. We would also anticipate publishing additional subregulatory guidance and adding specific fields in MCPAR that would accommodate this measure and data stratification reporting to simplify the process for States.

B. Provisions of the Proposed Regulations

Throughout this document, the term "PAHP" is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it is specifically addressed as a "Non-Emergency Medical Transportation (NEMT) PAHP." 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) 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 management (PCCMs) or PCCM entities.

For CHIP, the preamble uses "CHIP" when referring collectively to separate child health programs and Medicaid expansion programs. We use "separate CHIP" specifically in reference to separate child health programs and also in reference to any proposed changes in subpart L of part 457, which are only applicable to separate child health programs operating in a managed care delivery system. Also note in this proposed rule, all proposed changes to Medicaid managed care regulations are equally applicable to Medicaid expansion managed care programs as described at § 457.1200(c).1. Access (42 CFR 438.2, 438.10, 438.66, 438.68, 438.206, 438.207, 438.214, 438.602, 457.1207, 457.1218, 457.1230, 457.1250, 457.1285)

a. Enrollee experience surveys (§§ 438.66(b) and (c), 457.1230(b))

In the 2016 final rule, we renamed and expanded § 438.66 *State Monitoring Requirements* to ensure that States had robust systems to monitor their managed care programs, utilize the monitoring results to make program improvements, and report to CMS annually the results of their monitoring activities. Existing regulations at § 438.66(c)(5) require States to use the data collected from their monitoring activities to improve the performance of their managed care programs, including results from any enrollee or provider satisfaction surveys conducted by the State or managed care plan. Some States currently use surveys to gather direct input from their managed care enrollees, which we believe is a valuable source of information on enrollees' actual and perceived access to services. As a general matter, disparities in access to care related to demographic factors such as race, ethnicity, language, or disability status are, in part, a function of the availability of the accessible providers who are willing to provide care and are competent in meeting the needs of populations in medically underserved communities. Surveys can focus on matters that are important to enrollees and for which they are the best and, sometimes, only source of information. Patient experience surveys can also focus on how patients experienced or perceived key aspects of their care, not just on how satisfied they were with their care. For example, experience surveys can focus on asking patients whether or how often they accessed health care, barriers they encountered in accessing health care, and their experience including communication with their doctors, understanding their medication instructions, and the coordination of their health care needs. Some States already use enrollee experience surveys and report that the data is an asset in their efforts to assess whether the managed care program is meeting its enrollees' needs.

One of the most commonly used enrollee experience survey in the health care industry, including for Medicare Advantage organizations, is the Consumer Assessment of Healthcare Providers and Systems (CAHPS®)[14]. CAHPS experience surveys are available for health plans, dental plans, and home and community-based services (HCBS) programs, as well as for patient

14 The acronym "CAHPS" is a registered trademark of the Agency for Healthcare Research and Quality.

experience with providers such as home health, condition specific care such as behavioral health, or facility-based care such as in a nursing home. A survey specially designed to measure the impact of long-term services and supports (LTSS) on the quality of life and outcomes of enrollees is the National Core Indicators-Aging and Disabilities (NCI-AD®) Adult Consumer Survey™[15]. Whichever survey is chosen by a State, it should complement data gathered from other network adequacy and access monitoring activities to provide the State with a more complete assessment of their managed care programs' success at meeting their enrollees' needs. To ensure that States' managed care program monitoring systems, required at § 438.66(a), appropriately capture the enrollee experience, we propose to revise § 438.66(b)(4) to explicitly include "enrollee experience." Section 438.66(c)(5) currently requires States to use the results from any enrollee or provider satisfaction surveys they choose to conduct to improve the performance of its managed care program. To ensure that States have the data from an enrollee experience survey to include in their monitoring activities and improve the performance of their managed care programs, we propose to revise § 438.66(c)(5) to require that States conduct an annual enrollee experience survey. To reflect this, we propose to revise § 438.66(c)(5) to add "an annual" before "enrollee" and add "experience survey conducted by the State" after "enrollee." We also propose to replace "or" with "and" to be explicit that use of provider survey results alone would not be sufficient to comply with § 438.66(c)(5). While we encourage States and managed care plans to utilize provider surveys, we are not proposing to mandate them at this time. We believe other proposals in this rule, such as enrollee surveys and secret shopper surveys, may yield information that would inform our decision on the use of provider surveys in the future. We invite comment on whether we should mandate the use of a specific enrollee experience survey, define characteristics of acceptable survey instruments, and the operational considerations of enrollee experience surveys States use currently.

15 NCI-AD Adult Consumer Survey™ is a copyrighted tool.

To reflect these proposals in the annual assessment of the operation of the managed care program report called the Managed Care Program Annual Report (MCPAR) required at § 438.66(e), we propose conforming edits in § 438.66(e)(2)(vii). We propose to include the results of an enrollee experience survey to the list of items that States must evaluate in their report and add "provider" before "surveys" to distinguish them from enrollee experience surveys. Additionally, consistent with the transparency proposals described in section I.B.1.f. of this section, we propose to revise § 438.66(e)(3)(i) to require that States post the report required in § 438.66(e)(1) on their website within 30 calendar days of submitting it to CMS. Currently § 438.66(e)(3)(i) only requires that the report be posted on the State's website but does not specify a timeframe; we believe that adding further specificity about the timing of when the report should be posted would be helpful to interested parties and bring consistency to this existing requirement. This proposal is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

For an enrollee experience survey to yield robust, usable results, it should be easy to understand, simple to complete, and readily accessible for all enrollees that receive it; therefore, we believe they should meet the interpretation, translation, and tagline criteria in § 438.10(d)(2). Therefore, we propose to add enrollee experience surveys as a document subject to the requirements in § 438.10(d)(2). This would ensure that enrollees that receive a State's enrollee experience survey would be fully notified that oral interpretation in any language and written translation in the State's prevalent languages would be readily available, and how to request auxiliary aids and services, if needed.

These proposals are authorized by section 1932(b)(5) of the Act which requires managed care organizations to demonstrate adequate capacity and services by providing assurances to the State and CMS that it has the capacity to serve the expected enrollment in its service area, including assurances that it offers an appropriate range of services and access to preventive and

primary care services for the population expected to be enrolled in such service area, and maintains a sufficient number, mix, and geographic distribution of providers of services. The authority for our proposals is extended to prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) through regulations based on our authority under section 1902(a)(4) of the Act. Because enrollee experience survey results would provide direct and candid input from enrollees, States and managed care plans could use the results to determine if their networks offer an appropriate range of services and access as well as if it provides a sufficient number, mix, and geographic distribution of providers to meet their enrollees' needs. Enrollee experience survey data would enable managed care plans to assess whether their networks are providing sufficient capacity as experienced by their enrollees and that assessment would inform the assurances that the plan is required to provide to the State and CMS. These proposals are also authorized by section 1932(c)(1)(A)(i) and (iii) of the Act which require States that contract with MCOs to develop and implement a quality assessment and improvement strategy that includes: standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity and procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees and requirements for provision of quality assurance data to the State. Data from enrollee experience surveys would enable States to use the results to evaluate whether their plans' networks are providing access to covered services within reasonable timeframes and in a manner that ensures continuity of care. These data would also inform the development and maintenance of States' quality assessment and improvement strategies and would be critical to States' monitoring and evaluation of the quality and appropriateness of care and services provided to enrollees.

We remind States that in addition to the mandatory external quality review (EQR) activities under § 438.358(b), there is an existing optional EQR activity under § 438.358(c)(2) for the administration or validation of consumer or provider surveys of quality of care. States that

contract with MCOs and use external quality review organizations (EQROs) to administer or validate the proposed enrollee experience surveys may be eligible to receive up to a 75 percent enhanced Federal match, pursuant to § 438.370, to reduce the financial burden of conducting or validating the proposed enrollee survey(s).

We request comment on the cost and feasibility of implementing enrollee experience surveys for each managed care program as well as the extent to which States already use enrollee experience surveys for their managed care programs.

We propose that States would have to comply with § 438.66(b) and (c) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We have proposed this applicability date in § 438.66(f).

We did not adopt the managed care State monitoring requirements described at § 438.66 in the 2016 final rule for separate CHIPs because we wished to limit administrative burden on separate CHIP managed care plans, which typically serve smaller populations. Since we did not adopt MCPAR, we do not plan to adopt the new Medicaid enrollee experience survey requirements proposed at § 438.66(b) and (c) for separate CHIPs. However, States currently collect enrollee experience data for CHIP through annual CAHPS surveys as required at section 2108(e)(4) of the Act. Currently, there are no requirements for States to use these data to evaluate their separate CHIP managed care plans network adequacy or to make these survey results available to beneficiaries to assist in selecting a managed care plan. We believe that enrollee experience data can provide an invaluable window into the performance of managed care plans and assist States in their annual review and certification of network adequacy for separate CHIP MCOs, PIHPs, and PAHPs. For this reason, we propose to amend § 457.1230(b) to require States to evaluate annual CAHPS survey results as part of the State's annual analysis of network adequacy as described in § 438.207(d). Since States already collect CAHPS survey data for CHIP and would likely not need the same timeframe to implement as needed for

implementing the proposed Medicaid enrollee experience surveys requirement, we propose for the provision at § 457.1230(b) to be applicable 60 days after the effective date of the final rule. However, we are open to a later applicability date such as 1, 2, or 3 years after the effective date of the final rule. We invite comment on the appropriate applicability date for this provision.

We also believe that access to enrollee experience data is critical in affording separate CHIP beneficiaries the opportunity to make informed decisions when selecting their managed care plan(s). To this end, we propose at § 457.1207 to require States to post comparative summary results of CAHPS surveys by managed care plan annually on State websites as described at § 438.10(c)(3). The posted summary results must be updated annually and allow for easy comparison between the managed care plans available to separate CHIP beneficiaries. We seek public comment on other approaches to including CHIP CAHPS survey data for the dual purposes of improving access to managed care services and enabling beneficiaries to have useful information when selecting a managed care plan.

b. Appointment wait time standards (§§ 438.68(e), 457.1218)

In the 2020 final rule, we revised § 438.68(b)(1) and (2) by replacing the requirement for States to set time and distance standards with a more flexible requirement that States set a quantitative network adequacy standard for specified provider types. We explained that quantitative network adequacy standards that States may elect to use included minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation requirements (for example, extended evening or weekend hours); and combinations of these quantitative measures. We encouraged States to use the quantitative standards in combination- not separately- to ensure that there are not gaps in access to, and availability of, services for enrollees. (85 FR 72802)

Key to the effectiveness of the Medicaid and CHIP program is ensuring that it provides timely access to high-quality services in a manner that is equitable and consistent. During the

COVID-19 public health emergency (PHE), managed care plans have faced many challenges ensuring access to covered services and those challenges shed light on opportunities for improvement in monitoring timely access. These challenges include workforce shortages, changes in providers' workflows and operating practices, providers relocating leaving shortages in certain areas, and shifts in enrollee utilization such as delaying or forgoing preventive care. Some of these challenges may become permanent and thus, States and managed care plans need to adjust their monitoring, evaluation, and planning strategies to ensure equitable access to all covered services.

On February 17, 2022, we issued a request for information[16] (RFI) soliciting public input on improving access in Medicaid and CHIP, including ways to promote equitable and timely access to providers and services. Barriers to accessing care represented a significant portion of comments received, with common themes related to providers not accepting Medicaid and recommendations calling for us to set specific quantitative access standards. Many commenters urged us to consider developing a Federal standard for timely access to providers and services, but giving State Medicaid and CHIP agencies the flexibility to impose more stringent requirements. A recently published study[17] examined the extent to which Medicaid managed care plan networks may overstate the availability of physicians in Medicaid, and evaluated the implications of discrepancies in the "listed" and "true" networks for beneficiary access. The authors concluded that findings suggest that current network adequacy standards might not reflect actual access and that new methods are needed that account for physicians' willingness to serve Medicaid patients. Another review of 34 audit studies demonstrated that Medicaid is associated with a 1.6-fold lower likelihood in successfully scheduling a primary care

16 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*.

17 *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747*.

appointment and a 3.3-fold lower likelihood in successfully scheduling a specialty appointment when compared with private insurance.[18]

Based on the RFI comments received, research, engagement with interested parties, and our experience in monitoring State managed care programs, we are persuaded about the need for increased oversight of network adequacy and overall access to care, and propose a new quantitative network adequacy standard. Specifically, we propose to redesignate existing § 438.68(e) regarding publication of network adequacy standards to § 438.68(g) and create a new § 438.68(e) titled "Appointment wait time standards."

In § 438.68(e)(1)(i) through (iv), we propose that States develop and enforce wait time standards for routine appointments for four types of services: outpatient mental health and substance use disorder (SUD)- adult and pediatric, primary care- adult and pediatric, obstetrics and gynecology (OB/GYN), and an additional type of service determined by the State (in addition to the three listed) in an evidence-based manner for Medicaid. We include "If covered in the MCO's, PIHP's, or PAHP's contract" before the first three service types (paragraphs (e)(1)(i) through (iii)) to be clear that standards only need to be developed and enforced if the service is covered by the managed care plan's contract, but the forth service (paragraph (e)(1)(iv)) must be one that is covered by the plan's contract. For example, we understand that primary care and OB/GYN is likely not covered by a behavioral health PIHP; therefore, a State would not be required to set appointment wait time standards for primary care and OB/GYN for the behavioral health PIHP and would only have to set appointment wait time standards for mental health and SUD as well as one State-selected provider type. To ensure that our proposal to have States set appointment wait time standards for mental health and SUD as well as one State-selected provider type for behavioral PIHPs and PAHPs is feasible, we request comment on whether behavioral health PIHPs and PAHPs include provider types other than mental health and SUD in

18 W. Hsiang, A. Lukasiewicz, and M. Gentry, "Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis," SAGE Journals, April 5, 2019, available at *https://journals.sagepub.com/doi/full/10.1177/0046958019838118*.

their networks. Although we believe behavioral health PIHPs and PAHPs may include other provider types, we want to validate our understanding. We propose to adopt the proposed wait time standards for separate CHIP through an existing cross-reference at § 457.1218. We are proposing primary care, OB/GYN, and mental health and SUD because they are indicators of core population health; therefore, we believe proposing to require States to set appointment wait time standards for them would have the most impact on access to care for Medicaid and CHIP managed care enrollees.

At § 438.68(e)(1)(iv), we propose that States select a provider type in an evidence-based manner to give States the opportunity to use an appointment wait time standard to address an access challenge in their local market. We are not proposing to specify the type of evidence to be used in this rule; rather, we defer to States to consider multiple sources, such as encounter data, appeals and grievances, and provider complaints, as well as to consult with their managed care plans to select a provider type. We believe proposing that States select one of the provider types subject to an appointment wait time standard would encourage States and managed care plans to analyze network gaps effectively and then innovate new ways to address the challenges that impede timely access. States would identify the provider type(s) they choose in existing reporting in MCPAR, per § 438.66(e), and the Network Adequacy and Access Assurances Report, per § 438.207(d).

To be clear that the appointment wait time standards proposed in § 438.68(e) cannot be the quantitative network adequacy standard required in § 438.68(b)(1), we propose to add "…, other than for appointment wait times…" in § 438.68(b)(1). We are not proposing to define routine appointments in this rule; rather, we defer to States to define it as they deem appropriate. We encourage States to work with their managed care plans and their network providers to develop a definition of "routine" that would reflect usual patterns of care and current clinical standards. We acknowledge that defining "urgent" and "emergent" for appointment wait time standards could be much more complex given the standards of practice by specialty and the

patient-specific considerations necessary to determine those situations. We invite comments on defining these terms should we undertake additional rulemaking in the future. We clarify that setting appointment wait time standards for routine appointments as proposed at § 438.68(e)(1) would be a minimum; States are encouraged to set additional appointment wait time standards for other types of appointments. For example, States may consider setting appointment wait time standards for emergent or urgent appointments as well.

To provide States with flexibility to develop appointment wait time standards that reflect the needs of their Medicaid and CHIP managed care populations and local provider availability while still setting a level of consistency, we propose maximum appointment wait times at § 438.68(e)(1): State developed appointment wait times must be no longer than 10 business days for routine outpatient mental health and substance use disorder appointments in § 438.68(e)(1)(i) and no longer than 15 business days for routine primary care in § 438.68(e)(1)(ii) and OB/GYN appointments in § 438.68(e)(1)(iii). We are not proposing a maximum appointment wait time standard for the State-selected provider type. These proposed maximum timeframes were informed by standards for the individual insurance Marketplace established under the Affordable Care Act that will begin in 2024 of 10 business days for behavioral health and 15 business days for primary care services; we note that we elected not to adopt the Marketplace's appointment wait time standard of 30 business days for non-urgent specialist appointments as we believe focusing on primary care, OB/GYN, and mental health and SUD is the most appropriate starting place for Medicaid managed care standards. These proposed timeframes were also informed by engagement with interested parties, including comments in response to the RFI. We are proposing to require appointment wait times for routine appointments only in this rule as we believe that providers utilize more complex condition and patient-specific protocols and clinical standards of care to determine scheduling for urgent and emergent care. We may address standards for other types of appointments in future rulemaking and hope that information from

the use of appointment wait time standards for routine appointments may inform future proposals.

In developing this proposal, we considered appointment wait time standards between 30-calendar days and 45-calendar days. Some interested parties stated that these standards would be more appropriate for routine appointments and would more accurately reflect current appointment availability for most specialties. However, we believe 30- calendar days and 45-calendar days as the maximum wait time may be too long as a standard; we understand it may be a realistic timeframe currently for some specialist appointments but we were not convinced that they should be the standard for outpatient mental health and substance use disorder, primary care, and OB/GYN appointments. We invite comment on aligning with the Marketplace standards at 10- and 15-business days, or whether wait time standards should differ, and if so, what standards would be the most appropriate.

To make the appointment wait time standards as effective as possible, we defer to States on whether and how to vary appointment wait time standards for the same provider type; for example, by adult versus pediatric, telehealth versus in-person, geography, service type, or other ways. However, wait time standards must, at a minimum, reflect the timing proposed in § 438.68(e)(1). We encourage States to consider the unique access needs of certain enrollees when setting their appointment wait time standards to facilitate obtaining meaningful results when assessing managed care plan compliance with the standards.

As a general principle, we seek to align across Medicaid managed care, CHIP managed care, the Marketplace, and Medicare Advantage (MA) when reasonable to build consistency for individuals that may change coverage over time and to enable more effective and standardized comparison and monitoring across programs. Proposing 90 percent compliance with 10- and 15-business day maximum appointment wait time standards would be consistent with standards set for Marketplace plans for plan year 2024.[19] However, we note that for MA, CMS expects MA

19 *https://www.cms.gov/sites/default/files/2022-04/Final-2023-Letter-to-Issuers_0.pdf*.

plans to set reasonable standards for primary care services for urgently needed services or emergencies immediately; services that are not emergency or urgently needed, but in need of medical attention within one week; and routine and preventive care within 30 days.[20]

To ensure that managed care plans' contracts reflect their obligation to comply with the appointment wait time standards, we propose to revise § 438.206(c)(1)(i) to include appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1230(a). We believe this is necessary since our proposal at § 438.68(e)(1) to develop and enforce appointment wait time standards is a State responsibility; proposing this revision to § 438.206(c)(1)(i) would specify the corresponding managed care plan responsibility.

We propose to revise the existing applicability date in § 438.206(d) for Medicaid, which is applicable for separate CHIPs through an existing cross-reference at § 457.1230(a) and a proposed cross-reference at § 457.1200(d), to reflect that States would have to comply with § 438.206(c)(1)(i) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance.

Current requirements at § 438.68(c)(1) and (2) for Medicaid, and through a cross-reference at § 457.1218 for separate CHIP, direct States to consider twelve elements when developing their network adequacy standards. We remind States that § 438.68(c)(1)(ix) includes the availability and use of telemedicine, e-visits, and/or other evolving and innovative technological solutions as an element that States must consider when developing their network adequacy standards. Services delivered via telehealth seek to improve a patient's health through two-way, real time interactive communication between the patient, and the provider. Services delivered in this manner can, for example, be used for assessment, diagnosis, intervention, consultation, and supervision across distances. Services can be delivered via telehealth across all

20 MCM Chapter 4 (*www.cms.gov*).

populations served in Medicaid including, but not limited to children, individuals with disabilities, and older adults. States have broad flexibility to cover telehealth through Medicaid and CHIP, including the methods of communication (such as telephonic or video technology commonly available on smart phones and other devices) to use.[21] States need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68 that accurately reflect the practical use of both types of care in their State. Therefore, States should review encounter data to gauge telehealth use by enrollees over time and the availability of telehealth appointments by providers and account for that information when developing their appointment wait time standards. We also remind States that they have broad flexibility with respect to covering services provided via telehealth and may wish to include quantitative network adequacy standards or specific appointment wait time standards for telehealth *in addition* to in-person appointment standards, as appropriate based on current practices and the extent to which network providers offer telehealth services. Although States have broad flexibility in this area, we remind States of their responsibility under section 504 of the Rehabilitation Act and section 1557 of the Affordable Care Act to ensure effective communications for patients with disabilities for any telehealth services that are offered and to provide auxiliary aids and services at no cost to the individual to ensure that individuals with disabilities are able to access and utilize services provided via telehealth; we also remind States of their responsibilities under Title VI of the Civil Rights Act of 1964, including the obligation to take reasonable steps to ensure meaningful language access for persons with limited English proficiency when providing telehealth services. [22]

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21 *https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf*.
22 US Department of Justice, Civil Rights Division and Department of Health and Human Services, Office for Civil Rights, "Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons," July 29, 2022, available online at *https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html*.

Current Medicaid regulations at § 438.68(e), and through a cross-reference at § 457.1218 for separate CHIP, require States to publish the network adequacy standards required by § 438.68(b)(1) and (2) on their websites and to make the standards available upon request at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services. To ensure transparency and inclusion of the new proposed appointment wait time standards in this provision, we propose several revisions: to redesignate § 438.68(e) to § 438.68(g); to replace "and" with a comma after "(b)(1);" add "(b)" before "(2)" for clarity; and add a reference to (e) after "(b)(2)." We believe these changes make the sentence clearer and easier to read. Lastly, § 438.68(e) currently includes "…the Web site required by § 438.10." For additional clarity in redesignated § 438.68(g), we propose to replace "438.10" with "§ 438.10(c)(3)" to help readers more easily locate the requirements for State websites. These proposed changes apply equally to separate CHIP managed care through existing cross-references at §§ 457.1218 and 457.1207.

At § 438.68(e)(2), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218, we propose that managed care plans would be deemed compliant with the standards established in paragraph (e)(1) when secret shopper results, described in section I.B.1.c. of this rule, reflect a rate of appointment availability that meets State established standards at least 90 percent of the time. By proposing a minimum compliance rate for appointment wait time standards, we would provide States with leverage to hold their managed care plans accountable for ensuring that their network providers offer timely appointments. Further, ensuring timely appointment access 90 percent of the time would be an important step toward helping States ensure that the needs of their Medicaid and CHIP populations are being met timely. As with any provision of part 438 and subpart L of part 457, we may require States to take corrective action to address noncompliance.

To ensure that appointment wait time standards would be an effective measure of network adequacy, we believe we need some flexibility to add provider types to address new

access or capacity issues at the national level. Therefore, at § 438.68(e)(3), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218, we propose that CMS may select additional types of appointments to be added to § 438.68(e)(1) after consulting with States and other interested parties and providing public notice and opportunity to comment. From our experience with the COVID-19 PHE as well as multiple natural disasters in recent years, we believe it prudent to explicitly state that we may utilize this flexibility as we deem appropriate in the future.

We recognize that situations may arise when an MCO, PIHP, or PAHP may need an exception to the State established provider network standards, including appointment wait times. Section 438.68(d) currently provides that, to the extent a State permits an exception to any of the provider-specific network standards, the standard by which an exception would be evaluated and approved must be specified in the MCO, PIHP, or PAHP contract and must be based, at a minimum, on the number of providers in that specialty practicing in the MCO's, PIHP's, or PAHP's service area. We propose to make minor grammatical revisions to § 438.68(d)(1) by deleting "be" before the colon and inserting "be" as the first word of § 438.68(d)(1)(i) and (ii), which is included in separate CHIP regulations through an existing cross-reference at § 457.1218. We also propose to add a new standard at § 438.68(d)(1)(iii) for Medicaid, and through an existing cross-reference at § 457.1218 for separate CHIP, for reviews of exception requests, which would require States to consider the payment rates offered by the MCO, PIHP, or PAHP to providers included in the provider group subject to the exception. Managed care plans sometimes have difficulty building networks that meet network adequacy standards due to low payment rates. We believe that States should consider whether this component is a contributing factor to a plan's inability to meet the standards required by § 438.68(b)(1) and (2) and (e), when determining whether a managed care plan should be granted an exception. We remind States of their obligation at § 438.68(d)(2) to monitor enrollee access on an ongoing basis

to the provider types in managed care networks that operate under an exception and report their findings as part of the annual Medicaid MCPAR required at § 438.66(e).

Our proposal for States to develop and enforce appointment wait time standards proposed at § 438.68(e) and the accompanying secret shopper surveys of plan's compliance with them (described in section I.B.1.c. of this proposed rule) proposed at § 438.68(f) are authorized by section 1932(b)(5) of the Act, and is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act, and authorized for CHIP through section 2103(f)(3) of the Act. We believe that secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State's appointment wait time standards and these data would aid managed care plans as they assess their networks, pursuant to § 438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area and that it offers appropriate access to preventive and primary care services for their enrollees. States should find the results of the secret shopper surveys a rich source of information to assess compliance with the components of their quality strategy that address access to care and determine whether covered services are available within reasonable timeframes, as required in section 1932(c)(1)(A)(i) of the Act and required for CHIP through section 2103(f)(3) of the Act.

Section 1932(d)(5) of the Act requires that, no later than July 1, 2018, contracts with MCOs and PCCMs, as applicable, must include a provision that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under this title, title XVIII, or title XXI must be terminated from participating as a provider in any network. Although States have had to comply with this provision for several years, we believe we should reference this important provision in 42 CFR part 438, as well as use our authority under section 1902(a)(4) of the Act to apply it to PIHPs and PAHPs. To do this, we propose a new § 438.214(d)(2) to reflect that States must ensure through their MCO, PIHP, and PAHP contracts that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act)

from participation under this title, title XVIII, or title XXI must be terminated from participating as a provider in any Medicaid managed care plan network.

We propose that States would have to comply with § 438.68(b)(1), (e), and (g) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 3 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We propose that States would have to comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule. We propose that States would have to comply with § 438 (d)(1)(iii) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 2 years after the effective date of the final rule. We have proposed these applicability dates in § 438.68(h) for Medicaid, and for separate CHIPs through an existing cross-reference at § 457.1218 and a proposed cross-reference at § 457.1200(d).

c. Secret shopper surveys (§§ 438.68(f), 457.1207, 457.1218)

We recognize that in some States and for some services, Medicaid beneficiaries face significant gaps in access to care. Evidence suggests that in some localities and for some services, it takes Medicaid beneficiaries longer to access medical appointments compared to individuals with other types of health coverage.[23] This may be exacerbated by difficulties in accessing accurate information about managed care plans' provider networks; although Medicaid and CHIP managed care plans are required to make regular updates to their online provider directories in accordance with §§ 438.10(h)(3) and 457.1207 respectively, analyses of these directories suggest that a significant share of provider listings include inaccurate information on, for example, how to contact the provider, the provider's network participation, and whether the provider is accepting new patients.[24] Relatedly, analyses have shown that the vast majority of

23 W. Hsiang, A. Lukasiewicz, and M. Gentry, "Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis," SAGE Journals, April 5, 2019, available at *https://journals.sagepub.com/doi/full/10.1177/0046958019838118*.

24 A. Burman and S. Haeder, "Directory Accuracy and Timely Access in Maryland's Medicaid Managed Care Program," Journal of Health Care for the Poor and Underserved, available at

services delivered to Medicaid beneficiaries are provided by a small subset of health providers listed in managed care plan provider directories, with a substantial share of listed providers delivering little or no care for Medicaid beneficiaries.[25] Some measures of network adequacy may not be as meaningful as intended if providers are "network providers" because they have a contract with a managed care plan, but in practice are not actually accepting new Medicaid enrollees or impose a cap on the number of Medicaid enrollees they will see.

To add a greater level of validity and accuracy to States' efforts to measure network adequacy and access, we propose to require States to use secret shopper surveys as part of their monitoring activities. Secret shopper surveys are a form of research that can provide high-quality data and actionable feedback to States and managed care plans and can be performed either as "secret" meaning the caller does not identify who they are performing the survey for or "revealed" meaning the caller identifies the entity for which they are performing the survey. While both types of surveys can produce useful results, we believe the best results are obtained when the survey is done as a secret shopper and the caller pretends to be an enrollee (or their representative) trying to schedule an appointment. Results from these surveys should be unbiased, credible, and reflect what it is truly like to be an enrollee trying to schedule an appointment, which is a perspective not usually provided by, for example, time and distance measures or provider-to-enrollee ratios. Many States and managed care plans currently use some type of survey to monitor access; however, we believe there should be some consistency to their use for Medicaid managed care programs to enable comparability.

To ensure consistency, we propose a new § 438.68(f), and propose to require that States use independent entities to conduct annual secret shopper surveys of managed care plan compliance with appointment wait time standards proposed at § 438.68(e) and the accuracy of

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https://pubmed.ncbi.nlm.nih.gov/35574863/; A. Bauman and S. Haeder, "Potemkin Protections: Assessing Provider Directory Accuracy an Timely Access for Four Specialties in California," Journal of Health Politics, Policy and Law, 2022, available at *https://pubmed.ncbi.nlm.nih.gov/34847230/*.

25 A. Ludomirsky, et. al., "In Medicaid Managed Care Networks, Care is Highly Concentrated Among a Small Percentage of Physicians," Health Affairs, May 2022, available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747*.

certain data in all managed care plans' electronic provider directories required at § 438.10(h)(1). These proposed changes apply equally to separate CHIPs through existing cross-references at §§ 457.1218 and 457.1207. We believe that the entity that conducts these surveys must be independent of the State Medicaid or CHIP agency and its managed care plans subject to the survey to ensure unbiased results. Therefore, at § 438.68(f)(3)(i), we propose to consider an entity to be independent of the State if it is not part of the State Medicaid agency and, at § 438.68(f)(3)(ii), to consider an entity independent of a managed care plan subject to a secret shopper survey if the entity is not an MCO, PIHP, or PAHP; is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys; and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. Given the valuable data the proposed secret shopper surveys could provide States, we believe requiring the use of an independent entity to conduct the surveys would be critical to ensure unbiased results.

We also propose to require States to use secret shopper surveys to determine the accuracy of certain provider directory information in MCOs', PIHPs', and PAHPs' most current electronic provider directories at § 438.68(f)(1)(i). Since we believe that paper directory usage is dwindling due to the ever-increasing use of electronic devices and because electronic directory files are usually used to produce paper directories, we are not requiring secret shopper validation of paper directories. Rather, we propose in § 438.68(f)(1)(i)(A) through (C) to require surveys of electronic provider directory data for primary care providers, OB/GYN providers, and outpatient mental health and substance use disorder providers, if they are included in the managed care plan's provider directories. We are proposing these provider types because they are the provider types with the highest utilization in many Medicaid managed care programs.

To ensure that a secret shopper survey can be used to validate directory data for every managed care plan, we propose in § 438.68(f)(1)(i)(D) to require secret shopper surveys for provider directory data for the provider type selected by the State for its appointment wait time standards in § 438.68(e)(1)(iv). We recognize that the State-chosen provider type may vary

across managed care plan types and thus, States may have to select multiple provider types to accommodate all of their managed care programs. For example, a State may select a provider type from their MCOs' directories that is not a provider type included in their mental health PIHP's directories; just as the State may select a provider type from their behavioral health PIHPs' directories that is not a provider type included in their dental PAHPs' directories. We note that the State-chosen provider type cannot vary among plans of the same type within the same managed care program. Although this degree of variation between States would limit comparability, we believe that the value of validating provider directory data outweighs this limitation and that having results for provider types that would be important to State specific access issues would be a rich source of data for States to evaluate managed care plan performance and require the impacted plan to implement timely remediation, if needed.

At § 438.68(f)(1)(ii)(A) through (D), we propose to require that States use independent entities to conduct annual secret shopper surveys to verify the accuracy of four pieces of data in each MCO, PIHP, or PAHP electronic provider directory required at § 438.10(h)(1): the active network status with the MCO, PIHP, or PAHP; the street address as required at § 438.10(h)(1)(ii); the telephone number as required at § 438.10(h)(1)(iii); and whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi). We believe these are the most critical pieces of information that enrollees rely on when seeking network provider information. Inaccuracies in this information can have a tremendously detrimental effect on enrollees' ability to access care since finding providers that are not in the managed care plan's network, have inaccurate addresses and phone numbers, or finding providers that are not accepting new patients listed in a plan's directory can delay their ability to contact a network provider and ultimately, receive care.

To maximize the value of using secret shopper surveys to validate provider directory data, identified errors must be corrected as quickly as possible. Therefore, at § 438.68(f)(1)(iii) and (iv) respectively, we propose that States must receive information on all provider directory

data errors identified in secret shopper surveys no later than 3 business days from identification by the entity conducting the secret shopper survey and that States must then send that data to the applicable managed care plan within 3 business days of receipt. We also propose in § 438.68(f)(1)(iii) that the information sent to the State must be "sufficient to facilitate correction" to ensure that enough detail is provided to enable the managed care plans to quickly investigate the accuracy of the data and make necessary corrections. We note that States could delegate the function of forwarding the information to the managed care plans to the entity conducting the secret shopper surveys so that the State and managed care plans receive the information at the same time. This would hasten plans' receipt of the information as well as alleviate State burden. To ensure that managed care plans use the data to update their electronic directories, we propose at § 438.10(h)(3)(iii) to require MCOs, PIHPs, and PAHPs to use the information from secret shopper surveys required at § 438.68(f)(1) to obtain corrected information and update provider directories no later than the timeframes specified in § 438.10(h)(3)(i) and (ii), and included in separate CHIP regulations through an existing cross-reference at § 457.1207. While updating provider directory data after it has been counted as an error in secret shopper survey results would not change a managed care plan's compliance rate, it would improve provider directory accuracy more quickly and thus, improve access to care for enrollees.

To implement section 5123 of the Consolidated Appropriations Act of 2023,[26] we propose to revise § 438.10(h)(1) by adding "searchable" before "electronic form" to require that managed care plan electronic provider directories be searchable. We also propose to add paragraph (ix) to § 438.10(h)(1) to require that managed care plan provider directories include information on whether each provider offers covered services via telehealth. These proposals would align the text in § 438.10(h) with section 1932(a)(5) of the Act, as amended by section 5123 of the Consolidated Appropriations Act of 2023. Section 5123 of the Consolidated

26 BILLS-117hr2617enr.pdf (*congress.gov*).

Appropriations Act of 2023 specifies that the amendments to section 1932(a)(5) of the Act will take effect on July 1, 2025; therefore, we propose that States would have to comply with the revisions to § 438.10(h)(1) and new (h)(1)(ix) by July 1, 2025.

Our proposals for a secret shopper survey of provider directory data proposed at § 438.68(f)(1) are authorized by section 1932(a)(5)(B)(i) of the Act for Medicaid and through section 2103(f)(3) of the Act for CHIP, which require each Medicaid MCO to make available the identity, locations, qualifications, and availability of health care providers that participate in their network. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. We propose that secret shopper surveys include verification of certain providers' active network status, street address, telephone number, and whether the provider is accepting new enrollees; these directory elements reflect the identity, location, and availability, as required for Medicaid in section 1932(a)(5)(B)(i) of the Act and required for CHIP through section 2103(f)(3) of the Act. Although the statute does not explicitly include "accurate" to describe "the identity, locations, qualifications, and availability of health care providers," we believe it is the intent of the text and therefore, utilizing secret shopper surveys to identify errors in provider directories would help managed care plans ensure the accuracy of the information in their directories. Further, our proposal at § 438.10(h)(3)(iii) for managed care plans to use the data from secret shopper surveys to make timely corrections to their directories would also be consistent with statutory intent to reflect accurate identity, locations, qualifications, and availability information. Secret shopper survey results would provide vital information to help managed care plans fulfill their obligations to make the identity, locations, qualifications, and availability of health care providers that participate in the network available to enrollees and potential enrollees.

We believe using secret shopper surveys could also be a valuable tool to help States meet their enforcement obligations of appointment wait time standards, required in § 438.68(e). Secret shopper surveys are perhaps the most commonly used tool to assess health care

appointment availability and can produce unbiased, actionable results. At § 438.68(f)(2), we propose to require States to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards proposed in § 438.68(e)(1). We also propose in § 438.68(f)(2)(i) that, after consulting with States and other interested parties and providing public notice and opportunity to comment, we may select additional provider types to be added to secret shopper surveys of appointment wait time standards. We believe that after reviewing States' assurances of compliance and accompanying analyses of secret shopper survey results as proposed at § 438.207(d), and through an existing cross-reference at § 457.1230(b) for separate CHIP, we may propose additional provider types be subject to secret shopper surveys in future rulemaking.

In section I.B.1.b. of this proposed rule, we explained that States need to balance the use of telehealth with the availability of providers that can provide in-person care and enrollees' preferences for receiving care to ensure that they establish network adequacy standards under § 438.68(e) that accurately reflect the practical use of telehealth and in-person appointments in their State. To ensure that States reflect this, in § 438.68(f)(2)(ii), we propose that appointments offered via telehealth only be counted towards compliance with appointment wait time standards if the provider also offers in-person appointments and that telehealth visits offered during the secret shopper survey be separately identified in the survey results. We believe it would be appropriate to prohibit managed care plans from meeting appointment wait time standards with telehealth appointments alone and by separately identifying telehealth visits in the results because this would help States determine if the type of appointments being offered by providers is consistent with expectations and enrollees' needs. We note that this proposal is consistent with the requirement for QHPs beginning in 2024[27]. Managed care encounter data in Transformed Medicaid Statistical Information system (T-MSIS) reflects that most care is still provided in-person and that use of telehealth has quickly returned to near pre-pandemic levels. We believe

27 *https://www.cms.gov/sites/default/files/2022-04/Final-2023-Letter-to-Issuers_0.pdf.*

by explicitly proposing to limit the counting of telehealth visits to meet appointment wait time standards, as well as the segregation of telehealth and in-person appointment data, secret shopper survey results would produce a more accurate reflection of what enrollees actually experience when attempting to access care. We considered aligning appointment wait times and telehealth visits with the process used by MA for demonstrating overall network adequacy, which permits MA organizations to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits. However, we believe our proposal would provide States and CMS with more definitive data to assess the use of telehealth and enrollee preferences and would be the more appropriate method to use at this time. We request comment on this proposal.

Our proposal for secret shopper surveys of plans' compliance with appointment wait time standards proposed at § 438.68(f)(2) is authorized by section 1932(b)(5) of the Act for Medicaid and through section 2103(f)(3) of the Act for CHIP, because secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State's appointment wait time standards. This data should aid managed care plans as they assess their networks, pursuant to § 438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area. States should find the results of the secret shopper surveys a rich source of information to assess compliance with the components of their quality strategy that address access to care and determine whether covered services are available within reasonable timeframes, as required in section 1932(c)(1)(A)(i) of the Act for Medicaid and section 2103(f)(3) of the Act for CHIP.

It is critical that secret shopper survey results be obtained in an unbiased manner using professional techniques that ensure objectivity. To reflect this, we propose at § 438.68(f)(3) that any entity that conducts secret shopper surveys must be independent of the State Medicaid

agency and its managed care plans subject to a secret shopper survey. In § 438.68(f)(3)(i) and (ii), we propose the criteria for an entity to be considered independent: Section 438.68(f)(3)(i) proposes that an entity cannot be a part of any State governmental agency to be independent of a State Medicaid agency and § 438.68(f)(3)(ii) proposes that to be independent of the managed care plans subject to the survey, an entity would not be an MCO, PIHP, or PAHP, would not be owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and would not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys. We propose to define "independent" by using criteria that is similar, but not as restrictive, as the criteria used for independence of enrollment brokers and specified at § 438.810(b)(1). We believe this consistency in criteria would make it easier for States to evaluate the suitability of potential survey entities. We remind States that the optional EQR activity at § 438.358(c)(5) could be used to conduct the secret shopper surveys proposed at § 438.68(f) and for secret shopper surveys conducted for MCOs, States may be able to receive enhanced Federal financial participation (FFP), pursuant to § 438.370.

Secret shopper surveys can be conducted in many ways, using varying levels of complexity and gathering a wide range of information. We want to give States flexibility to design their secret shopper surveys to produce results that not only validate managed care plans' compliance with provider directory data accuracy as proposed at § 438.68(f)(1) and appointment wait time standards at § 438.68(f)(2), but also provide States the opportunity to collect other information that would assist them in their program monitoring activities and help them achieve programmatic goals. To provide this flexibility, we are proposing a limited number of methodological standards for the required secret shopper surveys. In § 438.68(f)(4), we propose that secret shopper surveys would have to be completed for a statistically valid sample of providers and: (1) use a random sample; and (2) include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract. We believe these would be the most basic standards that all secret shopper surveys would have to meet to produce useful results that enable comparability

between plans and among States. We propose in § 438.68(f)(4)(iii) that secret shopper surveys to determine plan compliance with appointment wait time standards would have to be completed for a statistically valid sample of providers to be clear that a secret shopper surveys must be administered to the number providers identified as statistically valid for each plan. To ensure consistency, equity, and context to the final compliance rate for each plan, we believe it would be important that inaccurate provider directory data not reduce the number of surveys administered. Therefore, as a practical matter, if the initial data provided by a State to the entity performing the survey does not permit surveys to be completed for a statistically valid sample, the State would need to provide additional data to enable completion of the survey for an entire statistically valid sample. We do not believe this provision would need to apply to secret shopper surveys of provider directory data proposed in paragraph (f)(1) since the identification of incorrect directory data is the intent of those surveys and should be reflected in a plan's compliance rate.

Because we believe secret shopper survey results can produce valuable data for States, managed care plans, enrollees and other interested parties, we propose at § 438.68(f)(5), that the results of these surveys would be reported to CMS and posted on the State's website. Specifically, at § 438.68(f)(5)(i), we propose that the results of the secret shopper surveys of provider directory data validation at § 438.68(f)(1) and appointment wait time standards at § 438.68(f)(2) would be reported to CMS annually using the content, form, and submission times proposed in § 438.207(d). At § 438.68(f)(5)(ii), we propose that States post the results on the State's website required at § 438.10(c)(3) within 30 calendar days of the State submitting them to CMS. We believe using the existing report required at § 438.207(d) would lessen burden on States, particularly since we published the Network Adequacy and Access Assurances Report template[28] in July 2022 and are also developing an electronic reporting portal to facilitate States' submissions. We anticipate revising the data fields in the Network Adequacy and Access

28 *https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx*.

Assurances Report[29] to include specific fields for secret shopper results, including the provider type chosen by the State as required in § 438.68(e)(1)(iv) and (f)(1)(i)(D). This proposal is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

We recognize that implementing secret shopper surveys would be a significant undertaking, especially for States not already using them; but we believe that the data produced by successful implementation of them would be a valuable addition to States' and CMS' oversight efforts. As always, technical assistance would be available to help States effectively implement and utilize secret shopper surveys. We invite comment on the type of technical assistance that would be most useful for States as well as States' best practices and lessons learned from using secret shopper surveys.

We also propose that States would have to comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule.

d. Assurances of adequate capacity and services- Provider payment analysis (§§ 438.207(b), 457.1230(b))

We believe there needs to be greater transparency in Medicaid and CHIP provider payment rates in order for States and CMS to monitor and mitigate payment-related access barriers. There is considerable evidence that Medicaid payment rates, on average, are lower than Medicare and commercial rates for the same services and that provider payment influences access, with low rates of payment limiting the network of providers willing to accept Medicaid patients, capacity of those providers who do participate in Medicaid, and investments in emerging technology among providers that serve large numbers of Medicaid beneficiaries. However, there is no standardized, comprehensive, cross-State comparative data source available

29 *https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-reporting/index.html#NETWORK:~:text=Report.%20%C2%A0The%20current-,excel%20template,-(XLSX%2C%20218.99%20KB*.

to assess Medicaid and CHIP payment rates across clinical specialties, health plans, and States. Given that a critical component of building a managed care plan network is payment, low payment rates can harm access to care for Medicaid and CHIP enrollees in a number of ways. Evidence suggests that low Medicaid physician fees limit physicians' participation in the program, particularly for behavioral health and primary care providers.[30,31] Relatedly, researchers have found that increases in the Medicaid payment rates are directly associated with increases in provider acceptance of new Medicaid patients. In short, two key drivers of access – provider network size and capacity – are inextricably linked with Medicaid provider payment levels and acceptance of new Medicaid patients.[32,33] While many factors affect provider participation, given the important role rates play in assuring access, greater transparency is needed to understand when and to what extent provider payment may influence access in State Medicaid and CHIP programs to specific provider types or for Medicaid and CHIP beneficiaries enrolled in specific plans.

We also believe that greater transparency and oversight is warranted as managed care payments have grown significantly as a share of total Medicaid payments; in FY 2021, the Federal government spent nearly $250 billion on payments to managed care plans.[34] With this growth, we seek to develop, use, and facilitate State use of data to generate insights into important, provider rate related indicators of access. Unlike fee-for-service (FFS) Medicaid and CHIP programs, managed care plans generally have the ability to negotiate unique reimbursment rates for individual providers. Generally, unless imposed by States through a State directed

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30 Holgash K, Heberlein M. Physician acceptance of new Medicaid patients. Washington (DC): Medicaid and CHIP Payment and Access Commission; 2019 Jan 24. Available from *https://www.macpac.gov/wp-content/uploads/2019/01/Physician-Acceptance-of-New-Medicaid-Patients.pdf*.
31 Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood)*. 2021;40(2). doi:10.1377/hlthaff.2020.00611.
32 National Bureau of Economic Research, "Increased Medicaid Reimbursement Rates Expand Access to Care," October 2019, available at *https://www.nber.org/bh-20193/increased-medicaid-reimbursement-rates-expand-access-care*.
33 Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff (Millwood)*. 2021;40(2). doi:10.1377/hlthaff.2020.00611.
34 Congressional Budget Office, "Baseline Projections – Medicaid," May 2022, available at *https://www.cbo.gov/system/files/2022-05/51301-2022-05-medicaid.pdf.*

payment or mandated by statute (such as Federally qualified health centers payment requirements established under section 1902(bb) of the Act), there are no Federal regulatory or statutory minimum or maximum limits on the payment rates a managed care plan can negotiate with a network provider. As such, there can be tremendous variation among plans' payment rates, and we often do not have sufficient visibility into those rates to perform analyses that would promote a better understanding of how these rates are impacting access. Section 438.242(c)(3) for Medicaid, and through cross-reference at § 457.1233(d) for separate CHIP, requires managed care plans to submit to the State all enrollee encounter data, including allowed amounts and paid amounts, that the State is required to report to CMS. States are then required to submit those data to T-MSIS as required in § 438.818 for Medicaid, and through cross-reference at § 457.1233(d) for separate CHIP. However, variation in the quantity and quality of T-MSIS data, particularly for data on paid amounts, remains. We believe that provider payment rates in managed care are inextricably linked with provider network sufficiency and capacity and seek to propose a process through which managed care plans must report, and States must review and analyze, managed care payment rates to providers as a component of States' responsibility to ensure network adequacy and enrollee access consistent with State and Federal standards. Linking payment levels to quality of care is consistent with a strategy that we endorsed in our August 22, 2022 CIB[35] urging States to link Medicaid payments to quality measures to improve the safety and quality of care.

To ensure comparability in managed care plans' payment analyses, we propose to require a payment analysis that managed care plans would submit to States per § 438.207(b)(3) and States would review and include in the assurance and analysis to CMS per § 438.207(d). Specifically, we propose to replace the periods at the end of § 438.207(b)(1) and (2) with semi-colons and add "and" after § 438.207(b)(2) to make clear that (b)(1) through (3) would all be

35 *https://www.medicaid.gov/federal-policy-guidance/downloads/cib08222022.pdf*.

required for Medicaid managed care, and for separate CHIP through an existing cross-reference at § 457.1230(b).

At § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose to require that MCOs, PIHPs, and PAHPs submit annual documentation to the State that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract. We propose that the analysis would use paid claims data from the immediate prior rating period to ensure that all payments are captured, including those that are negotiated differently than a plan's usual fee schedule. We also believe it is important to use claims data to ensure that utilization would be considered to prevent extremely high or low payments from inappropriately skewing the results. We acknowledge that paid claims data would likely not be complete within 180 days of the end of a rating period, which is when this analyis is proposed to be reported by the State in § 438.207(d)(3)(ii). However, we believe that the data would be sufficiently robust to produce a reasonable percentage that reflects an appropriate weighting to each payment based on actual utilization and could be provided to the State far enough in advance of the State submitting its reporting to CMS to be incorporated. We believe this analysis of payments would provide States and CMS with vital information to assess the adequacy of payments to providers in managed care programs, particularly when network deficiencies or quality of care issues are identified or grievances are filed by enrollees regarding access or quality.

In § 438.207(b)(3)(i) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose to require that each MCO, PIHP, and PAHP would use paid claims data from the immediate prior rating period to determine the total amount paid for evaluation and management current procedural terminology (CPT) codes for primary care, OB/GYN, mental health, and SUD services. Due to the unique payment requirements in section 1902(bb) of the Act for Federally qualified health centers and rural health clinics, we propose in § 438.207(b)(3)(iv) to exclude these provider types from the analysis. We further propose that

this analysis provide the percentage that results from dividing the total amount the managed care plan paid by the published Medicare payment rate for the same codes on the same claims. Meaning, the payment analysis would reflect the comparison of how much the managed care plan paid for the evaluation and managment CPT codes to the published Medicare payment rates including claim-specific factors such as provider type, geographic location where the service was rendered, and the site of service. In § 438.207(b)(3)(i)(A) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we also propose that the plans would include in the analysis separate total amounts paid and separate comparison percentages to Medicare for primary care, OB/GYN, mental health, and substance use disorder services for ease of analysis and clarity. Lastly in § 438.207(b)(3)(i)(B) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), we propose that the percentages would have to be reported separately if they differ between adult and pediatric services. We believe the proposals in § 438.207(b)(3)(i)(A) and (B) would ensure sufficient detail in the data to enable more granular analysis across plans and States as well as to prevent some data from obscuring issues with other data. For example, if payments for adult primary care are significantly lower than pediatric primary care, providing separate totals and comparison percentages would prevent the pediatric data from artificially inflating the adult totals and percentages. We believe this level of detail would be necessary to prevent misinterpretation of the data.

We propose in § 438.207(b)(3)(ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to require that the payment analysis provide 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 or CHIP FFS program would have paid for the same claims. We propose two differences between this analysis and the analysis in § 438.207(b)(3)(i): first, this analysis would use all codes for the services as there are no evaluation and management CPT codes for these LTSS; and second, we propose the comparison be to Medicaid or CHIP FFS payment rates, as

applicable, due to the lack of comparable Medicare rates for these services. We propose these three services as we believe these have high impact to help keep enrollees safely in the community and avoid institutionalization. Again, we believe this analysis of payment rates would be important to provide States and CMS with information to assess the adequacy of payments to providers in managed care programs, particularly when enrollees have grievances with services approved in their care plans not being delivered or not delivered in the authorized quantity. We request comment on whether in-home habilitation provided to enrollees with IDD should be added to this analysis.

We believe that managed care plans could perform the analyses in § 438.207(b)(3)(i) and (ii) by: (1) Identifying paid claims in the prior rating period for each required service type; (2) identifying the appropriate codes and aggregating the payment amounts for the required service types; and (3) calculating the total amount that would be paid for the same codes on the claims at 100 percent of the appropriate published Medicare rate, or Medicaid/CHIP FFS rate for the analysis in § 438.207(b)(3)(ii), applicable on the date of service. For the aggregate percentage, divide the total amount paid (from 2. above) by the amount for the same claims at 100 percent of the appropriate published Medicare rate or Medicaid/CHIP FFS, as appropriate (from 3. above). We believe this analysis would require a manageable number of calculations using data readily available to managed care plans.

To ensure that the payment analysis proposed in paragraph (b)(3) is appropriate and meaningful, we propose at § 438.207(b)(3)(iii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to exclude payments for claims for the services in (b)(3)(i) for which the managed care plan is not the primary payer. A comparison to payment for cost sharing only or payment for a claim for which another payer paid a portion would provide little, if any, useful information.

The payment analysis proposed at § 438.207(b)(3) is authorized by sections 1932(c)(1)(A)(ii) and 2103(f)(3) of the Act, which requires States' quality strategies to include

an examination of other aspects of care and service directly related to the improvement of quality of care. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. Because the proposed payment analysis would generate data on each managed care plan's payment levels for certain provider types as a percent of Medicare or Medicaid FFS rates, States could use the analysis in their examination of other aspects of care and service directly related to the improvement of quality of care, particularly access. Further, sections 1932(c)(1)(A)(iii) and 2103(f)(3) of the Act authorizes the proposals in this section as enabling States to compare payment data among managed care plans in their program could provide useful data to fulfill their obligations for monitoring and evaluating quality and appropriateness of care.

We also propose to revise § 438.207(f) to reflect that States would have to comply with § 438.207(b)(3) no later than the first rating period that begins on or after 2 years after the effective date of the final rule as we believe this is a reasonable timeframe for compliance.

e. Assurances of adequate capacity and services reporting (§§ 438.207(d), 457.1230(b))

Currently at § 438.207(d), States are required to review the documentation submitted by their managed care plans, as required at § 438.207(b), and then submit to CMS an assurance of their managed care plans' compliance with §§ 438.68 and 438.206. To make States' assurances and analyses more comprehensive, we propose to revise § 438.207(d) to explicitly require States to include the results from the secret shopper surveys proposed in § 438.68(f) (see section I.B.1.c. of this proposed rule) and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b). We also propose to require States to include the payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this proposed rule) to their assurance and analyses reporting. Additionally, on July 6, 2022, we published a CIB[36] that provided a reporting template Network Adequacy and Access Assurances Report[37] for the

36 *https://www.medicaid.gov/federal-policy-guidance/downloads/cib07062022.pdf*.
37 *https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx*.

reporting required at § 438.207(d). To be clear that States would have to use the published template, we propose to explicitly require that States submit their assurance of compliance and analyses required in § 438.207(d) in the "format prescribed by CMS." The published template would fulfill this requirement as would future versions including any potential electronic formats. We believe the revision proposed in § 438.207(d) would be necessary to ensure consistent reporting to CMS and enable effective analysis and oversight. Lastly, because we propose new requirements related to the inclusion of the payment analysis and the timing of the submission of this reporting to CMS, we propose to redesignate the last sentence in § 438.207(d) as § 438.207(d)(1) and create a new § 438.207(d)(2) and (3).

In § 438.207(d)(2) for Medicaid and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b), we propose that the States' analysis required in § 438.207(d)(1) must include the payment analysis required of plans in § 438.207(b)(3) and provide the elements specified in paragraphs (d)(2)(i) and (ii). Specifically, § 438.207(d)(2)(i) proposes to require States to include the data submitted by each plan and § 438.207(d)(2)(ii) proposes to require States to use the data from its plans' reported payment analysis percentages and weight them using the member months associated with the applicable rating period to produce a Statewide payment percentage for each service type. We believe these data elements would provide valuable new data to support States' assurances of network adequacy and access and we would revise the Network Adequacy and Access Assurances Report template published in July 2022 to add fields for States to easily report these data. We remind States that § 438.66(a) and (b) require States to have a monitoring system for all of their managed care programs and include all aspects, including the performance of their managed care plans in the areas of availability and accessibility of services, medical management, provider network management, and appeals and grievances. Accordingly, States should have ample data from their existing monitoring activities and which would be supplemented by the proposal requirements in this rule, to improve the performance of their managed care programs for all covered services, as

required in § 438.66(c). Because concerns around access to primary care, mental health, and SUD services have been raised nationally, we expect States to review and analyze their plans' data holistically to provide a robust, comprehensive analysis of the adequacy of each plan's network and level of realistic access and take timely action to address deficiencies.

Section 438.207(d) was codified in 2002 (67 FR 41010) as part of the implementing regulations for section 1932(b)(5) of the Act ''Demonstration of Adequate Capacity and Services.'' In the 2016 final rule, we made minor revisions to the language but did not address the timing of States' submission of their assurance and analysis. Given the July 2022 release of the Network Adequacy and Access Assurances Report template for the assurance and analysis, we believe it would be appropriate to clarify this important aspect of the reporting requirement. To simplify the submission process and enable States and CMS to allot resources most efficiently, we propose to establish submission times in § 438.207(d)(3)(i) through (iii) that correspond to the times for managed care plans to submit documentation to the State in § 438.207(c)(1) through (3). Specifically for Medicaid, we propose that States submit their assurance and analysis at § 438.207(d)(3): (1) at the time it submits a completed readiness review, as specified at § 438.66(d)(1)(iii); (2) on an annual basis and no later than 180 calendar days after the end of each contract year; and (3) any time there has been a significant change as specified in § 438.207(c)(3) and with the submission of the associated contract. We also propose in § 438.207(d)(3) that States must post the report required in § 438.207(d) on their website within 30 calendar days of submission to CMS. We believe the information in this report would be important information for interested parties to have access to on a timely basis and 30 calendar days seems adequate for States to post the report after submitting.

Since we did not adopt the MCPAR requirements for separate CHIP managed care in the 2016 final rule, we are also not adopting the proposed submission timeframe at § 438.207(d)(3)(i). However, we propose for separate CHIPs to align with Medicaid for the

proposed network adequacy analysis submission timeframes at § 438.207(d)(3)(ii) and (iii) through the existing cross-reference at § 457.1230(b).

In § 438.207(e), we propose a conforming revision to add a reference to the secret shopper evaluations proposed at § 438.68(f) as part of the documentation that States must make available to CMS, upon request, and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b). We believe this would be necessary as the current text of § 438.207 (e) only addresses the documentation provided by the managed care plans.

Sections 1932(b)(5) and 2103(f)(3) of the Act require Medicaid and CHIP MCOs to demonstrate adequate capacity and services by providing assurances to the State and CMS, as specified by the Secretary, that it has the capacity to serve the expected enrollment in its service area, including assurances that it offers an appropriate range of services and access to preventive and primary care services for the population expected to be enrolled in such service area, and maintains a sufficient number, mix, and geographic distribution of providers of services. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. Our proposals to require States to include the secret shopper surveys proposed in § 438.68(f) as well as the reimbursment analysis proposed in § 438.207(b)(3) to their assurance and analyses reporting proposed at § 438.207(d) are authorized by section 1932(b)(5) of the Act for Medicaid and authorized for CHIP through section 2103(f)(3) of the Act because the States' reports reflect the documentation and assurances provided by their managed care plans of adequate capacity, an appropriate range of services, and access to a sufficient number, mix, and geographic distribution of network providers. Sections 1932(b)(5) and 2103(f)(3) of the Act also require that the required assurances be submitted to CMS in a time and manner determined by the Secretary; that information is proposed in § 438.207(d)(3)(i) through (iii) and corresponds to the requirements for submission of documenation from managed care plans in § 438.207(c)(3).

We also propose to revise § 438.207(g) to reflect that States would have to comply with paragraph (d)(2) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and paragraph (d)(3) no later than the first managed care plan rating period that begins on or after 1 year after the effective date of the final rule. We propose that States would not be held out of compliance with the requirements of paragraphs (e) of this section prior to the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule, so long as they comply with the corresponding standard(s) codified in paragraph (e) contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. We propose that States would have to comply with paragraph (f) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe these are reasonable timeframes for compliance given the level of new burden imposed by each.

f. Remedy plans to improve access (§ 438.207(f))

For FFS programs, we rely on § 447.203(b)(8) to require States to submit corrective action plans when access to care issues are identified. Because of the numerous proposals in this rule that would strengthen States' monitoring and enforcement of access requirements and the importance of timely remediation of access issues, we believe we should have a similar process set forth in part 438 for managed care programs. In § 438.68(e), we propose a process that would require States to carefully develop and enforce their managed care plans' use of appointment wait time standards to ensure access to care for Medicaid managed care enrollees. As proposed in a new § 438.207(f), when the State, MCO, PIHP, PAHP, or CMS identifies any access issues, including any access issues with the standards specified in §§ 438.68 and 438.206, the State would be required to submit a plan to remedy the access issues consistent with this proposal. If we determine that an access issue revealed under monitoring and enforcement rises to the level of a violation of access requirements under section 1932(c)(1)(A)(i) of the Act, as incorporated in section 1903(m)(2)(A)(xii) of the Act, we have the authority to disallow Federal financial

participation (FFP) for the payments made under the State's managed care contract for failure to ensure adequate access to care. We intend to closely monitor any State remedy plans that would be needed under this proposal to ensure that both us and States would adequately and appropriately address emerging access issues in Medicaid managed care programs.

Using § 447.203(b)(8) as a foundation, we propose to redesignate existing § 438.207(f) as § 438.207(g) and propose a new requirement for States to submit remedy plans in new § 438.207(f), titled Remedy plans *to* improve access. In § 438.207(f)(1), we propose that when the State, MCO, PIHP, PAHP, or CMS identifies an issue with a managed care plan's performance with regard to any State standard for access to care under this part, including the standards at §§ 438.68 and 438.206, States would follow the steps set forth in paragraphs (i) through (iv). First, in paragraph (1)(i), States would have to submit to CMS for approval a remedy plan no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue. We believe 90 calendar days would be sufficient time for States to effectively assess the degree and impact of the issue and develop an effective set of steps including timelines for implementation and completion, as well as responsible parties. In § 438.207(f)(1)(ii), we propose that the State would have to develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties. We believe 12 months would be a reasonable amount of time for States and their managed care plans to implement actions to address the access issue and improve access to services by enrollees of the MCO, PIHP, or PAHP. We do not propose to specify that the remedy plan would be implemented by the managed care plans or the State; rather, we propose that the remedy plan would identify the responsible party required to make the access improvements at issue, which would often include actions by both States and their managed care plans. Additionally, we believe this proposal acknowledges that certain steps that may be needed to address provider shortages can only be implemented by States. For example, changing scope of practice laws to

enable more providers to fill gaps in access or joining interstate compacts to enable providers to practice geographically due to the opportunity to hold one multistate license valid for practice in all compact States, streamlined licensure requirements, reduced expenses associated with obtaining multiple single-State licenses, and the creation of systems that enable electronic license application processes. Lastly, in § 438.207(f)(1)(ii), we propose some approaches that States could consider to address the access issue, such as increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization.

We propose in § 438.207(f)(1)(iii) to require States to ensure that improvements in access are measurable and sustainable. We believe it would be critical that the remedy plan produce measurable results in order to monitor progress and, ultimately, bring about the desired improvements in access under the managed care plan. We also propose that the improvements in access achieved by the actions be sustainable so that enrollees would be able to continue receiving the improved access to care and managed care plans would continue to ensure its provision. In paragraph (f)(1)(iv) of this section, we propose that States submit quarterly progress updates to CMS on implementation of the remedy plan so that we would be able to determine if the State was making reasonable progress toward completion and that the actions in the plan are effective. Not properly monitoring progress of the remedy plan could significantly lessen the effectiveness of it and allow missed opportunities to make timely revisions and corrections.

Lastly, in paragraph (f)(2) of this section we propose that if the remedy plan required in paragraph (f)(1) of this section does not address the managed care plan's access issue within 12 months, we may require the State to continue to take steps to address the issue for another 12 months and may require revision to the remedy plan. We believe proposing that we be able to

extend the duration of actions to improve access and/or require the State to make revision to the remedy plan would be critical to ensuring that the State's and managed care plans' efforts are effective at addressing the identified access issue.

These proposals are authorized by section 1902(a)(4)(A) of the Act, which provides for methods of administration found necessary by the Secretary for the proper and efficient operation of the plan as we believe States taking timely action to address identified access issues is fundamental and necessary to the operation of an effective and efficient Medicaid program. The proposal for States to submit quarterly progress reports is authorized by section 1902(a)(6) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Lastly, we believe these proposals are also authorized by section 1932(c)(1)(A)(i) and (iii) of the Act which require States that contract with MCOs to develop and implement a quality assessment and improvement strategy that includes (and extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act): standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate primary care and specialized services capacity and procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees and requirements for provision of quality assurance data to the State. Implementing timely actions to address managed care plan access issues would be an integral operational component of a State's quality assessment and improvement strategy.

g. Transparency (§§ 438.10(c), 438.602(g), 457.1207, 457.1285)

In the 2016 final rule, we finalized § 438.10(c)(3) for Medicaid, which is included in separate CHIP regulations through cross-reference at § 457.1207, which required States to operate a website that provides specific information, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites. A State's website may be the single most important resource for information about its Medicaid program and there are multiple

requirements for information to be posted on a State's website throughout 42 CFR part 438. Current regulations at § 438.10(c)(6)(ii) require certain information to be "prominent and readily accessible" and § 438.10(a) defines "readily accessible" as "electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions." Despite these requirements, we have received input from numerous and varied interested parties since the 2016 final rule about how challenging it can be to locate regulatorily required information on some States' websites.

There is variation in how "user-friendly" States' websites are, with some States making navigation on their website fairly easy and providing information and links that are readily available and presenting required information on one page. However, we have not found this to be the case for most States. Some States have the required information scattered on multiple pages that requires users to click on many links to locate the information they seek. While such websites may meet the current minimum standards in part 438, they do not meet our intent of providing one place for interested parties to look for all required information. Therefore, we believe revisions are necessary to ensure that all States' websites required by § 438.10(c)(3) provide a consistent and easy user experience. We acknowledge that building websites is a complex and costly endeavor that requires consideration of many factors, but we believe that States and managed care plans share an obligation to build websites that quickly and easily meet the needs of interested parties without undue obstacles. We note that State and managed care plan websites must be compliant with civil rights laws, including the Americans with Disabilities Act (ADA), section 504 of the Rehabilibation Act, Title VI of the Civil Rights Act of 1964, and section 1557 of the Affordable Care Act. In this proposed rule, we believe that there are several minimal qualities that all websites should include, such as being able to:

- Function quickly and as expected by the user;
- Produce accurate results;

- Use minimal, logical navigation steps;
- Use words and labels that users are familiar with for searches;
- Allow access, when possible, without conditions such as establishment of a user account or password,
- Provide reasonably comparable performance on computers and mobile devices,
- Provide easy access to assistance via chat; and
- Provide multilingual content for individuals with LEP.

We also believe that States and managed care plans should utilize web analytics to track website utilization and inform design changes. States should create a dashboard to regularly quantify website traffic, reach, engagement, sticking points, and audience characteristics. Given the critical role that websites fill in providing necessary and desired program information, we believe proposing additional requirements on States' websites are appropriate.

We acknowledge that States and managed care plans may have information accessible through their websites that is not public facing; for example, enrollee specific protected health information. Proper security mechanisms should continue to be utilized to prevent unauthorized access to non-public facing information, such as the establishment of a user account and password or entry of other credentials. Data security must always be a priority for States and managed care plans and the proposals in § 438.10(c)(3) in no way diminish that obligation for States.

To increase the effectiveness of States' websites and add some consistency to website users' experence, we propose in § 438.10(c)(3) to revise "websites" to "webpages" in the reference to managed care plans. We propose this change to clarify that if States provide required content on their website by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, the link on the State's site would have to be to the specific page that includes the requested information. We believe this would prevent States from showing links to a landing page for the managed care plan that then leaves the user to start searching for the specific

information needed. Next, we propose to add "States must:" to paragraph (c)(3) before the items specified in new (c)(3)(i) through (iv). In § 438.10(c)(3)(i), we propose to require that all information, or links to the information, required in this part to be posted on the State's website, be available from one page. We believe that when website users have to do repeated searches or click through multiple pages to find information, they are more likely to give up trying to locate it. As such, we have carefully chosen the information that is required in 42 CFR part 438 to be posted on States' websites to ensure effective communication of information and believe it represents an important step toward eliminating common obstacles for States' website users.

At § 438.10(c)(3)(ii), we propose to require that States' websites use clear and easy to understand labels on documents and links so that users can easily identify the information contained in them. We believe that using terminology and the reading grade level consistent with that used in other enrollee materials, such as handbooks and notices, would make the website more familiar and easy to read for enrollees and potential enrollees. Similar to having all information on one page, using clear labeling would reduce the likelihood of users having to make unncessary clicks as they search for specific information.

In § 438.10(c)(3)(iii), we propose to require that States check their websites at least quarterly to verify that they are functioning as expected and that the information is the most currently available. Malfunctioning websites or broken links can often render a website completely ineffective, so monitoring a website's performance and content is paramount. While we are proposing that a State's website be checked for functionality and information timeliness no less than quarterly, we believe this is a minimum standard and that States should implement continual monitoring processes to ensure the accuracy of their website's performance and content.

Lastly, in § 438.10(c)(3)(iv), to enable maximum effectiveness of States' websites, we propose to require that States' websites explain that assistance in accessing the information is available at no cost to them, including information on the availability of oral interpretation in all

languages and written translation in each prevalent non-English language, alternate formats, auxiliary aids and services, and a toll-free TTY/TDY telephone number. This proposal is consistent with existing information requirements in § 438.10(d) and section 1557 of the Affordable Care Act. Clear provision of this information would help to ensure that all users have access to States' websites and can obtain assistance when needed.

The Medicaid managed care website transparency revisions proposed at § 438.10(c)(3)(i) through (iv) would apply to separate CHIP through the existing cross-reference at § 457.1207.

To help States monitor their website for required content, we propose to revise § 438.602(g) to contain a more complete list of information. While we believe the list proposed in § 438.602(g) would help States verify their website's compliance, we clarify that a requirement to post materials on a State's website in 42 CFR part 438 or any other Federal regulation but omitted from § 438.602(g), is still in full force and effect. Further, requirements on States to post specific information on their websites intentionally remain throughout 42 CFR part 438 and are not replaced, modified, or superceded by the items proposed in § 438.602(g)(5) through (12). Currently § 438.602(g) specifies four types of information that States must post on their websites; we propose to add nine more as (g)(5) through (g)(13): (5) enrollee handbooks, provider directories, and formularies required at § 438.10(g), (h), and (i); (6) information on rate ranges required at § 438.4(c)(2)(iv); (7) reports required at §§ 438.66(e) and 438.207(d); (8) network adequacy standards required at § 438.68(b)(1) and (2), and (e); (9) secret shopper survey results required at § 438.68(f); (10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C); (11) links to all required Application Programming Interfaces including as specified in § 431.60(d) and (f); (12) quality related information required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i); and (13) documentation of compliance with requirements in subpart K - Parity in Mental Health and Substance Use Disorder Benefits. Although we are proposing to itemize these nine types of information in § 438.602(g)(5) through (13), we note that all but the following three are currently required to be posted on States'

websites: the report at § 438.207(d), secret shopper survey results at § 438.68(f), and State directed payment evaluation reports at § 438.6(c)(2)(v)(C). Lastly, in § 438.10(c)(3), we propose to make the list of website content more complete by removing the current references to paragraphs (g) through (i) only and including a reference to § 438.602(g) and "elsewhere in this part."

We propose to revise § 438.10(j) to reflect that States would have to comply with § 438.10(c)(3) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and that States would have to comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule. Lastly, we propose that States must comply with § 438.10(h)(3)(iii) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule. We believe these proposed compliance dates would provide reasonable time for compliance given the varying levels of State and managed care plan burden.

We propose to add § 438.602(j) to require States to comply with § 438.602(g)(5) through (13) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance.

For separate CHIP managed care, we currently require States to comply with the transparency requirements at § 438.602(g) through an existing cross-reference at § 457.1285. We propose to align with Medicaid in adopting most of the consolidated requirements for posting on a State's website proposed at § 438.602(g)(5) through (13) for separate CHIP:

We propose to adopt the provision at § 438.602(g)(5) (which specifies that States must post enrollee handbooks, provider directories, and formularies on the State's website) because requirements at § 438.10(g) through (i) are currently required for separate CHIP through an existing cross-reference at § 457.1207.

We do not plan to adopt the provision at § 438.602(g)(6) (which requires that States must post information on rate ranges on their websites) because we do not regularly review rates for separate CHIP.

We propose to adopt the provision at § 438.602(g)(7) (which specifies that States must post their assurances of network adequacy on the State's website) since the proposed network adequacy reporting at § 438.207(d) would apply to separate CHIP through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this proposed rule). Since we did not adopt the managed care program annual reporting requirements at § 438.66(e) for separate CHIP, we propose to exclude this reporting requirement at § 457.1230(b)..

We propose to adopt the provision at § 438.602(g)(8) (which requires State network adequacy standards to be posted on the State's website) for separate CHIP because we propose to adopt the new appointment wait time reporting requirements through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this proposed rule), though we propose to exclude references to LTSS as not applicable to separate CHIP.

We propose to adopt the provision at § 438.602(g)(9) (which specifies that States must post secret shopper survey results on the State's website) for separate CHIP network access reporting to align with our proposed adoption of secret shopper reporting at § 438.68(f) through an existing cross-reference at § 457.1218 (see section I.B.1.c. of this proposed rule).

We do not propose to adopt the provision at § 438.602(g)(10) (which directs States to post SDP evaluation reports on the State's website) because State directed payments are not applicable to separate CHIP.

We propose to adopt the provision at § 438.602(g)(11) (which specifies that States must post required information for Application Programming Interfaces on the State's website) given the existing requirements at § 457.1233(d).

We propose to adopt the provision at § 438.602(g)(12) (which requires States to post quality-related information on the State's website) for separate CHIP as required through cross-

references at § 457.1240(c) and (e), as well as the applicable EQR report through a cross-reference at § 457.1250(a). However, we propose to exclude the reference to § 438.362(c) since MCO EQR exclusion is not applicable to separate CHIP.

We propose to adopt the provision at § 438.602(g)(13) (which requires States to post documentation of compliance with parity in mental health and substance use disorder benefits on the State's website) for separate CHIP through the existing cross-reference at § 457.1285. However, we propose to replace the reference to subpart K of part 438 with CHIP parity requirements at § 457.496 in alignment with contract requirements at § 457.1201(l).

We propose to amend § 457.1285 to state, the State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2) and 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Our proposals for requirements for States' websites at § 438.10(c)(3) and the list proposed in § 438.602(g) are authorized by sections 1932(a)(5)(A) and 2103(f)(3) of the Act for Medicaid and which require each State, enrollment broker, or managed care entity to provide all enrollment notices and informational and instructional materials in a manner and form which may be easily understood by enrollees and potential enrollees. The authority for our proposals is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. We believe that our proposals would make States' websites easier to use by incorporating easily understood labels, having all information accessible from one page, verifying the accurate functioning of the site, and clearly explaining the availability of assistance- all of which would directly help States fulfill their obligation to provide informational materials in a manner and form which may be easily understood.

h. Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b), 438.214(b))

Throughout 42 CFR part 438, we use "behavioral health" to mean mental health and SUD. However, it is an imprecise term that does not capture the full array of conditions that are intended to be included, and some in the SUD treatment community have raised concerns with its use. It is important to use clear, unambiguous terms in regulatory text. Therefore, we propose to change "behavioral health" throughout 42 CFR part 438 as described here. In the definition of PCCM entity at § 438.2 and for the provider types that must be included in provider directories at § 438.10(h)(2)(iv), we propose to replace "behavioral health" with "mental health and substance use disorder;" for the provider types for which network adequacy standards must be developed in § 438.68(b)(1)(iii), we propose to remove "behavioral health" and the parentheses; and for the provider types addressed in credentialing policies at § 438.214(b), we propose to replace "behavioral" with "mental health." We also propose in the definition of PCCM entity at § 438.2 to replace the slash between "health systems" and "providers" with "and" for grammatical accuracy.

Similarly, we also propose to change "psychiatric" to "mental health" in § 438.3(e)(2)(v) and § 438.6(e). We believe that "psychiatric" does not capture the full array of services that can be provided by IMDs.

These proposals are authorized by section 1902(a)(4)(A) of the Act, which provides for methods of administration found necessary by the Secretary for the proper and efficient operation of the plan, because use of clear, unambiguous terms in regulatory text is imperative for proper and efficient operation of the plan.

2. State Directed Payments (42 CFR 438.6, 438.7, 430.3)

a. Background

Section 1903(m)(2)(A) of the Act requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound. CMS has historically used our authority under section 1902(a)(4) of the Act to apply the same requirements to contracts between States and PIHPs or PAHPs. Under risk-based

managed care arrangements with the State, Medicaid managed care plans have the responsibility to negotiate payment rates with providers. Subject to certain exceptions, States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60, respectively). However, there are circumstances in which a State may believe that requiring managed care plans to make specified payments to health care providers is an important tool in furthering the State's overall Medicaid program goals and objectives; for example, funding to ensure certain minimum payments are made to safety net providers to ensure access to care, funding to enhance behavioral health care providers as mandated by State legislative directives, or funding for quality payments to ensure providers are appropriately rewarded for meeting certain program goals. Because this type of State direction reduces the plan's ability to effectively manage costs, CMS, in the 2016 final rule, established specific exceptions to the general rule prohibiting States from directing the expenditures of MCOs, PIHPs and PAHPs at § 438.6(c)(1)(i) through (iii). These exceptions came to be known as State directed payments (SDPs).

The current regulations at § 438.6(c) specify the parameters for how and when States may direct the expenditures of their Medicaid managed care plans and the associated requirements and prohibitions on such arrangements. Permissible SDPs include directives that certain providers of the managed care plan participate in value-based purchasing (VBP) models, that certain providers participate in multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives, or that the managed care organization adhere to certain fee schedule requirements (for example, minimum fee schedules, maximum fee schedules, and uniform dollar or percentage increases). Among other requirements, § 438.6(c) requires SDPs to be based on the utilization and delivery of services under the managed care contract and expected to advance at least one of the objectives in the State's managed care quality strategy.

All SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). Further, § 438.6(c)(2)(ii) requires that most SDPs be approved in writing prior to implementation.[38] To obtain written prior approval, States must submit a "preprint" form to CMS to document how the SDP complies with the Federal requirements outlined in § 438.6(c).[39] States must obtain written approval of certain SDPs in order for CMS to approve the corresponding Medicaid managed care contract(s) and rate certifications(s). States were required to comply with this prior approval requirement for SDPs no later than the rating period for Medicaid managed care contracts starting on or after July 1, 2017.

Each SDP preprint submitted to CMS is reviewed by a Federal review team to ensure that the payments comply with the regulatory requirements in § 438.6(c) and other applicable law. The Federal review team consists of subject matter experts from various components and groups within CMS, which regularly include those representing managed care policy and operations, quality, and actuarial science. Over time, these reviews have expanded to include subject matter experts on financing of the non-Federal share and demonstration authorities when needed. The CMS Federal review team works diligently to ensure a timely review and that standard operating procedures are followed for a consistent and thorough review of each preprint. Most preprints are reviewed on an annual basis; SDPs that are for VBP arrangements, delivery system reform, or performance improvement initiatives and that meet additional criteria in the Federal regulations are eligible for multi-year approval.

CMS has issued guidance to States regarding SDPs on multiple occasions. In November 2017, CMS published the initial preprint form[40] along with guidance for States on the use of

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38 State directed payments that are minimum fee schedules for network providers that provide a particular service under the contract using State plan approved rates as defined in § 438.6(a) are not subject to the written prior approval requirement at § 438.6(c)(2)(ii); however, they must comply with the requirements currently at § 438.6(c)(2)(ii)(A) through (F) (other than the requirement for prior written approval) and be appropriately documented in the managed care contract(s) and rate certification(s).

39 *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf*.

40 *https://www.medicaid.gov/sites/default/files/2020-02/438-preprint.pdf*.

SDPs.[41] In May 2020, CMS published guidance on managed care flexibilities to respond to the COVID-19 public health emergency (PHE), including how States could use SDPs in support of their COVID-19 response efforts.[42] In January 2021, CMS published additional guidance for States to clarify existing policy, and also issued a revised preprint form that States must use for rating periods beginning on or after July 1, 2021.[43] The revised preprint form is more comprehensive compared to the initial preprint, and it is designed to systematically collect the information that CMS identified as necessary as part of our review of SDPs to ensure compliance with the Federal regulatory requirements.[44] This includes identification of the estimated total dollar amount for the SDP, an analysis of provider reimbursement rates for the class(es) of providers that the SDP is targeting, and information about the sources of the non-Federal share used to finance the SDP.

Since § 438.6(c) was issued in the 2016 final rule, States have requested approval for an increasing number of SDPs. The scope, size, and complexity of the SDP arrangements submitted by States for approval has also grown steadily and quickly. In calendar year 2017, CMS received 36 preprints for our review and approval from 15 States. In contrast, in calendar year 2021, CMS received 223 preprints from 39 States. For calendar year 2022, CMS received 298 preprints from States. In total, as of December 2022, CMS has reviewed more than 1,100 SDP proposals and approved 993 proposals since the 2016 final rule was issued.[45]

SDPs also represent a notable amount of spending. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion in 2020.[46] The U.S. Government Accountability

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41 *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib11022017.pdf.*
42 *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051420.pdf.*
43 *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*
44 *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*
45 The number of proposals includes initial preprints, renewals and amendments. An individual SDP program could represent multiple SDP proposals as described here (that is, an initial application, 1 renewal, and 3 amendments).
46 Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf*. Projected payment amounts are for the most recent rating period, which may differ from calendar year or fiscal year 2020.

Office (GAO) also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 approved preprints.[47] Our internal analysis of all SDPs approved from when § 438.6(c) was issued in the 2016 final rule through March 2022 estimates that the total spending for each SDP approved for the most recent rating period for States is nearly $48 billion[48] (Federal and State) with at least half being dollars that States are requiring be paid in addition to the rates negotiated between the plans and providers. The aforementioned nearly $48 billion is an annual figure.[49]

As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, CMS recognizes the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives as part of our review process, as well as ensuring that SDPs are developed and implemented with appropriate fiscal and program integrity guardrails. The proposed changes in this notice of proposed rulemaking are intended to ensure the following policy goals:

(1) Medicaid managed care enrollees receive access to high-quality care under SDP payment arrangements;

(2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDP payment arrangements; and

(3) CMS and States have the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and transparency of SDP payment arrangements.

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47 U.S. Government Accountability Office, "Medicaid: State Directed Payments in Managed Care," June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

48 This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through March 31, 2022 under CMS' standard review process. Rating periods differ by State; some States operating their managed care programs on a calendar year basis while others operate on a State fiscal year basis, which most commonly is July to June. The most recent rating period for which the SDP was approved as of March 2022 also varies based on the review process reflective of States submitting proposals later than recommended (close to or at the end of the rating period), delays in State responses to questions, and/or reviews taking longer due to complicated policy concerns (for example, financing).

49 As part of the revised preprint form, States are asked to identify if the payment arrangement requires plans to pay an amount in addition to negotiated rates vs. limiting or replacing negotiated rates. Approximately half of the total dollars identified for the SDP actions included were identified by States for payment arrangements that required plans to pay an amount in addition to the rates negotiated between the plan and provider(s) rates.

We are issuing this proposal based on our authority to interpret and implement section 1903(m)(2)(A)(iii) of the Act, which requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound and our authority under section 1902(a)(4) of the Act to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan. As explained in the 2016 final rule, regulation of SDPs is necessary to ensure that Medicaid managed care plans have sufficient discretion to manage the risk of covering the benefits outlined in their contracts, which is integral to ensuring that capitation rates are actuarially sound as defined in § 438.4 (81 FR 27582). We have historically relied on section 1902(a)(4) of the Act to extend the same requirements adopted under section 1903(m)(2)(A)(iii) of the Act for MCOs related to actuarially sound capitation rates to PIHPs and PAHPs. Where a proposal is also based on interpreting and implementing other authority, we note that in the applicable explanation of the proposed policy.

We did not adopt the Medicaid managed care SDP requirements described at § 438.6 in the 2016 final rule for separate CHIPs because there was no statutory requirement to do so and we wished to limit the scope of new regulations and administrative burden on separate CHIP managed care plans. For similar reasons, we are not proposing to adopt the new Medicaid managed care SDP requirements proposed at §§ 438.6 and 438.7 for separate CHIPs.

We are proposing to define State directed payments as a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section. We are proposing this definition as it is currently used by States and CMS in standard interactions as well as in published guidance to describe these contract requirements. Defining this term also improves the readability of the related regulations. We have also proposed to rename the header for this section to "***State Directed Payments under MCO, PIHP, or PAHP contracts"*** reflect this term.

In addition, we are proposing several revisions to § 438.6 to further specify and add to the existing requirements and standards for SDPs. First, we are proposing revisions, including: expanding the scope of § 438.6(c) consistent with recent guidance; exempting SDPs that establish payment rate minimums at 100 percent of the Medicare rate from written prior approval; incorporating SDPs for non-network providers in certain circumstances; setting new procedures and timeframes for the submission of SDPs and related documentation; codifying and further specifying standards and documentation requirements on total payment rates; further specifying and strengthening existing requirements related to financing as well as the connection to the utilization and delivery of services; updating and providing flexibilities for States to pursue VBP through managed care; strengthening evaluation requirements and other areas; and addressing how SDPs are incorporated into capitation rates or reflected in separate payment terms. The proposed regulatory provisions include both new substantive standards and new documentation and contract term requirements. In addition, we are proposing a new appeal process for States that are dissatisfied with CMS's determination related to a specific SDP preprint and new oversight and monitoring standards. In recognition of the scope of changes we are proposing, some of which will require significant time for States to implement, we are proposing a series of applicability dates over a roughly 5-year period for compliance. These applicability dates are discussed later in section I.B.2.p. of this proposed rule.

We solicit feedback on our proposals.

A more detailed outline of the remaining parts of this section is provided below:

b. Contract Requirements Considered to be SDPs (Grey Area Payments)

c. Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), (c)(2), and (c)(5)(iii)(A)(*5*))

d. Non-Network Providers (§ 438.6(c)(1)(iii))

e. SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (ix))

f. Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for certain SDPs and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I) and (c)(2)(iii))

g. Financing (§ 438.6(c)(2)(ii)(G) and (H))

h. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§ 438.6(c)(2)(vii))

i. Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi))

j. Quality and Evaluation (§ 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7))

k. Contract Term Requirements (§ 438.6(c)(5))

l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J), (c)(6), and 438.7(f))

m. SDPs included through Adjustments to Base Capitation Rates (§ 438.7(c)(4) through (6))

n. Appeals (§ 430.3(d))

o. Reporting Requirements to Support Oversight (§ 438.6(c)(4))

p. Applicability Dates (§ 438.6(c)(4), 438.6(c)(8), and 438.7(g)(2) and (3))

b. Contract Requirements Considered to be SDPs (Grey Area Payments)

Under § 438.6(c), States are not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan unless it is an SDP that complies with § 438.6(c), is permissible in a specific provision under Title XIX, is permissible through an implementing regulation of a Title XIX provision related to payments to providers, or is a permissible pass-through payment that meets requirements in § 438.6(d). States are also not permitted to make payments directly to providers for services covered under the contract between the State and a managed care plan as specified in § 438.60.

In our November 2017 CMCS Informational Bulletin (CIB) entitled “Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts,” we noted instances

where States may include general contract requirements for provider payments that would not be subject to approval under § 438.6(c) as long as the State was not mandating a specific payment methodology or amounts under the contract. [50] We also noted that these types of contract requirements would not be pass-through payments subject to the requirements under § 438.6(d), as we believed they maintained a link between payment and the delivery of services. One scenario in the CIB described contract language generally requiring managed care plans to make 20 percent of their provider payments as VBP or alternative payment arrangements when the State does not mandate a specific payment methodology and the managed care plan retains the discretion to negotiate with network providers the specific terms for the amount, timing, and mechanism of such VBP or alternative payment arrangements. We continue to believe that this scenario does not meet the criteria for an SDP nor a pass-through payment but as our thinking has evolved, we believe that the aforementioned VBP scenario represents the State imposing a quality metric on the managed care plans rather than the providers. We believe that this specific type of contractual condition and measure of plan accountability is permissible, so long as it meets the requirements for an incentive arrangement under § 438.6(b)(2) or, a withhold arrangement under § 438.6(b)(3).

The other scenario described the State contractually implementing a general requirement for Medicaid managed care plans to increase provider payment for covered services provided to Medicaid enrollees covered under the contract, where the State did not mandate a specific payment methodology or amount(s) and managed care plans retain the discretion for the amount, timing, and mechanism for making such provider payments. At the time, we believed that these areas of flexibility for the plan would be sufficient to exclude the State's contract requirement from the scope of § 438.6(c). However, as we have continued to review managed care contracts and rate certifications since November 2017, we have grown increasingly concerned that excluding the latter type of vague contractual requirement for increased provider payment from

50 *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf.*

the requirements of § 438.6(c) created an unintended loophole in regulatory oversight, presenting a significant program integrity risk. For example, some States include general contract requirements for significant increases to provider payments that require the State to add money to the capitation rates paid to the managed care plans as part of rate development for a specific service (for example, hospital services) but without any further accountability to ensure that the additional funding included in the capitation payments is paid to providers for a specific service or benefit provided to a specific enrollee covered under the contract. While this is similar to the definition of pass-through payment in § 438.6(a), these contractual requirements do not meet all of the other requirements in § 438.6(d) to be permissible pass-through payments. We commonly refer to these types of contractual arrangements as "grey area payments" as they do not completely comply with § 438.6(c) nor § 438.6(d).

Upon reflection and based on our experience since the 2017 CIB, we concluded that general contractual requirements to increase provider payment rates circumvent the intent of the 2016 final rule and the subsequent 2017 Pass-Through Payment Final Rule to improve the fiscal integrity of the program and ensure the actuarial soundness of all capitation rates.[51] As we stated in the preamble of the 2016 final rule "[w]e believe that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services to beneficiaries covered under the contract. … In our review of managed care capitation rates, we have found pass-through payments being directed to specific providers that are generally not directly linked to delivered services or the outcomes of those services. These pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services." Further, "[a]s a whole, [42 CFR] § 438.6(c) maintains the MCO's, PIHP's, or PAHP's ability to fully utilize the payment under that contract for the delivery and quality of services by limiting States' ability to

51 *https://www.federalregister.gov/documents/2017/01/18/2017-00916/medicaid-program-the-use-of-new-or-increased-pass-through-payments-in-medicaid-managed-care-delivery.*

require payments that are not directly associated with services delivered to enrollees covered under the contract."

In January 2021, we published SMDL #21-001,[52] through which we sought to close the unintentional loophole created in the November 2017 CIB and realign our implementation of the regulation with the original intent of the 2016 final rule and the 2017 final rule. The 2021 SMDL provides that if a State includes a general contract requirement for provider payment that provides for or adds an amount to the provider payment rates, even without directing the specific amount, timing or methodology for the payments, and the provider payments are not clearly and directly linked specifically to the utilization and delivery of a specific service or benefit provided to a specific enrollee, then CMS will require the contractual requirement to be modified to comply with § 438.6(c) or (d) beginning with rating periods that started on or after July 1, 2021. We maintain this interpretation. At this time, we also believe it is important to further specify our stance that any State direction of a managed care plan's payments to providers, regardless of specificity or even if tied specifically to utilization and delivery of services, is prohibited unless § 438.6(c) or (d) permits the arrangement. State wishing to impose quality requirements or thresholds on managed care plans, such as the requirement that a certain percentage of provider payments be provided through a VBP arrangement, must do so within the parameters of § 438.6(b). We do not believe any changes are needed to the regulation text in § 438.6(c) or (d) to reflect this reinterpretation and clarification because this preamble provides an opportunity to again bring this important information to States' attention; CMS will continue this narrower interpretation of § 438.6(c) and (d). We solicit comments on whether additional clarification about these grey area payments is necessary or, if revision to the regulation text would be helpful.

c. Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), § 438.6(c)(2), and § 438.6(c)(5)(iii)(A)(*5*))

52 *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

In § 438.6(c), States are permitted to direct managed care plans' expenditures under the contract as specified in § 438.6(c)(1)(i) through (iii), subject to written prior approval based on complying with the requirements in § 438.6(c)(2). In the preamble to the 2020 final rule, we noted our observation that a significant number of proposals submitted by States for review under § 438.6(c)(2) required managed care plans to adopt minimum fee schedules specified under an approved methodology in the Medicaid State plan. In response, we adopted several revisions to § 438.6(c) in the 2020 final rule.[53] We defined "State plan approved rates" in § 438.6(a) as "amounts calculated for specific services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan," and excluded supplemental payments that are paid in addition to State plan approved rates. We also revised § 438.6(c)(1)(iii)(A) to explicitly address SDPs that are a minimum fee schedule for network providers that provide a particular service under the contract using State plan approved rates and revised § 438.6(c)(2)(ii) to exempt these specific SDP arrangements from the written prior approval requirement. However, SDPs described in paragraph § 438.6(c)(1)(iii)(A) must comply with the requirements currently at § 438.6(c)(2)(ii)(A) through (F) (other than the requirement for written prior approval) and be appropriately documented in the managed care contract(s) and rate certification(s).

This piece of the 2020 final rule was, in part, intended to eliminate unnecessary and duplicative review processes in an effort to promote efficient and effective administration of the Medicaid program. This rule improved States' efforts to timely implement certain SDP arrangements that meet their local goals and objectives without drawing upon State staff time unnecessarily. We continue to believe exempting payment arrangements based on an approved State plan rate methodology from written prior approval does not increase program integrity risk or create a lack of Federal oversight. We continue to review the corresponding managed care

53 *https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicaid-and-childrens-health-insurance-program-chip-managed-care*.

contracts and rate certifications which include these SDPs. The State plan review and approval process ensures that Medicaid State plan approved 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, as required under section 1902(a)(30) of the Act.

As we have continued to review and approve SDPs since the 2020 final rule, we believe this same rationale applies to SDPs that adopt a minimum fee schedule using Medicare approved rates for providers that provide a particular service under the contract. Medicare rates are developed under Title XVIII of the Act and there are annual rulemakings associated with Medicare payment for benefits available under Parts A and B in the Medicare Fee-for-Service (FFS) program. Additionally, section 1852(a)(2) of the Act provides that Medicare Advantage plans pay out-of-network providers at least the amount payable under FFS Medicare for benefits available under Parts A and B, taking into account cost sharing and permitted balance billing.[54] These considerations mean that prior written approval by CMS is not necessary to ensure that the standards for SDPs in current § 438.6(c)(2) are met.

Consistent with how we have considered State plan rates to be reasonable, appropriate, and attainable under §§ 438.4 and 438.5, Medicare approved rates too meet this same threshold. Therefore, we are proposing to exempt SDPs that adopt a minimum fee schedule based on total published Medicare payment rates from written prior approval as it would be unnecessary and duplicative. We propose to amend § 438.6(c) to provide specifically for SDPs that require use of a minimum fee schedule using FFS Medicare payment rates.

First, we propose to add a new definition to § 438.6(a) for "total published Medicare payment rate" as amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B. We propose to re-designate the existing

54 See also 42 CFR 422.100(b) and 422.214 and guidance in the "MA Payment Guide for Out of Network Payments", April 15, 2015, available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf.

§ 438.6(c)(1)(iii)(B) through (D) as § 438.6(c)(1)(iii)(C) through (E), respectively, and add a new § 438.6(c)(1)(iii)(B) explicitly recognizing SDP arrangements that are a minimum fee schedule using a total published Medicare payment rate in effect no more than 3 years prior to the start of the rating period as a permissible type of SDP. We are also proposing to revise proposed re-designated paragraph (c)(1)(iii)(C) to take into account the proposed new category of SDPs that use one or more total published Medicare payment rates. As part of the proposals for paragraphs (c)(1)(iii)(A) through (E), we also propose to streamline the existing regulation text to eliminate the phase "as defined in paragraph (a)" as unnecessary; we expect that interested parties and others who read these regulations will read them completely and recognize when defined terms are used.

We also propose to restructure § 438.6(c)(2) and amend its paragraph heading to *Standards for State directed payments* as discussed fully in later sections. As part of this restructuring, we propose to re-designate part of the provision in § 438.6(c)(2)(ii) to § 438.6(c)(2)(i) to describe which SDPs require written prior approval. This revision includes proposing a conforming revision in § 438.6(c)(2)(i) to reflect the re-designation of § 438.6(c)(1)(iii)(B) through (D) as (c)(1)(iii)(C) through (E). This revision will ensure that that SDPs described in paragraph (c)(1)(iii)(B) along with the SDPs described in paragraph (c)(1)(iii)(A), are not included in the written prior approval requirement. States that adopt a minimum fee schedule using 100 percent of total published Medicare payment rates will still need to document these SDPs in the corresponding managed care contracts and rate certifications and those types of SDPs must still comply with requirements for all SDPs other than prior written approval by CMS, just as minimum fee schedules tied to State plan approved rates described in paragraph (c)(1)(iii)(A) must comply. SDPs described under paragraphs (c)(1)(iii)(A) and (B) would still need to comply with the standards listed in the proposed restructured § 438.6(c)(2)(ii). (See sections II.2.f. through l. for proposed new requirements and revisions to existing requirements for all SDPs to be codified in paragraph (c)(2)(ii).)

Our proposal to exempt certain SDPs from written prior approval from CMS is specific to SDPs that require the Medicaid managed care plan to use a minimum fee schedule that is equal 100 percent of the total published Medicare payment rate. SDP arrangements that use a different percentage (whether higher or lower than 100 percent) of a total published Medicare payment rate as the minimum payment amount or are simply based off of an incomplete total published Medicare payment rate would be included in the SDPs described in paragraph (c)(1)(iii)(C). Our review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable, and will not negatively impact access to care. Accordingly, we believe that SDPs that propose provider payment rates that are incomplete or either above or below 100 percent of total published Medicare payment rates may not always meet these criteria and thus, should remain subject to written prior approval by CMS.

We are also not proposing to remove the written prior approval requirement for SDPs for provider rates tied to a Medicare fee schedule in effect more than 3 years prior to the start of the rating period. This is reflected in our proposed revision to redesignated paragraph (c)(1)(iii)(C) to describe fee schedules for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in proposed new paragraph (c)(1)(iii)(B). We propose the limit of 3 years to be consistent with how § 438.5(c)(2) requires use of data that is at least that recent for rate development. Our review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable, and will not negatively impact access to care. Accordingly, we believe that SDPs that propose provider payment rates tied to a total published Medicare payment rate in effect more than 3 years prior to the start of the rating period may not always meet these criteria and thus, should remain subject to written prior approval by CMS.

We solicit public comments on our proposal to specifically address SDPs that are for minimum fee schedules using 100 percent of the amounts in a total published Medicare payment rate for providers that provide a particular service provided that the total published Medicare

payment rate was in effect no more than 3 years prior to the start of the rating period and on our proposal to exempt these specific types of SDP arrangements from the prior written approval requirement in § 438.6(c)(2)(ii).

We are also proposing to add new § 438.6(c)(5) (with the paragraph heading *Requirements for Medicaid Managed Care Contract Terms for State directed payments)*, for oversight and audit purposes. Proposed new paragraph (c)(5)(iii)(A)(5) would require the managed care plan contract to include certain information about the Medicare fee schedule used in the SDP, regardless of whether the SDP was granted an exemption from written prior approval under § 438.6(c)(1)(iii)(B). That is, for SDPs which use total published Medicare payment rates, the contract would need to specify which Medicare fee schedule(s) the State directs the managed care plan to use and any relevant and material adjustments due to geography, such as rural designations, and provider type, such as Critical Access Hospital or Sole Community Hospital designation.

The managed care contract would also need to identify the time period for which the Medicare fee schedule is in effect as well as the rating period for which it is used for the SDP. Consistent with § 438.6(c)(1)(iii)(B), the Medicare fee schedule must be in effect no more than 3 years prior to the start of the rating period for the services provided in the arrangement. This 3-year requirement is similar to § 438.5 rate setting, under which data that the actuary relies upon must be from the 3 most recent years that have been completed, prior to the rating period for which rates are being developed. For example, should a State seek to implement a § 438.6(c)(1)(iii)(B) fee schedule in calendar year 2025, the Medicare fee schedule must have been in effect for purposes of Medicare payment at least at the beginning of calendar year 2021.

Requiring sufficient language in the contract regarding the Medicare fee schedule would provide clarity to CMS, managed care plans, and providers regarding the explicit Medicare payment methodology being used under the contract. For broader discussion of § 438.6(c)(5), see section I.B.2.k. of this proposed rule.

We request comment on other material or significant information about a Medicare fee schedule that would need to be included to ensure the managed care contract sufficiently describes this type of SDP.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

d. Non-Network Providers (§ 438.6(c)(1)(iii))

We are proposing to remove the term "network" from the descriptions of SDP arrangements in current (and revised as proposed) § 438.6(c)(1)(iii). Existing regulations specify that for a State to require an MCO, PIHP or PAHP to implement a fee schedule under § 438.6(c)(1)(iii), the fee schedule must be limited to "network providers." This limitation is not included in § 438.6(c)(1)(i) or (ii) for SDP arrangements that are VBP and multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives. In our experience working with States, limiting the descriptions of SDP arrangements subject to § 438.6(c)(iii) to those that involve only network providers has proven to be too narrow and has created an unintended barrier to States' and CMS' policy goals to ensure access to quality care for beneficiaries.

In the 2016 final rule, we finalized current § 438.6(c)(1)(iii) to include "network" before "providers" in this provision.[55] As previously noted, the regulation at § 438.6(c)(1) generally prohibits States from directing the MCO's, PIHP's or PAHP's expenditures under the contract unless it meets one of the exceptions (as provided in a specific provision in Title XIX, in another regulation implementing a Title XIX provision related to payment to providers, a SDP that complies with § 438.6(c), or a pass-through payment that complies with § 438.6(d)). Therefore, the inclusion of the word "network" in the SDP arrangement descriptions in the 2016 final rule

55 *https://www.federalregister.gov/d/2016-09581/p-1269*.

has prevented States from including contract requirements to direct their Medicaid managed care plans on how to pay non-network providers.

In our work with States over the years, some States have noted concerns with the requirement that permissible SDPs only apply (or include) payments by Medicaid managed care plans to network providers. States have noted that limiting SDPs to network providers is impractical in large and diverse States. Several States had, prior to rulemaking, pre-existing contractual requirements with managed care plans that required a specific level of payment (such as the State's Medicaid FFS rates) for non-network providers. This aligns with our experience working with States as well, and we note section 1932(b)(2)(D) of the Act requires that non-network providers furnishing emergency services must accept as payment in full an amount equal to the Medicaid State plan rate for those services. Some States have historically required plans to pay non-network providers at least the Medicaid State plan approved rate or another rate established in the managed care contract. Many States with enrollees on their borders rely on providers in neighboring States to deliver specialty services, such as access to children's hospitals.

While we support States' and plans' efforts to develop strong provider networks and to focus their efforts on providers who have agreed to participate in plan networks, executing network agreements with every provider may not always be feasible for plans. For example, in large hospital systems, it may be impractical for every plan to obtain individual network agreements with each rounding physician delivering care to Medicaid managed care enrollees. In such instances, States may have an interest in ensuring that their Medicaid managed care plans pay non-network providers at a minimum level to avoid access to care concerns. We have also encountered situations in which States opt to transition certain benefits, which were previously carved out from managed care, from fee-for-service into managed care. In these instances, States would like to require their managed care plans to pay out-of-network providers a minimum fee schedule in order to maintain access to care while allowing plans and providers adequate time to

negotiate provider agreements and provider payment rates for the newly incorporated services. Consequently, we are proposing these changes to provide States a tool to direct payment to non-network providers as well as network providers.

Therefore, we are proposing to remove the term "network" from the descriptions of permissible SDP arrangements in § 438.6(c)(1)(iii). Under this proposal, the permissible SDPs are described as payment arrangements or amounts "for providers that provide a particular service under the contract" and this will permit States to direct payments under their managed care contracts for both network and non-network providers, subject to the requirements in paragraph (c). We note that, as proposed, all of the standards and requirements under § 438.6(c) would still be applicable to SDPs that direct payment arrangements for non-network providers.

Finally, as pass-through payments (PTPs) are separate and distinct from SDPs, we are maintaining the phrase "network provider" in § 438.6(d)(1) and (6). Existing PTPs are subject to a time-limited transition period and in accordance with § 438.6(d)(3) and (5), respectively, hospital PTPs must be fully eliminated by no later than the rating period beginning July 1, 2027 and NF and physician services PTPs were required to have been eliminated by no later than the rating period July 1, 2022 with the exceptions of pass-through payments for States transitioning services and populations in accordance with § 438.6(d)(6). Therefore, we do not believe that it is appropriate or necessary to eliminate the word "network" from § 438.6(d).

We solicit public comments on our proposal. In particular, we seek comment on whether this change would result in negative unintended consequences.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

e. SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (ix))

Since we established the ability for States to direct the expenditures of their managed care plans in the 2016 final rule, we have encouraged States to submit their requests for written prior approval 90 days in advance of the start of the rating period whenever possible. We also

recommend that States seek technical assistance from CMS in advance of formally submitting the preprint for review to CMS for more complicated proposals to facilitate the review process.

Submitting 90 days in advance of the rating period provides CMS and the State time to work through the written prior approval process before the State includes the SDP in their managed care plan contracts and the associated rate certifications. If States include SDPs in managed care contracts and capitation rates before we issue written prior approval, any changes to the SDP made as a result of the review process would likely then necessitate contract and rate amendments,[56] creating additional work for States, actuaries, CMS, and managed care plans. Submitting SDP preprints at least 90 days in advance of the rating period can help reduce the need for subsequent contract and rate amendments to address any inconsistencies between the contracts and rate certifications and approved SDPs. State directed payments that are not submitted 90 days in advance of the affected rating period also cause delays in the approval of managed care contracts and rates because those approvals are dependent on the written prior approval of the SDP. Since we cannot approve only a portion of a State's Medicaid managed care contract, late SDP approvals delay approval of the entire contract and the associated capitation rates.

Some States have not been successful in submitting their SDP preprints in advance of the rating period for a variety of reasons. Sometimes it is due to changes in program design, such as a new benefit linked to the SDP being added to the Medicaid managed care contract during the rating period. Other unforeseen changes, such as public health emergencies (PHE) or natural disasters, can also create circumstances in which States need to respond to urgent concerns around access to care by implementing an SDP during the rating period. While we recognize that from time to time there may be a circumstance that necessitates a late preprint submission, we have found that some States routinely submit SDP preprints at the very end of the rating period with implementation dates retroactive to the start of the rating period. We have provided

56 The term "rate amendment" is used to reference an amendment to the initial rate certification.

repeated technical assistance to these States, and we published additional guidance in 2021[57] to reiterate our expectation that States submit SDP preprints before the start of a rating period. This guidance also made clear that CMS would not accept SDP preprints for rating periods that are closed; however, we have not been able to correct the situation with some States.

To make our processes more responsive to States' needs while ensuring that reviews linked to SDP approvals are not unnecessarily delayed, we propose a new § 438.6(c)(2)(viii)(A) through (C) to set the deadline for submission of SDP preprints that require written prior approval from CMS under paragraph (c)(2)(i) (redesignated from § 438.6(c)(2)(ii)). In § 438.6(c)(2)(viii)(A), we propose to require that all SDPs that require written prior approval from CMS must be submitted to CMS no later than 90 days in advance of the end of the rating period to which the SDP applies. This requirement applies if the payment arrangement for which the State is seeking written prior approval begins at least 90 days in advance of the end of the rating period. We strongly encourage all States to submit SDPs in advance of the start of the rating period to ensure CMS has adequate time to process the State's submissions and is able to support the State in incorporating these payments into their Medicaid managed care contracts and rate development. We are proposing to use a deadline of no later than 90 days prior to the end of the applicable rating period because we believe this minimum timeframe balances the need for State flexibility to address unforeseen changes that occur after the managed care plan contracts and rates have been developed with the need to ensure timely processing of managed care contracts and capitation rates. When a State fails to submit all required documentation for any SDP arrangement that requires written prior approval 90 days prior to the end of the rating period to which the SDP applies, the SDP would not be eligible for written prior approval; therefore, the State would not be able to include the SDP in its Medicaid managed care contracts and rate certifications for that rating period.

57 *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

In § 438.6(c)(2)(viii)(B), we propose to address the use of shorter-term SDPs in response to infrequent events, such as PHEs and natural disasters, by permitting States to submit all required documentation before the end of the rating period for SDP proposals that would start less than 90 days before the end of the rating period. We believe this flexibility would be appropriate to allow States to effectively use SDPs during the final quarter of the rating period to address urgent situations that affect access to and quality of care for Medicaid managed care enrollees.

There are SDPs, such as VBP and delivery system reform, that can be approved under § 438.6(c)(3) for up to three rating periods. For these, we propose in § 438.6(c)(2)(viii)(C) that the same timeframes described in § 438.6(c)(2)(viii)(A) and (B) apply to the first rating period of the SDP.

To illustrate these timeframes, we are using an SDP eligible for annual approval that a State is seeking to include in their CY 2025 rating period. For example, under the current regulations, CMS would strongly recommend that a State seeking approval of an SDP for the calendar year (CY) 2025 rating period would ideally submit the preprint by October 3, 2024. However, under this proposal to revised § 438.6(c)(2)(viii), if the start of the SDP was on or before October 2, 2025, the State must submit the preprint no later than October 2, 2025 in order for CMS to accept it for review; if the State submitted the preprint for review after that date, CMS could not grant written prior approval of the preprint for the CY 2025 rating period. The State could instead seek written prior approval for the CY 2026 rating period instead if the preprint could not be submitted for the CY 2025 rating period by the October 2, 2025 deadline.

We considered an alternative requiring all SDPs to be submitted prior to the start of the rating period for which the State was requesting written prior approval. This would be a notable shift from current practice, which requires all preprints be submitted prior to the end of the rating period. Requiring that States submit all preprints prior to the start of the rating period would reduce administrative burden and better align with the prospective nature of risk-based managed

care. However, instituting such a deadline could potentially be too rigid for States that needed to address an unanticipated or acute concern during the rating period.

Lastly, we considered an alternative of requiring that States submit all SDPs in advance of the start of the payment arrangement itself. For example, a State may seek to start a payment arrangement halfway through the rating period (for example, an SDP for payments starting July 1, 2025 for States operating on a CY rating period). Under this alternative approach, the State would have to submit the preprint for prior approval before July 1, 2025 in order for it to be considered for written prior approval. This would provide additional flexibility for States establishing new SDPs, but would limit the additional flexibility for that SDP to that initial rating period. If the State wanted to renew the SDP the subsequent rating period (for example, CY 2026), it would have to resubmit the preprint before the start of that rating period.

As discussed in section I.B.2.p. of this proposed rule on Applicability and Compliance dates, we are proposing that States must comply with these new submission timeframes beginning with the first rating period beginning on or after 2 years after the effective date of the final rule. In the interim, we would continue our current policy of not accepting submissions for SDPs after the rating period has ended. We solicit public comment on our proposals and these alternatives, as well as additional options that would also meet our goals for adopting time limits on when an SDP can be submitted to CMS for written prior approval.

For amendments to approved SDPs, we propose at § 438.6(c)(2)(ix) to require all amendments to SDPs approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) to be submitted for written prior approval as well. We also propose at § 438.6(c)(2)(ix)(A) to require that all required documentation for written prior approval of such amendments be submitted prior to the end of the rating period to which the SDP applies in order for CMS to consider the amendment. To illustrate this, we again provide the following example for an SDP approved for one rating period (CY 2025). If that SDP was approved by CMS prior to the start of the rating period (December 31, 2024 or earlier) and it began January 1, 2025, then the State would have to

submit any amendment to the preprint for that rating period before December 31, 2025. After December 31, 2025, CMS would not accept any amendments to that SDP for that CY 2025 rating period. The same would be true for an SDP that was approved for one rating period after the start of the rating period (for example, approval on October 1, 2025 for a CY 2025 rating period). the State would have until December 31, 2025 to submit any amendment to the preprint for CMS review; after December 31, 2025, CMS would not accept any amendments to that SDP for that rating period.

We further propose § 438.6(c)(2)(ix)(B) to set timelines for the submission of amendments to SDPs approved for multiple rating periods as provided in paragraph (c)(3). Under this proposal, § 438.6(c)(2)(ix)(A) and (B) would allow an amendment window for the proposal within the first 120 days of each of the subsequent rating periods for which the SDP is approved after the initial rating period. The amendment process for the first year of the multiple rating periods would work the same way as it would for any SDP approved for one rating period and be addressed by proposed paragraph (xi)(A). However, in recognition that the SDP is approved for multiple rating periods, we are proposing in § 438.6(c)(2)(ix)(B) that the State would be able to amend the approved preprint for the second (CY 2026 in our example) and third (CY 2027 in our example) rating periods within the first 120 days of the CY 2026 rating period (for example, by May 1, 2026). The requested amendment could not make any retroactive changes to the SDP for the CY 2025 rating period because the CY 2025 rating period would be closed in this example. The State would not be permitted to amend the payment arrangement after May 1, 2026 for the CY 2026 rating period. The State would be able to do the same for the CY 2027 rating period as well – amend the SDP within the first 120 days of the CY 2027 rating period, but only for the CY 2027 rating period and not for the concluded CY 2025 or CY 2026 rating periods.

As proposed, these deadlines are mandatory for written prior approval of an SDP or any amendment of an SDP. When a State fails to submit all required documentation for any amendments within these specified timeframes, the SDP would not be eligible for written prior

approval. Therefore, the State would not be able to include the amended SDP in its Medicaid managed care contracts and rate certifications for that rating period. The State could continue to include the originally approved SDP as documented in the preprint in its contracts for the rating period for which the SDP was originally approved. We note that written prior approval of an SDP does not obligate a State to implement the SDP. If a State chose not to implement an SDP for which CMS has granted prior approval, elimination of an SDP would not require any prior approval, under our current regulations or this proposal. We solicit comment on this aspect of our proposal.

We are proposing regulatory changes in §§ 438.6(c)(5)(vi) and 438.7(c)(6) to require the submission of related contract requirements and rate certification documentation no later than 120 days after the start of the SDP or the date we granted written prior approval of the SDP, whichever is later. States should submit their rate certifications prior to the start of the rating period, and § 438.7(c)(2) requires that any rate amendments[58] comply with Federal timely filing requirements. However, we believe given the nature of SDPs, there should be additional timing restrictions on when revised rate certifications that include SDPs can be provided for program integrity purposes. We also remind States that these proposals do not supersede other requirements regarding submission of contract and rate certification documentation when applicable, including but not limited to those that require prior approval or approval prior to the start of the rating period such as requirements outlined in §§ 438.3(a), 438.4(c)(2), and 438.6(b)(1). These proposals are discussed in later sections: section I.B.2.k on Contract Requirements for SDPs; section I.B.2.l on Separate Payment Terms; and section I.B.2.m on SDPs included as adjustments to base rates.

We are making these proposed regulatory changes to institute submission timeframes to ensure efficient and proper administration of the Medicaid program. We had also considered an alternative of requiring that States submit all amendments to SDPs for written prior approval

58 The term "rate amendment" is used to reference an amendment to the initial rate certification.

within either 120 days of the start of the payment arrangement or 120 days of CMS issuing written prior approval, whichever was later. To illustrate this, we again provide the following example for an SDP approved for one rating period (CY 2025). If that SDP was approved by CMS prior to the start of the rating period (December 31, 2024 or earlier) and it began January 1, 2025, then the State would have 120 days after the start of the payment arrangement (May 1, 2025) to submit any amendment to the preprint for that rating period. After May 1, 2025, CMS would not accept any amendments to that SDP for that CY 2025 rating period. If, however, that SDP were approved after the start of the rating period (for example, October 1, 2025 for a CY 2025 rating period); the State would have 120 days from that written prior approval (January 29, 2026) to submit any amendment to the preprint for CMS review; after January 29, 2026, CMS would not accept any amendments to that SDP for that rating period. Requiring that States submit any amendments to the SDP preprint within 120 days of either the start of the payment arrangement or the initial approval could reduce some administrative burden by limiting the time period for amendments to preprints. However, the time frame would be specific to each preprint, which could present some challenges in ensuring compliance. Additionally, it would not preclude States from submitting amendments after the end of the rating period; in fact, it may encourage States to submit SDP preprints toward the end of the rating period to preserve the ability to amend the preprint after the end of the rating period. CMS does not believe such practices are in alignment with the prospective nature of risk-based managed care. We solicit public comment on our proposals and these alternatives, as well as additional options that would also meet our goals for adopting time limits on when amendments to SDPs can be submitted to CMS for written prior approval.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on these proposals.

f. Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations

for Certain SDPs, and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I), 438.6(c)(2)(iii))

Standard for Total Payment Rates for Each SDP. Section 1903(m)(2)(A)(iii) of the Act requires contracts between States and managed care plans that provide for payments under a risk-based contract for services and associated administrative costs to be actuarially sound. Under section 1902(a)(4) of the Act, CMS also has authority to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan. Further, actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract. In risk-based managed care, managed care plans have the responsibility to manage the financial risk of the contract, and one of the primary tools plans use is negotiating payment rates with providers. Absent Federal statutory requirements or specific State contractual restrictions, the specific payment rates and conditions for payment between risk-bearing managed care plans and their network providers are subject to negotiations between the plans and providers, as well as overall private market conditions. As long as plans are meeting the requirements for ensuring access to care and network adequacy, States typically provide managed care plans latitude to develop a network of providers to ensure appropriate access to covered services under the contract for their enrollees and fulfill all of their contractual obligations while managing the financial risk.

As noted earlier, both the volume of SDP preprints being submitted by States for approval and the total dollars flowing through SDPs have grown steadily and quickly since § 438.6(c) was promulgated in the 2016 final rule. MACPAC reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion.[59] Our internal analysis of all SDPs approved from when § 438.6(c) was issued in the 2016 final rule through

59 Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf*.

March 2022, provides that the total spending approved for each SDP for the most recent rating period for States is nearly $48 billion[60] with at least half of that spending being dollars that States are requiring be paid in addition to negotiated rates.[61] This $48 billion figure is an estimate of annual spending. As SDP spending continues to increase, we believe it is appropriate to apply additional regulatory requirements with respect to the totality of provider payment rates under SDPs to ensure proper fiscal and programmatic oversight in Medicaid managed care programs, and we are proposing several related regulatory changes as well as exploring other potential payment rate and expenditure limits.

As noted in the 2016 final rule, section 1903(m)(2)(A)(iii) of the Act requires that contracts between States and Medicaid managed care organizations for coverage of benefits use prepaid payments to the entity that are actuarially sound. By regulation based on section 1902(a)(4) of the Act, CMS extended the requirement for actuarially sound capitation rates to PIHPs and PAHPs. The regulations addressing actuarially sound capitation rates are at §§ 438.4 through 438.7.

Currently § 438.6(c)(2) specifies that SDPs must be developed in accordance with § 438.4, the standards specified in § 438.5 and generally accepted actuarial principles and practices. Under the definition in § 438.4, actuarially sound capitation rates are "projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract..." Consistent with this definition in § 438.4, we noted in the State Medicaid Director Letter #21-001 published on January 8, 2021 that CMS

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60 This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through March 31, 2022 under CMS' standard review process. Rating periods differ by State; some States operating their managed care programs on a calendar year basis while others operate on a State fiscal year basis, which most commonly is July to June. The most recent rating period for which the SDP was approved as of March 2022 also varies based on the review process reflective of States submitting proposals later than recommended (close to or at the end of the rating period), delays in State responses to questions, and/or reviews taking longer due to complicated policy concerns (for example, financing).

61 As part of the revised preprint form, States are asked to identify if the payment arrangement requires plans to pay an amount in addition to negotiated rates vs. limiting or replacing negotiated rates. Approximately half of the total dollars identified for the SDP actions included were identified by States for payment arrangements that required plans to pay an amount in addition to the rates negotiated between the plan and provider(s) rates.

requires States to demonstrate that SDPs result in provider payment rates that are reasonable, appropriate, and attainable as part of the preprint review process. We are proposing here to codify this standard regarding the provider payment rates for each SDP more clearly in the regulation. As part of the proposed revisions in § 438.6(c)(2)(ii) to specify the standards that each SDP must meet, we are proposing a new standard at § 438.6(c)(2)(ii)(I) to codify our current policy that each SDP ensure that the total payment rate for each service, and each provider class included in the SDP must be reasonable, appropriate and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. We propose in § 438.6(a) to define "total payment rate" as the aggregate for each managed care program of: (1) the average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the SDP; (2) the effect of the SDP on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; (3) the effect of any and all other SDPs on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; and (4) the effect of any and all allowable pass-through payments, as defined in § 438.6(a), paid to any and all providers in the provider class specified in the SDP for which the State is seeking written prior approval on the average rate paid to providers in the specified provider class. We note that while the total payment rate described above is collected for each SDP, the information provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. We assess if the total payment level across all SDPs in a managed care program is reasonable, appropriate and attainable.

We note that, currently, § 438.6(c)(1)(iii)(A) describes an SDP that sets a minimum fee schedule using Medicaid State plan approved rates for a particular service. As proposed in

section I.B.2.c, § 438.6(c)(1)(iii)(B) would describe an SDP that sets a minimum fee schedule using 100 percent of the total published Medicare payment rate that was in effect no more than 3 years prior to the start of the applicable rating period for a particular service. An SDP that sets a minimum fee schedule using Medicaid State plan approved rates for a particular service does not currently require prior written approval by CMS per § 438.6(c)(2)(ii), and we are proposing in § 438.6(c)(2)(i) to not require prior approval for an SDP that sets a minimum fee schedule using 100 percent of the total published Medicare payment rate. We also believe that both of these specific payment rates would be (and therefore meet the requirement that) reasonable, appropriate and attainable because CMS has reviewed and determined these payment rates to be appropriate under the applicable statute and implementing regulations for Medicaid and Medicare respectively. However, for other SDP arrangements, additional analysis and consideration is necessary to ensure that the payment rates directed by the State meet the standard of reasonable, appropriate and attainable.

The proposed standard at § 438.6(c)(2)(ii)(I) also includes a requirement that upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. While we are not proposing to require States to provide documentation in a specified format to demonstrate that the total payment rate is reasonable, appropriate and attainable for all services (see next section for documentation requirements for some SDPs), we intend to continue requesting information from all States for all SDPs documenting the different components of the total payment rate as described earlier in section I.B.2.f. of this proposed rule using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. We formalized this process in the revised preprint form[62] published in January 2021, and described it in the accompanying SMDL. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities and to ensure managed care

62 *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

payments are reasonable, appropriate and attainable. Based on our ongoing monitoring of payment rates, we may issue guidance further detailing documentation requirements and a specified format to demonstrate that the total payment rate is reasonable, appropriate and attainable for all services.

We solicit comments on our proposed changes.

Establishment of Payment Rate Limitations for Certain SDPs. As noted, a number of other entities, including MACPAC[63] and GAO,[64] have released reports focused on SDPs. Both noted concerns about the growth of SDPs and lack of a regulatory payment ceiling. Our proposed standard at § 438.6(c)(2)(ii)(I) would codify our current practice of determining whether the total payment rate is reasonable, appropriate, and attainable for each SDP. However, neither in our guidance nor in our proposed regulatory requirement at § 438.6(c)(2)(ii)(I) have we defined the terms "reasonable, appropriate and attainable" as they are used for SDPs. To address this, we are proposing several regulatory standards to establish when the total payment rates for certain SDPs are reasonable, appropriate and attainable. We are proposing to adopt at § 438.6(c)(2)(iii) both specific standards and the documentation requirements necessary for ensuring compliance with the specific standards for the types of SDPs described in paragraphs (c)(1)(i),(ii), and (iii)(C) through (E) where the SDP is for one or more of the following types of services: inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center.

To explain and provide context for proposed new paragraph (c)(2)(iii), we discuss the historical use of the average commercial rate (ACR) benchmark for SDPs, the proposed payment limit for inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services (including proposed definitions for these

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63 *https://www.macpac.gov/publication/june-2022-report-to-congress-on-medicaid-and-chip/ June 2022 Report to Congress on Medicaid and CHIP, Chapter 2.*

64 *U.S. Government Accountability Office, "Medicaid: State Directed Payments in Managed Care," June 28, 2022, available at https://www.gao.gov/assets/gao-22-105731.pdf.*

types of services) and some alternatives we are also considering, the proposed requirement for States to demonstrate the ACR, and the proposed requirements for States to demonstrate compliance with the ACR and total payment rate comparison requirement. We have included further sub-headers to help guide the reader through this section.

1. Historical Use of the Average Commercial Rate Benchmark for SDPs

In late 2017, we received an SDP preprint to raise inpatient hospital payment rates broadly that would result in a total payment rate that exceeded 100 percent of Medicare rates in that State, but the payments would remain below the ACR for that service and provider class in that State. We had concerns about whether the payment rates were still reasonable, appropriate, and attainable for purposes of CMS approval of the SDP as being consistent with the existing regulatory requirement that all SDPs must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices. We realized that approving an SDP that exceeded 100 percent of Medicare rates would be precedent-setting for CMS. We explored using an internal total payment rate benchmark that could be applied uniformly across all SDPs to evaluate preprints for approval and to ensure that payment rates projected to be paid to providers under the SDP(s) remained reasonable, appropriate, and attainable.

Medicare is a significant payer in the health insurance market, and Medicare reimbursement is a standardized benchmark used in the industry. Medicare reimbursement is also a benchmark used in Medicaid FFS, including the Upper Payment Limits (UPLs) that apply to classes of institutional providers, such as hospitals, nursing facilities, and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID), that are based on Medicare payment rates. The UPLs apply an overall payment ceiling based on how much Medicare would have paid in total as a mechanism for determining economy and efficiency of payment for State

plan services while allowing for facility-specific payments.[65] Generally for inpatient and outpatient services, these UPL requirements apply to three classes of facilities based on ownership status: State-owned, non-State government-owned, and private. Hospitals within a class can be paid different amounts and facility-specific total payment rates can vary, sometimes widely, so long as in the aggregate, the total amount that Medicaid paid across the class is no more than what Medicare would have paid.

When considering the Medicaid FFS UPL methodologies, we had some concerns that applying the same standards for the total payment rate under SDPs to three classes based on ownership status, would not be appropriate for implementing the SDP requirements. In some States, SDPs have become a method to meet their quality and access goals in Medicaid managed care.

Currently, § 438.6(c)(2)(ii)(B) provides States with broader flexibility than what is required for FFS UPLs in defining the provider class for which States can implement SDPs. This flexibility has proven important for States to target their efforts to achieve their stated policy goals tied to their managed care quality strategy. For example, CMS has approved SDPs where States proposed and implemented SDPs that applied to provider classes defined by criteria such as participation in State health information systems. In other SDPs, the eligible provider class was established by participation in learning collaboratives which were focused on health equity or social determinants of health. In both cases, the provider class under the SDP was developed irrespective of the facility's ownership status. These provider classes can be significantly wider or narrower than the provider class definitions used for Medicaid UPL demonstrations in Medicaid FFS. Therefore, the provider classes in some approved SDPs did not align with the classes used in Medicaid FFS UPL demonstrations, which are only based on ownership or operation status (that is, State government-owned or operated, Non-State government-owned or

65 The Upper Payment Limit regulations for FFS Medicaid are §§ 447.272 (inpatient hospital services), 447.321 (outpatient hospital services) and 447.325 (other inpatient and outpatient facility services).

operated, and privately-owned and operated facilities) and include all payments made to all facilities that fit in those ownership-defined classes. Not all providers providing a particular service in Medicaid managed care programs must be included in an SDP. Under § 438.6(c)(2)(ii)(B), States are required to direct expenditures equally, using the same terms of performance, for a *class* of providers furnishing services under the contract; however, they are not required to direct expenditures equally using the same terms of performance for *all providers* providing services under the contract.

Without alignment across provider classes, CMS could have faced challenges in applying a similar standard of the Medicaid FFS UPL to each provider class that the State specified in the SDP irrespective of how each provider class that the State specified in the SDP compared to the ownership-defined classes used in the Medicaid FFS UPL. Given the diversity in provider classes States have proposed and implemented under SDPs approved by CMS at the time (and subsequently), combined with the fact that not all providers of a service under the contract are necessarily subject to the SDP, CMS had concerns that applying the Medicaid FFS UPL to each provider class under the SDP could have resulted in situations in managed care where provider payments under SDPs would not align with Medicaid FFS policy. In some instances, payments to particular facilities could potentially be significantly higher than allowed in Medicaid FFS, and in others, facility-specific payments could potentially be significantly lower than allowed in Medicaid FFS.

We note that States have been approved to make Medicaid FFS supplemental payments up to the ACR for qualified practitioners affiliated with and furnishing services (for example, physicians under the physician services benefit) in academic medical centers, physician practices, and safety net hospitals.[66] CMS had previously approved SDPs that resulted in total

66 CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional information on this and other payment demonstrations is published on Medicaid.gov at *https://www.medicaid.gov/medicaid/financial-management/payment-limit-demonstrations/index.html*. Instructions specific to qualified practitioner services ACR are further described in the following instructions:

payment rates up to the ACR for the same providers that States had approved State plan authority to make supplemental payments up to the ACR in Medicaid FFS. Additionally, while CMS does not review the provider payment rate assumptions for all services underlying Medicaid managed care rate development, we had recently approved Medicaid managed care contracts in one State where plans are paid capitation rates developed assuming the use of commercial rates paid to providers for all services covered in the contract.

For these reasons, in 2018, CMS ultimately interpreted the current § 438.6(c)(2)(i) (which we propose to re-designate as § 438.6(c)(2)(ii)(I) and (J) along with revisions to better reflect our interpretation) to allow total payment rates in an SDP up to the ACR. The statutory and regulatory requirements for the UPL in Medicaid FFS do not apply to risk-based managed care plans; therefore, permitting States to direct MCOs, PIHPs, PAHPs to make payments higher than the UPL does not violate any Medicaid managed care statutory or regulatory requirements. We adopted ACR as the standard benchmark for all SDPs. this standard benchmark for all SDPs applied ACR more broadly (that is, across more services and provider types) than allowed under Medicaid FFS, due to the Medicare payment-based UPLs applicable in FFS. Our rationale in 2018 for doing so was that using the ACR allowed States more discretion than the Medicaid FFS UPL because it allows States to ensure that Medicaid managed care enrollees have access to care that is comparable to access for the broader general public. Also, we believed using the ACR presented the least disruption for States as they were transitioning existing, and often long-standing, pass-through payments[67] into SDPs, while at the same time providing a ceiling for

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https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used. As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.

67 Pass-through payments are defined in § 438.6(a) as, "any amount required by the State to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for a specific service or benefit provided to a specific enrollee covered under the contract, a provider payment methodology permitted under § 438.6(c), a sub-capitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments."

SDPs to protect against the potential of SDPs threatening States' ability to comply with our interpretation of current § 438.6(c)(2)(i) that total provider payment rates resulting from SDPs be reasonable, appropriate and attainable. Finally, using the ACR provided some parity with Medicaid FFS payment policy for payments for qualified practitioners affiliated with and furnishing services at academic medical centers, physician practices, and safety net hospitals where CMS has approved rates up to the ACR.[68]

Therefore, since 2018, we have used the ACR as a benchmark for total payment rates for all SDP reviews. Under this policy, States have had to document the total payment rate specific to each service type included in the SDP and specific to each provider class identified. For example, if an SDP provides a uniform increase for inpatient and outpatient hospital services with two provider classes (rural hospitals and non-rural hospitals), the State would be required to provide an analysis of the total payment rate (average base rate paid by plans, the effect of the SDP, the effect of any other approved SDP(s), and the effect of any permissible pass-through payments) using a standardized measure (for example, Medicaid State plan approved rates or Medicare) for each service and each class included in the SDP. In the example above, the State would be required to demonstrate the total payment rates for inpatient services for rural hospitals, inpatient services for non-rural hospitals, outpatient services for rural hospitals and outpatient services for non-rural hospitals separately. We formalized this process in the revised preprint form[69] published in January 2021, and described it in the accompanying SMDL. While CMS has collected this information for each SDP submitted for written prior approval, we

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68 CMS has approved Medicaid State plan amendments authorizing such targeted Medicaid supplemental payment methodologies for qualified practitioner services up to the average commercial rate under 1902(a)(30)(A) of the Act. Additional information on this and other payment demonstrations is published on Medicaid.gov at . Instructions specific to qualified practitioner services ACR are further described in the following instructions: *https://www.medicaid.gov/medicaid/downloads/upl-instructions-qualified-practitioner-services-replacement-new.pdf#:~:text=CMS%20has%20approved%20SPAs%20that%20use%20the%20following,payments%20or%20an%20alternate%20fee%20schedule%20is%20used*. As practitioner payments are not subject to Medicaid UPL requirements under 42 CFR part 447 subparts C and F, the ACR is a mechanism by which CMS can review Medicaid practitioner supplemental payments compared to average commercial market rates where private insurance companies have an interest in setting reasonable, competitive rates in a manner that may give assurance that such rates are economic and efficient, consistent with section 1902(a)(30)(A) of the Act.

69 *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

historically requested the impact not only of the SDP under review, but any other payments made by the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period.

When a State has not demonstrated that the total payment rate for each service(s) and provider class(es) included in each SDP arrangement is at or below either the Medicare or Medicaid FFS rate (when Medicare does not cover the service), CMS has requested documentation from the State to demonstrate that the total payment rates that exceed the Medicare or the Medicaid FFS rate do not exceed the ACR for the service and provider class. CMS has worked with States to collect documentation on the total payment rate, which has evolved over time. CMS has not knowingly approved an SDP where the total payment rate, inclusive of all payments made by the plan to any providers included in the provider class for the same rating period, was projected to exceed the ACR.

2. Proposed Payment Rate Limit for Inpatient Hospital Services, Outpatient Hospital Services, Qualified Practitioner Services at Academic Medical Centers, and Nursing Facility Services

While CMS has not knowingly approved an SDP that includes payment rates that are projected to exceed the ACR, States are increasingly submitting preprints that would push total payment rates up to the ACR. Therefore, we propose to move away from the use of an internal benchmark to a regulatory limit on the projected total payment rate, using the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services. We are also considering other potential options for this limit on total payment rate for these four services.

CMS believes that using the ACR as a limit is likely appropriate as it is generally consistent with the need for managed care plans to compete with commercial plans for providers to participate in their networks to furnish comparable access to care for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services.

While Medicaid is a substantial payer for these services, it is not the most common payer for inpatient hospital, outpatient hospital and qualified practitioner services at an academic medical center. Looking at the National Health Expenditures data for 2020, private health insurance pays for 32 percent of hospital expenditures, followed by Medicare (25 percent) and Medicaid (17 percent). There is a similar breakdown for physician and clinical expenditures – private health insurance pays for 37 percent of physician and clinical expenditures, followed by Medicare (24 percent) and Medicaid (11 percent).[70] For these three services, commercial payers typically pay the highest rates, followed by Medicare, followed by Medicaid.[71,72,73,74]

Based on both CMS' experience with SDPs for inpatient hospital services, outpatient hospital services and qualified practitioner services at an academic medical center as well as data from the National Health Expenditure survey and other external studies examining payment rates across the Medicaid, Medicare and commercial markets, we believe that for these three services , the ACR payment rate limit would likely be reasonable, appropriate and attainable while allowing States the flexibility to further State policy objectives through implementation of SDPs.

We also believe that this proposed ACR payment rate limit aligns with the SDP actions submitted to CMS. Based on our internal data collected from our review of SDPs, the most common services for which States seek to raise total payment rates up to the ACR are qualified practitioner services at academic medical centers, inpatient hospital services, and outpatient hospital services. Looking at approvals since 2017 through March 2022, we have approved 145

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70 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData.

71 Congressional Budget Office, "The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services," January 2022, available at *https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf.*

72 E. Lopez, T. Neumann, "How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature," Kaiser Family Foundation, April 15, 2022, available at *https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/.*

73 Medicaid and CHIP Payment and Access Commission, "Medicaid Hospital Payment: A Comparison across States and to Medicare," April 2017, available at *https://www.macpac.gov/wp-content/uploads/2017/04/Medicaid-Hospital-Payment-A-Comparison-across-States-and-to-Medicare.pdf.*

74 C. Mann, A. Striar, "How Differences in Medicaid, Medicare, and Commercial Health Insurance Payment Rates Impact Access, Health Equity, and Cost," The Commonwealth Fund, August 17, 2022, available at *https://www.commonwealthfund.org/blog/2022/how-differences-medicaid-medicare-and-commercial-health-insurance-payment-rates-impact*.

preprint actions that were expected to yield SDPs equal to the ACR: 33 percent of these payments are for professional services at academic medical centers; 18 percent of these payments are for inpatient hospital services; 17 percent of these payments are for outpatient hospital services; 2 percent are for nursing facilities. Altogether, this means that at least two thirds of the SDP submissions intended to raise total payment rates up to the ACR were for these four provider classes. While States are pursuing SDPs for other types of services, very few States are pursuing SDPs that increase total payment rates up to the ACR for those other categories or types of covered services.

While there have not been as many SDP submissions to bring nursing facilities up to a total payment rate near the ACR, there have been a few that have resulted in notable payment increases to nursing facilities. In the same internal analysis referenced above, 2 percent of the preprints approved that were expected to yield SDPs equal to the ACR were for nursing facilities. There have also been concerns raised as part of published audit findings about a particular nursing facility SDP.[75] Therefore, we propose to include these four services – inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services – in § 438.6(c)(2)(iii) and limit the projected total payment rate for each of these four services to ACR for any SDP arrangements described in paragraphs (c)(1)(i) through (iii), excluding (c)(1)(iii)(A) and (B), that are for any of these four services. States directing MCO, PIHP or PAHP expenditures in such a manner that results in a total payment rate above the ACR for any of these four types of services would not be approvable under our proposal. Such arrangements would violate the standard proposed in § 438.6(c)(2)(ii)(I) that total payment rates be reasonable, appropriate and attainable and the standard proposed in § 438.6(c)(2)(iii) setting specific payment level limits for certain types of SDPs. We note that while the total payment rate is collected for each SDP, the information

75 U.S. Department of Health and Human Services Office of the Inspector General, "Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program," A-06-18-07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp*.

provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. The proposed total payment limit would apply across all SDPs in a managed care program; States would not be able to for example, create multiple SDPs that applied, in part or in whole, to the same provider classes and be projected to exceed the ACR. These proposals are based on our authority to interpret and implement section 1903(m)(2)(A)(iii) of the Act, which requires contracts between States and MCOs to provide payment under a risk-based contract for services and associated administrative costs that are actuarially sound and in order to apply these requirements to PIHPs and PAHPs as well as MCOs, on our authority under section 1902(a)(4) of the Act to establish methods of administration for Medicaid that are necessary for the proper and efficient operation of the State plan.

For some services where Medicaid is the most common or only payer (such as HCBS[76], mental health services[77], substance use disorder services[78], and obstetrics and gynecology services[79,80]), interested parties have raised concerns about access to care more specifically. For example, one State recently shared data from its internal analysis of the landscape of behavioral health reimbursement in the State that showed Medicaid managed care reimbursement for behavioral health services is higher than commercial reimbursement. Further, a study[81] authorized through Oregon's Legislature outlined several disparities in behavioral health

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76 The National Health Expenditures data for 2020 who that Medicaid is the primary payer for other health, residential and personal care expenditures, paying for 58 percent of such expenditures where private insurance only paid for 7 percent of such services. For home health care expenditures, Medicare paid for 34 percent of such services, followed by Medicaid at 32 percent followed by private insurance (13 percent.) *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData*.

77 *https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html*

78 *https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/*.

79 *https://www.acog.org/advocacy/policy-priorities/medicaid*.

80 *https://www.kff.org/womens-health-policy/issue-brief/medicaid-coverage-for-women/*.

81 J. Zhu, *et al.*, "Behavioral Health Workforce Report to the Oregon Health Authority and State Legislature," February 1, 2022, available at *https://www.oregon.gov/oha/ERD/SiteAssets/Pages/Government-Relations/Behavioral%20Health%20Workforce%20Wage%20Study%20Report-Final%20020122.pdf.*

payment, including a concern that within the commercial market, behavioral health providers often receive higher payment rates when furnishing services to out-of-network patients, potentially reducing incentives for these providers to join Medicaid managed care or commercial health plan networks. Instituting a limit on SDP payment amounts that is tied to the ACR, particularly when access concerns have also been raised in the commercial markets too, may have a deleterious effect on access to care for Medicaid managed care enrollees.

We acknowledge that some States have had difficulty with providing payment rate analyses demonstrating that the total payment rate is below ACR, including for services other than inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at academic medical centers. For example, based on our experience, some States have found it difficult to obtain data on commercial rates paid for HCBS. States have noted that this is due to the fact that commercial markets do not generally offer HCBS, making the availability of commercial rates for such services scarce or nonexistent. This same concern has been raised for other services, such as behavioral health and substance use disorder services, among others, where Medicaid is the most common payer and commercial markets do not typically provide similar levels of coverage.

Therefore, we are not proposing at this time to establish in § 438.6(c)(2)(iii) payment rate ceilings for each SDP for services other than inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at academic medical centers that States include in SDPs. While SDPs for all other services will still need to meet the proposed standard at § 438.6(c)(2)(ii)(I) that the total payment rate for each SDP (meaning the payment rate to providers) is reasonable, appropriate and attainable, at this time we believe further research is needed before codifying a specific payment rate limit for these services to ensure that such limits do not result in inappropriately reducing payment rates and negatively affecting access to care. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities and to ensure managed care payments

are reasonable, appropriate and attainable. Depending on our future experience, we may revisit this issue as necessary.

For clarity and consistency in applying these proposed new payment limits, we propose to define several terms in § 438.6(a), including a definition for "inpatient hospital services" that would be the same as specified at 42 CFR 440.10, "outpatient hospital services" that would be the same as specified in § 440.20(a) and "nursing facility services" that would be the same as specified at § 440.40(a). Relying on existing regulatory definitions will prevent confusion and provide consistency across Medicaid delivery systems.

We also propose definitions in § 438.6(a) for both "academic medical center" and "qualified practitioner services at an academic medical center" to clearly articulate which SDP arrangements would be limited based on the proposed payment rate. We propose to define "academic medical center" as a facility that includes a health professional school with an affiliated teaching hospital. We propose to define "qualified practitioner services at an academic medical center" as professional services provided by physicians and non-physician practitioners affiliated with or employed by an academic medical center.

At this time, we are not proposing to establish a payment rate ceiling for qualified practitioners that are not affiliated with or employed by an academic medical center. We have not seen a comparable volume or size of SDP preprints for provider types not affiliated with hospitals or academic medical centers, and we believe establishing a payment ceiling would likely be burdensome on States and could inhibit States from pursuing SDPs for providers such as primary care physicians and mental health providers and we seek comment on this issue. Depending on our future experience, we may revisit this policy choice in the future but until then, qualified practitioner services furnished at other locations or settings will be subject to the general standard we currently use that is proposed to be codified at § 438.6(c)(2)(ii)(I) that total payment rates for each service and provider class included in the SDP must be reasonable, appropriate and attainable.

We believe that establishing a total payment rate limit of the ACR for these four services appropriately balances the need for additional fiscal guardrails while providing States flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. In our view, utilizing the ACR in a managed care delivery system is appropriate and acknowledges the market dynamics at play to ensure that managed care plans can build provider networks that are comparable to the provider networks in commercial health insurance and ensure access to care for managed care enrollees. However, we recognize that formally codifying a payment rate limit of ACR for these four service types may raise some questions. First, codifying a payment rate limit of ACR for these four service types may incent States and interested parties to implement additional payment arrangements that raise total payment rates up to the ACR for other reasons beyond advancing access to care and enhancing quality of care in Medicaid managed care. The majority of SDPs that increase total payment rates up to the average commercial rate are primarily funded by either provider taxes, IGTs, or a combination of these two sources of the non-Federal share. These SDPs represent some of the largest SDPs in terms of total dollars that are required to be paid in addition to base managed care rates. We are concerned about incentivizing States to raise total payment rates up to the ACR based on the source of the non-Federal share, rather than based on furthering goals and objectives outlined in the State's managed care quality strategy. To mitigate this concern, which is shared not only by CMS but oversight bodies and interested parties such as MACPAC,[82] we are proposing additional regulatory changes related to financing the non-Federal share; see section I.B.2.g. of this proposed rule.

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82 MACPAC's report noted, "The largest directed payment arrangements are typically targeted to hospitals and financed by them. Of the 35 directed payment arrangements projected to increase payments to providers by more than $100 million a year, 30 were targeted to hospital systems and at least 27 were financed by provider taxes or IGTs. During our interviews, interested parties noted that the amount of available IGTs or provider taxes often determined the total amount of spending for these types of arrangements. Once this available pool of funding was determined, States then worked backward to calculate the percentage increase in provider rates. Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

In light of these concerns, we are considering alternatives to the ACR as a total payment rate limit for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center for each SDP. we are considering including in the final rule establishing the total payment rate limit at the Medicare rate; this is a standardized benchmark used in the industry, and is often a standard utilized in Medicaid FFS under upper payment limit (UPL) demonstrations in 42 CFR part 447. The Medicare rate is also not based on proprietary commercial payment data, and the payment data could be verified and audited more easily than the ACR. If we did include in the final rule a total payment rate limit at the Medicare rate, this may limit the growth in payment rates more than limiting the total payment rate to the ACR. We are also considering, and soliciting feedback on, establishing a total payment rate limit for all services, not limited to just these four services, for all SDP arrangements described in § 438.6(c)(1)(i), (ii), and (iii)(C) through (E) at the Medicare rate in the final rule. We invite public comments on these alternatives.

We do have some concerns about whether Medicare is an appropriate payment rate limit for managed care payments given the concerns and limitations we noted earlier in the "Historical Use of the Average Commercial Rate Benchmark for SDPs" section of this proposed rule, such as provider class limitations. Additionally, Medicare payment rates are developed for a population that differs from the Medicaid population. For example, Medicaid covers substantially more pregnant women and children than Medicare. Although Medicaid FFS UPLs are calculated as a reasonable estimate of what Medicare would pay for Medicaid services and account for population differences across the programs, it can be a challenging exercise to do so accurately. Therefore, we seek public comment to further evaluate if Medicare would be a reasonable limit for the total provider rate for the four types of services delivered through managed care that we propose, all services, and/or additional types of services. We note that beneficiaries enrolled in a managed care plan are often more aligned with individuals in commercial health insurance (such as, adults and kids), whereas the FFS population is generally

more aligned with the Medicare population (older adults and individuals with complex health care needs). To acknowledge the challenges in calculating the differences between the Medicaid and Medicare programs, we are also considering, and soliciting feedback on, whether the total payment rate limit for each SDP for these four services should be set at some level between Medicare and the ACR, or a Medicare equivalent of the ACR in the final rule. We invite public comments on these alternatives.

In considering these potential alternatives, we are also considering whether robust quality goals and objectives should be a factor in setting a total payment rate limit for each SDP for these four types of services. Specifically, we are also considering including in the final rule a provision permitting a total payment rate limit for any SDP arrangements described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDP arrangements described in § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate. As we noted earlier, CMS believes that establishing a total payment rate limit of the ACR for these four services provides States flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. Under this alternative policy we are considering including in the final rule, there would be an additional fiscal guardrail compared to our proposal by limiting the total payment rate for these four services to ACR for value-based initiatives only and further limiting the total payment rate for these four services to the Medicare rate for fee schedule arrangements (for example, uniform increases, minimum or maximum fee schedules). This alternative acknowledges the importance of robust quality outcomes and innovative payment models and could incentivize States to consider quality-based payment models that can better improve health outcomes for Medicaid managed care enrollees. We invite public comments on whether this potential alternative should be included in the final rule.

For each of these alternatives, we acknowledge that some States currently have SDPs that have total payment rates up to the ACR. Therefore, these alternative proposals could be more

restrictive, and States could need to reduce funding from current levels, which could have a negative impact on access to care and other health equity initiatives. we also seek public comment on whether or not CMS should consider a transition period in order to mitigate any disruption to provider payment levels if we adopt one of the alternatives for a total payment rate limit on SDP expenditures in the final rule.

We seek public comment on our proposal to establish a payment rate limit for SDP arrangements at the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services. Additionally, we solicit public comment on the alternatives we are considering to establish a payment rate limit at the Medicare rate, a level between Medicare and the ACR, or a Medicare equivalent of the ACR for these four service types. We also solicit public comment on whether the final rule should include a provision establishing a total payment rate limit for any SDP arrangements described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDP arrangements described in paragraph § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate.

3. Average Commercial Rate Demonstration Requirements

In order to ensure compliance with the provision currently proposed that the total payment rate for SDPs that require written prior approval from CMS for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical centers and nursing facility services do not exceed the ACR for the applicable services subject to the SDP, CMS will need certain information and documentation from the State. Therefore, we propose in § 438.6(c)(2)(iii) that States provide two pieces of documentation: (1) an ACR demonstration; and (2) a total payment rate comparison to the ACR. We propose the timing for these submissions in § 438.6(c)(2)(iii)(C). The ACR demonstration would be submitted with the initial preprint submission (new, renewal, or amendment) following the applicability date of this section and then updated at least every 3 years, so long as the State continues to include the SDP

in one or more managed care contracts. The total payment rate comparison to the ACR would be submitted with the preprint as part of the request for approval of each SDP and updated with each subsequent preprint submission (each amendment and renewal).

At § 438.6(c)(2)(iii)(A), we propose to specify the requirements for demonstration of the ACR if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. This demonstration must use payment data that: (1) is specific to the State; (2) is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section; (3) is specific to the service(s) addressed by the SDP; (4) includes the total reimbursement by the third party payer and any patient liability, such as cost sharing and deductibles; (5) excludes payments to FQHCs, RHCs and any non-commercial payers such as Medicare; and (6) excludes any payment data for services or codes that the applicable Medicaid managed care plans do not cover under the contracts with the State that will include the SDP. We consider Qualified Health Plans (QHPs) operating in the ACA Marketplace to be commercial payers for purposes of this proposed provision, and therefore, payment data from QHPs should be included when available.

At proposed § 438.6(c)(2)(iii)(A)(*1*), we would require States to use payment data specific to the State for the analysis, as opposed to regional or national analyses, to provide more accurate information for assessment. Given the wide variation in payment for the same service from State to State, regional or national analyses could be misleading, particularly when determining the impact on capitation rates that are State specific. Additionally, each State's Medicaid program offers different benefits and has different availability of providers. We currently request payment rate analyses for SDPs to be done at a State level for this reason and believe it would be important and appropriate to continue to do so.

At proposed § 438.6(c)(2)(iii)(A)(*2*), we would require States to use data that is no older than the 3 most recent and complete years prior to the start of the rating period of the initial

request following the applicability date of this section. This would ensure that the data is reflective of the current managed care payments and market trends. It also aligns with rate development standards outlined in § 438.5. For example, for the ACR demonstration for an SDP seeking written prior approval for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services for a CY 2025 rating period, the data used must be from calendar year 2021 and later. We used a calendar year for illustrative purpose only; States must use their rating period timeframe for their analysis.

We propose at § 438.6(c)(2)(iii)(A)(*3*) to require States to use data that is specific to the service type(s) included in the SDP; this would be a change from current operational practice. In provider payment rate analyses for SDPs currently, States are required to compare the total payment rate for each service and provider class to the corresponding service and provider class specific ACR. For example, States requiring their managed care plans to implement SDPs for inpatient hospital services for three classes of providers – rural hospitals, urban hospitals, and other hospitals – would have to produce payment rate analyses specific to inpatient hospital services in rural hospitals, inpatient hospital services in urban hospitals, and inpatient hospital services in other hospitals separately. Under our current operational practice, if the total payment rate for any of these three provider classes exceeds Medicare, CMS requests the State provide documentation demonstrating that the total payment rate does not exceed the ACR specific to both that service and that provider class. As noted later in this same section, we are proposing in § 438.6(c)(2)(iii)(B), to continue to require States to produce the total payment rate comparison to the ACR at a service and provider class level. However, our proposal to codify a requirement for an ACR demonstration includes changes to our approach to determining the ACR and would require States to submit the ACR demonstration, irrespective of if the total payment rate were at or below the Medicare rate or State plan rate for all preprints seeking written prior approval for the four services.

During our reviews of SDP preprints since the 2016 final rule, it has become clear that requiring an ACR analysis that is specific both to the service and provider class can have deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries. For example, we have often heard from States that rural hospitals commonly earn a larger share of their revenue from the Medicaid program than they do from commercial payers. There is also evidence that rural hospitals tend to be less profitable than urban hospitals and at a greater risk of closure.[83] These hospitals often serve a critical role in providing access to services for Medicaid beneficiaries living in rural areas where alternatives to care are very limited or non-existent. If States want to target funding to increase reimbursement for hospital services to rural hospitals, limiting the ceiling for such payments to the ACR for rural hospitals only would result in a lower ceiling than if the State were to broaden the category to include hospitals with a higher commercial payer mix (for example, payment data for hospital services provided at a specialty cardiac hospital, which typically can negotiate a higher rate with commercial plans). However, in doing so, the existing regulatory requirement for SDPs at § 438.6(c)(2)(ii)(B) requires that the providers in a provider class be treated the same – meaning they get the same uniform increase. This has resulted in some cases States not being able to use Medicaid funds to target hospitals that provide critical services to the Medicaid population, but instead must use some of those Medicaid funds to provide increases to hospitals that serve a lower share of Medicaid beneficiaries.

In another example to demonstrate the potential effects of requiring an ACR analysis that is specific to both the service and provider class level, a State could seek to implement an SDP that would provide different increases for different classes of hospitals (for example, rural and urban public hospitals would receive a higher percentage increase than teaching hospitals and short-term acute care hospitals). The SDP preprint could provide for separate additional

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83 MACPAC Issue Brief, "Medicaid and Rural Health." Published April 2021 *https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf.*

increases for hospitals serving a higher percentage of the Medicaid population and certain specialty services and capabilities. However, if the average base rate that the State's Medicaid managed care plans paid was already above the ACR paid for services to one of the classes (for example, rural hospitals), the State could not apply the same increases to this class as it would the other classes, even if the average base rate paid for the one class was below the ACR when calculated across all hospitals. In this example, the State would be left with the option of either eliminating the one class (for example, rural hospitals) from the payment arrangement or withdrawing the entire SDP proposed preprint even if the State still had significant concerns about access to care as it related to the one class (for example, rural hospitals). The focus on the ACR for the service at the provider class level has the potential to disadvantage providers with less market power, such as rural hospitals or safety net hospitals, which typically receive larger portions of their payments from Medicaid than from commercial payers. These providers typically are not able to negotiate rates with commercial payers on par with providers with more market power.

To provide States the flexibility they need to design SDPs to direct resources as they deem necessary to meet their programmatic goals, we propose to require an ACR demonstration using payment data specific to the service type (that is, by the specific type of service). This would allow States to provide an ACR analysis at just the service level instead of at the service and provider class level. For example, States could establish a tiered fee schedule or series of uniform increases, directing a higher payment rate to facilities that provide a higher share of services to Medicaid enrollees than to the payment rate to facilities that serve a lower share of services to Medicaid enrollees. States would still have a limit of the ACR, but allowing this to be measured at the service level and not at the service and provider class level would provide States flexibility to target funds to those providers that serve more Medicaid beneficiaries. Based on our experience, facilities that serve a higher share of Medicaid enrollees, such as rural hospitals and safety net hospitals, tend to have less market power to negotiate higher rates with commercial

plans. Allowing States to direct plans to pay providers using a tiered payment rate structure based on different criteria, such as the hospital's payer mix, without limiting the total payment rate to the ACR specific to each tier (which would be considered a separate provider class), but rather at the broader service level would provide States with tools to further the goal of parity with commercial payments, which may have a positive impact on access to care and the quality of care delivered. We would still permit States to elect to provide a demonstration of the ACR at both the service and provider class level or just at the service level if the State chooses to provide the more detailed and extensive analysis, but this level of analysis would no longer be required. We remind States that the statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, apply to all Medicaid expenditures regardless of delivery system (fee-for-service or managed care).

At § 438.6(c)(2)(iii)(B), we propose to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. Under this proposal, the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which written prior approval is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as defined in § 438.6(a) as a percentage of the average commercial rate, demonstrated pursuant to § 438.6(c)(2)(iii)(A), for each of the four categories of services (that is, inpatient hospital services, outpatient hospital services, nursing facility services or qualified practitioner services at an academic medical center) included in the SDP submitted to CMS for review and approval.

The proposed comparison of the total payment rate to the ACR would align with current practice with one exception. We are proposing to codify that the total payment rate comparison would be specific to each Medicaid managed care program to which the SDP under review would apply. Evaluating payment at the managed care program level would be consistent with the payment analysis described in section I.B.1.d. of this proposed rule. The total payment rate comparison proposed at § 438.6(c)(iii)(B) would be a more detailed analysis than is currently requested from States for SDP reviews. Under our proposal, these more detailed total payment rate comparisons would also have to be updated and submitted with each initial preprint, amendment and renewal per proposed § 438.6(c)(2)(iii)(C). In addition, we are proposing that the total payment rate comparison to ACR must be specific to both the service and the provider class; this is current practice today but differs from our proposal for the ACR demonstration, which is proposed to be service specific only.

We have proposed a set of standards and practices States must follow in conducting their ACR analysis. However, we are not proposing to require that States use a specific source of data for the ACR analysis. Further, at this time, we are not proposing to require States to use a specific template or format for the ACR analysis. In our experience working with States on conducting the analysis of the ACR, the availability of data differs by State and service. States are familiar with the process used for conducting a code-level analysis of the ACR for the qualified practitioner services at academic medical centers for Medicaid FFS.[84] Some States have continued to use this same process for documenting the ACR for SDPs as well, particularly when there is a limited number of providers from which to collect such data (for example, academic medical centers). However, code-level data analysis to determine the ACR has proven more challenging for other services, particularly when that service is provided by large numbers of providers. For example, the number of hospitals furnishing inpatient services in a given State can be hundreds of providers.

84 *https://www.medicaid.gov/medicaid/financial-management/payment-limit-demonstrations/index.html*.

Data for inpatient and outpatient hospital service payment rates tend to be more readily available in both the Medicare and commercial markets. States with SDPs for hospital services have provided analyses using hospital cost reports and all-payer claims databases. Others have relied on actuaries and outside consultants, which may have access to private commercial databases, to produce an ACR analysis. At times, States have purchased access to private commercial databases to conduct these analyses. We believe each of these approaches, provided the data used for the analyses meet the proposed requirements in § 438.6(c)(2)(iii), would be acceptable to meet our proposed requirements.

4. Average Commercial Rate Demonstration and Total Payment Rate Comparison Compliance

We propose at § 438.6(c)(2)(iii)(C) to require States to submit the ACR demonstration and the total payment rate comparison for review as part of the documentation necessary for written prior approval for payment arrangements, initial submissions or renewals, starting with the first rating period beginning on or after the effective date of this rule. The total payment rate comparison will need to be updated with each subsequent preprint amendment and renewal.

In recognition of the additional State resources required to conduct an ACR analysis, we propose to require that States update the ACR demonstration once every 3 years as long as the State continues to seek to include the SDP in the MCO, PIHP, or PAHP contract. This time period aligns with existing policy for ACR demonstrations for qualified practitioners in Medicaid FFS programs; specifically, those that demonstrate payment at the Medicare equivalent of the ACR.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

Expenditure Limit for SDPs. The increasing use by States of SDPs has been cited as a key area of oversight risk for CMS. Several oversight bodies, including MACPAC, OIG, and GAO,

have authored reports focused on CMS oversight of SDPs.[85,86,87] Both GAO and MACPAC have noted concerns about the growth of SDPs in terms of spending as well as fiscal oversight. Additionally, as States' use of SDPs in managed care programs continues to grow, some interested parties have raised concerns that the risk-based nature of capitation rates for managed care plans has diminished. Medicaid managed care plans generally have the responsibility under risk-based contracts to negotiate with its providers to set payment rates, except when a State believes the use of an SDP is a necessary tool to support the State's Medicaid program goals and objectives. In a risk contract, as defined in § 438.2, a managed care plan assumes risk for the cost of the services covered under the contract and incurs loss if the cost of furnishing the services exceeds the payments under the contract. States' use of SDPs and the portion of total costs for each managed care program varies widely and, in some cases, are a substantial portion of total program costs on an aggregate, rate cell, or category of service basis in a given managed care program or by managed care plan. For example, in one State, one SDP accounts for nine percent of the total projected capitation rates in a given managed care program, and as much as 43 percent of the capitation rates by rate cell for SFY 2023. In another State, SDPs accounted for over 50 percent of the projected Medicaid managed care hospital benefit component of the capitation rates in CY 2022. In a third State, the amount of SDP payments as a percentage of the capitation rates are between 12.5 percent and 40.3 percent by managed care plan and rate cell for SFY 2022. Some interested parties have raised concerns that such percentages are not reasonable in rate setting, and that States are potentially using SDP arrangements to circumvent Medicaid FFS UPLs by explicitly shifting costs from Medicaid FFS to managed care contracts.

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85 Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

86 U.S. Department of Health and Human Services Office of the Inspector General, "Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program," A-06-18-07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp*.

87 U.S. Government Accountability Office, "Medicaid: State Directed Payments in Managed Care," June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

CMS agrees with some of these concerns; and therefore, we are considering, and invite comment on, potentially imposing a limit on the amount of SDP expenditures in the final rule based on comments received. Imposing such a limit could help to address and improve program and fiscal protections to address the oversight risks identified by oversight bodies, ensure that risk-based contracts are used as intended, and that managed care plans that are "at risk" truly have the ability to manage how their revenue is used to cover all reasonable, appropriate, and attainable costs under the terms of the contract. Such an approach could have potential negative impacts on access to care that would need to be balanced with the need for improved program and fiscal integrity. We seek public comment on whether we should adopt a limit on SDP expenditures in the final rule.

To minimize burden on States, a limit on SDP expenditures could be structured similarly to the proposed 5 percent limit for ILOS expenditures, based on the ILOS cost percentage, proposed in § 438.16(c)(1) (see section I.B.4.b. of this proposed rule). However, we question whether the five percent limit proposed for ILOSs would be a reasonable limit for SDPs given the expansive nature of and associated services impacted by SDPs. Rather, we believe 10 to 25 percent of total costs could be more realistic for limiting SDP expenditures. Like with the ILOS cost percentage, CMS would not approve the related managed care contracts if the limit on SDP expenditures were exceeded. We seek public comment on both the overall approach of using a percent of total costs as well as on the appropriateness of 10 to 25 percent or what a reasonable percentage limit for SDP expenditures could be. We believe a limit on SDP expenditures could be structured in the following ways and invite comment on them as well as if the SDP expenditures limit should be imposed on a rate cell basis instead to inform our deliberative process.

One way to impose a limit on total SDP expenditures could be as a portion of the total costs for each Medicaid managed care program. Under such an approach, States would be required to produce the same type of calculation for the final State directed payment cost

percentage (see section I.B.2.j. of this proposed rule) except that for the numerator, States would be required to account for all SDPs applicable to that managed care program instead of just one SDP. Otherwise, the numerator and denominator would be calculated in the same manner as described for the final State directed payment cost percentage.

A second way to impose a limit on total SDP expenditures could be as a portion of the total costs for each Medicaid managed care program, but only focus on the costs related to inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers. Under this second approach, States would be required to produce the same type of calculation for the final State directed payment cost percentage (see section I.B.2.j. of this proposed rule) except the numerator would include all SDPs for inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center applicable to that managed care program instead of just one SDP. Similarly, the denominator would only include the portion of total Medicaid managed care payments made from the State to the plan related to these four service types.

If we finalize a limit on SDP expenditures, States would need to submit documentation to CMS to demonstrate compliance. We believe that requiring this documentation be submitted with one of these existing submission requirements rather than submitting separately would increase program efficiencies and reduce administrative burden. We are considering, and invite comment on, whether documentation to comply with a limit on the amount of SDP expenditures should be submitted with the associated managed care plan contract that includes the SDP contractual arrangement, the associated rate certification, or the SDP preprint.

We seek comment on these alternatives, including perspectives on how well the alternatives address the concerns we have identified and potential consequences of using overall expenditure limits for SDPs.

g. Financing (§ 438.6(c)(2)(ii)(G) and (H))

From our experience in working with States, it has become clear that SDPs provide an important tool for States in furthering the goals and objectives of their Medicaid programs within a managed care environment. In finalizing the standards and limits for SDPs and pass-through payments in the 2016 and 2017 final rules, we intended to ensure that the funding that was included in Medicaid managed care rate development was done so appropriately and in alignment with Federal statutory requirements applicable to the Medicaid program. This includes Federal requirements for the source(s) of the non-Federal share of SDPs.

Background on Medicaid Non-Federal Share Financing. Medicaid expenditures are jointly funded by the Federal and State governments. Section 1903(a)(1) of the Act provides for Federal payments to States of the Federal share of authorized Medicaid expenditures. The foundation of Federal-State shared responsibility for the Medicaid program is that the State must participate in the financial burdens and risks of the program, which provides the State with an interest in operating and monitoring its Medicaid program in the best interest of beneficiaries (see section 1902(a)(19) of the Act) and in a manner that results in receiving the best value for taxpayers for the funds expended. Sections 1902(a)(2), 1903(a), and 1905(b) of the Act require States to share in the cost of medical assistance and in the cost of administering the Medicaid program. FFP is not available for expenditures for services and activities that are not medical assistance authorized under a Medicaid authority or allowable State administrative activities. Additionally, FFP is not available to States for expenditures that do not conform to approved State plans, waiver, demonstration projects, or contracts, as applicable.

Section 1902(a)(2) of the Act and its implementing regulation in 42 CFR part 433, subpart B require States to share in the cost of medical assistance expenditures and permit other units of State or local government to contribute to the financing of the non-Federal share of medical assistance expenditures. These provisions are intended to safeguard the Federal-State partnership, irrespective of the Medicaid delivery system or authority (for example, FFS or managed care delivery system, and State plan, waiver, or demonstration authority), by ensuring

that States are meaningfully engaged in identifying, assessing, mitigating, and sharing in the risks and responsibilities inherent in operating a program as complex and economically significant as Medicaid, and that States are accordingly motivated to administer their programs economically and efficiently (see, for example, section 1902(a)(4) of the Act).

There are several types of permissible means for financing the non-Federal share of Medicaid expenditures, including, but not limited to: (1) State general funds, typically derived from tax revenue appropriated directly to the Medicaid agency; (2) revenue derived from health care-related taxes when consistent with Federal statutory requirements at section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B; (3) provider-related donations to the State which must be "bona fide" in accordance with section 1903(w) of the Act and implementing regulations at 42 CFR part 433, subpart B;[88] and (4) intergovernmental transfers (IGTs) from units of State or local government that contribute funding for the non-Federal share of Medicaid expenditures by transferring their own funds to and for the unrestricted use of the Medicaid agency.[89] Regardless of the source or sources of financing used, the State must meet the requirements at section 1902(a)(2) of the Act and § 433.53 that obligate the State to fund at least 40 percent of the non-Federal share of total Medicaid expenditures (both medical assistance and administrative expenditures) with State funds.

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88 "Bona fide" provider-related donations are truly voluntary and not part of a hold harmless arrangement that effectively repays the donation to the provider (or to providers furnishing the same class of items and services). As specified in § 433.54, a bona fide provider-related donation is made to the State or a unit of local government and has no direct or indirect relationship to Medicaid payments made to the provider, any related entity providing health care items or services, or other providers furnishing the same class of items or services as the provider or entity. This is satisfied where the donations are not returned to the individual provider, provider class, or a related entity under a hold harmless provision or practice. Circumstances in which a hold harmless practice exists are specified in § 433.54(c).

89 Certified public expenditures (CPEs) also can be a permissible means of financing the non-Federal share of Medicaid expenditures. CPEs are financing that comes from units of State or local government where the units of State or local governmental entity contributes funding of the non-Federal share for Medicaid by certifying to the State Medicaid agency the amount of allowed expenditures incurred for allowable Medicaid activities, including the provision of allowable Medicaid services provided by enrolled Medicaid providers. States infrequently use CPEs as a financing source in a Medicaid managed care setting, as managed care plans need to be paid prospective capitation payments and CPEs by nature are a retrospective funding source, dependent on the amount of expenditures the unit of State or local government certifies that it already has made.

Health care-related taxes and IGTs are a critical source of funding for many States' Medicaid programs, including for supporting the non-Federal share of many payments to safety net providers. Health care-related taxes made up approximately 17 percent ($37 billion) of all States' non-Federal share in 2018, the latest year for which data are available.[90] IGTs accounted for approximately 10 percent of all States' non-Federal share for that year. The Medicaid statute clearly permits certain health care-related taxes and IGTs to be used to support the non-Federal share of Medicaid expenditures, and CMS supports States' adoption of these non-Federal financing strategies where consistent with applicable Federal requirements. CMS approves hundreds of State payment proposals annually that are funded by health care-related taxes that appear to meet statutory requirements. The statute and regulations afford States flexibility to tailor health care-related taxes within certain parameters to suit their provider community, broader State tax policies, and the needs of State programs. However, all health care-related taxes must be imposed in a manner consistent with applicable Federal statutes and regulations, which prohibit direct or indirect "hold harmless" arrangements (see section 1903(w)(4) of the Act; 42 CFR 433.68(f)).

States first began to use health care-related taxes and provider-related donations in the mid-1980s as a way to finance the non-Federal share of Medicaid payments (Congressional Research Service, "Medicaid Provider Taxes," August 5, 2016, page 2). Providers would agree to make a donation or would support (or not oppose) a tax on their activities or revenues, and these mechanisms (donations or taxes) would generate funds that could then be used to raise Medicaid payment rates to the providers. Frequently, these programs were designed to hold Medicaid providers "harmless" for the cost of their donation or tax payment. As a result, Federal expenditures rapidly increased without any corresponding increase in State expenditures, since the funds used to increase provider payments came from the providers themselves and were

90 U.S. Government Accountability Office, "Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight," GAO-21-98, December 7, 2020, available at *https://www.gao.gov/products/gao-21-98*.

matched with Federal funds. In 1991, Congress passed the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments (Pub. L. 102-234, enacted December 12, 1991) to establish limits for the use of provider-related donations and health care-related taxes to finance the non-Federal share of Medicaid expenditures. Statutory provisions relating to health care-related taxes and donations are in section 1903(w) of the Act.

Section 1903(w)(1)(A)(i)(II) requires that health care-related taxes be broad-based as defined in section 1903(w)(3)(B), which specifies that the tax must be imposed with respect to a permissible class of health care items or services (as described in section 1903(w)(7)(A)) or with respect to providers of such items or services and generally imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers or with respect to all non-Federal, nonpublic providers; additionally, the tax must be imposed uniformly in accordance with section 1903(w)(3)(C) of the Act. However, section 1903(w)(1)(A)(iii) of the Act disallows the use of revenues from a broad-based health care related tax if there is in effect a hold harmless arrangement described in section 1903(w)(4) of the Act with respect to the tax. Section 1903(w)(4) of the Act specifies that, for purposes of section 1903(w)(1)(A)(iii) of the Act, there is in effect a hold harmless provision with respect to a broad-based health care related tax if the Secretary determines that any of the following applies: (A) the State or other unit of government imposing the tax provides (directly or indirectly) for a non-Medicaid payment to taxpayers and the amount of such payment is positively correlated either to the amount of the tax or to the difference between the amount of the tax and the amount of the Medicaid payment; (B) all or any portion of the Medicaid payment to the taxpayer varies based only upon the amount of the total tax paid; or (C) the State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax. Section 1903(w)(1)(A) of the Act specifies that, for purposes of determining the Federal matching funds to be paid to a State, the total amount of the State's Medicaid expenditures must be reduced by the amount of revenue received the State (or by a unit

of local government in the State) from impermissible health care-related taxes, including, as specified in section 1903(w)(1)(A)(iii) of the Act, from a broad-based health care related tax for which there is in effect a hold harmless provision described in section 1903(w)(4) of the Act.

In response to the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991, we published the "Medicaid Program; Limitations on Provider-Related Donations and Health Care-Related Taxes; Limitations on Payments to Disproportionate Share Hospitals" interim final rule with comment period in the November 24, 1992 **Federal Register** (57 FR 55118) (November 1992 interim final rule) and the subsequent final rule published in the August 13, 1993 **Federal Register** (58 FR 43156) (August 1993 final rule) establishing when States may receive funds from provider-related donations and health care-related taxes without a reduction in medical assistance expenditures for the purposes of calculating FFP.

After the publication of the August 1993 final rule, we revisited the issue of health care-related taxes and provider-related donations in the "Medicaid Program; Health-Care Related Taxes" final rule (73 FR 9685) which published in the February 22, 2008 **Federal Register** (February 2008 final rule). The February 2008 final rule, in part, made explicit that certain practices would constitute a hold harmless arrangement, in response to certain State tax programs that we believed contained hold harmless provisions. For example, five States had imposed a tax on nursing homes and simultaneously created programs that awarded grants or tax credits to private pay residents of nursing facilities that enabled these residents to pay increased charges imposed by the facilities, which thereby recouped their own tax costs. We believed that these payments held the taxpayers (the nursing facilities) harmless for the cost of the tax, as the tax program repaid the facilities indirectly, through the intermediary of the nursing facility residents. However, in 2005, the Department of Health and Human (HHS) Departmental Appeals Board (the Board) (Decision No. 1981) ruled that such an arrangement did not constitute a hold harmless arrangement under the regulations then in place (73 FR 9686-9687). Accordingly, in discussing revisions to the hold harmless guarantee test in § 433.68(f)(3), the February 2008 final

rule preamble explained that a State can provide a direct or indirect guarantee through a direct or indirect payment. We stated that a direct guarantee will be found when, "a payment is made available to a taxpayer or party related to the taxpayer with the reasonable expectation that the payment would result in the taxpayer being held harmless for any part of the tax" as a result of the payment (73 FR 9694). We noted parenthetically that such a direct guarantee can be made by the State through direct or indirect payments. *Id.* As an example of a party related to the taxpayer, the preamble cited the example of, "as a nursing home resident is related to a nursing home" (73 FR 9694). As discussed in this preamble to the February 2008 final rule, whenever there exists a "reasonable expectation" that the taxpayer will be held harmless for the cost of the tax by direct or indirect payments from the State, a hold harmless situation exists and the tax is impermissible for use to support the non-Federal share of Medicaid expenditures.

Non-Federal Share Financing and State Directed Payments. The statutory requirements in sections 1902(a)(2), 1903(a), 1903(w), and 1905(b) of the Act concerning the non-Federal share contribution and financing requirements, including those implemented in 42 CFR part 433, subpart B concerning health care-related taxes, bona fide provider related donations, and IGTs, apply to all Medicaid expenditures regardless of delivery system (fee-for-service or managed care). We employ various mechanisms for reviewing State methods for financing the non-Federal share of Medicaid expenditures. This includes, but is not limited to, reviews of fee-for-service SPAs, reviews of managed care SDPs, quarterly financial reviews of State expenditures reported on the Form CMS-64, focused financial management reviews, and reviews of State health care-related tax and provider-related donation proposals and waiver requests.

We reiterated this principle in the 2020 Medicaid managed care rule, noting "certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c)" (85 CFR 72765). Further, section 1903(m)(2)(A) of the Act limits FFP in

prepaid capitation payments to MCOs for coverage of a defined minimum set of benefits to cases in which the prepaid payments are developed on an actuarially sound basis for assuming the cost of providing the benefits at issue to Medicaid managed care enrollees. CMS has extended this requirement, through rulemaking under section 1902(a)(4) of the Act, to the capitation rates paid to PIHPs and PAHPs under a risk contract as well.

As part of our review of SDP proposals, we are increasingly encountering issues with State financing of the non-Federal share of SDPs, including use of health care-related taxes and IGT arrangements that may not be in compliance with the underlying Medicaid requirements for non-Federal share financing. In January 2021, CMS released a revised preprint form that systematically collects documentation regarding the source(s) of the non-Federal share for each SDP and requires States to provide additional assurances and details specific to each financing mechanism, which has contributed to our increased awareness of non-Federal share financing issues associated with SDPs.[91] Concerns around the funding of the non-Federal share for SDPs have been raised by oversight bodies,[92,93] and the Department of Health and Human Services Office of Inspector General (OIG) is currently conducting an audit of States' use of what are often referred to as Local Provider Participation Funds to support the non-Federal share of Medicaid payments, for which CMS has evidence that appears to suggest the use of hold harmless arrangements in connection with health care-related taxes.[94]

In recent years, we have identified instances in which States appear to be funding the non-Federal share of Medicaid SDP payments through health care-related tax programs that appear to involve an impermissible hold harmless arrangement. In these arrangements, with

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91 *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*
92 See U.S. Government Accountability Office, "Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight," GAO-21-98, December 7, 2020, available at *https://www.gao.gov/products/gao-21-98*.
93 See Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.
94 U.S. Department of Health and Human Services Office of the Inspector General, "States' Use of Local Provider Participation Funds as the State Share of Medicaid Payments", W-00-22-31557, report expected 2023, work plan available at *https://www.oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000626.asp*.

varying degrees of State awareness and involvement, providers appear to have pre-arranged agreements to redistribute Medicaid payments (or other provider funds that are replenished by Medicaid payments). These redistribution arrangements are not described on the States' SDP applications; if an SDP preprint stated that Medicaid payments ultimately would be directed to a recipient without being based on the delivery of Medicaid-covered services, we could not approve the SDP, because section 1903(a) of the Act limits Federal financial participation to expenditures for medical assistance and qualifying administrative activities (otherwise stated, FFP is not available in expenditures for payments to third parties unrelated to the provision of covered services or conduct of allowable administrative activities). Similarly, under 1903(w), FFP is not permissible in payments that would otherwise be matchable as medical assistance if the State share being matched does not comply with the conditions in section 1903(w), such as in the case of the type of hold harmless arrangement described above. The fact that these apparent hold harmless arrangements are not made explicit on SDP preprints should not affect our ability to disapprove SDPs when we cannot verify they do not employ redistribution arrangements.

These arrangements appear designed to redirect Medicaid payments away from the providers that furnish the greatest volume of Medicaid-covered services toward providers that provide fewer, or even no, Medicaid-covered services, with the effect of ensuring that taxpaying providers are held harmless for all or a portion of their cost of the health care-related tax. In the arrangements, a State or other unit of government imposes a health-care related tax, then uses the tax revenue to fund the non-Federal share of SDPs that require Medicaid managed care plans to pay the provider taxpayers. The taxpayers appear to enter a pre-arranged agreement to redistribute the Medicaid payments to ensure that all taxpayers, when accounting for both their original Medicaid payment (from the State through a managed care plan) and any redistribution payment received from another taxpayer(s) or other entity, receive back (and are thereby held harmless for) all or at least a portion of their tax amount.

Providers that serve a relatively low percentage of Medicaid patients or no Medicaid patients often do not receive enough Medicaid payments funded by a health care-related tax to cover the provider's cost in paying the tax. Providers in this position are unlikely to support a State or locality establishing or continuing a health care-related tax because the tax would have a negative financial impact on them. Redistribution arrangements like those just described seek to eliminate this negative financial impact or turn it into a positive financial impact for taxpaying providers, likely leading to broader support among the provider class of taxpayers for legislation establishing or continuing the tax. Based on limited information we have been able to obtain from providers participating in such arrangements, we believe providers with relatively higher Medicaid volume agree to redistribute some of their Medicaid payments to ensure broad support for the tax program, which ultimately works to these providers' advantage since the tax supports increased Medicaid payments to them (even net of Medicaid payments that they redistribute to other providers) compared to payment amounts for delivering Medicaid-covered services they would receive in the absence of the tax program. These redistribution arrangements therefore help ensure that State or local governments are successful in enacting or continuing provider tax programs.

The Medicaid statute in 1903(w) does not permit us to provide FFP in expenditures under any State payment proposal that would distribute Medicaid payments to providers based on the cost of a health care-related tax instead of based on Medicaid services, so payment redistribution arrangements often occur without notice to CMS (and possibly States) and are not described as part of a State payment proposal submitted for CMS review and approval (see, section 1903(w)(4) of the Act). Given that we cannot knowingly approve awarding FFP under this scenario, we believe that it would be inconsistent with the proper and efficient operation of the Medicaid State plan to approve an SDP when we know the payments would be funded under such an arrangement. For example, we would not approve an SDP that would require payment from a Medicaid managed care plan to a hospital that did not participate in Medicaid, in any

amount. Nor would we approve an SDP that would require payment from a Medicaid managed care plan (that is, a Medicaid payment) to a hospital with a low percentage of Medicaid revenue based on the difference between the hospital's total cost of a health care-related tax and other Medicaid payments received by the hospital. As a result, the redistribution arrangements seek to achieve what cannot be accomplished explicitly through a CMS-approved payment methodology (that is, redirecting Medicaid funds to hold taxpayer providers harmless for their tax cost, with a net effect of directing Medicaid payments to providers based on criteria other than their provision of Medicaid-covered services).

Redistribution arrangements undermine the fiscal integrity of the Medicaid program and are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements. Currently, § 433.68(f)(3), implementing section 1903(w)(4)(C) of the Act, provides that a hold harmless arrangement exists where a State or other unit of government imposing a health care-related tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold taxpayers harmless for all or any portion of the tax amount. The February 2008 final rule on health care-related taxes specified that hold harmless arrangements prohibited by § 433.68(f)(3) exist "[w]hen a State payment is made available to a taxpayer or a party related to the taxpayer (for example, as a nursing home resident is related to a nursing home), in the reasonable expectation that the payment would result in the taxpayer being held harmless for any part of the tax" (73 FR 9694, quoting preamble discussion from the proposed rule). Regardless of whether the taxpayers participate voluntarily, whether the taxpayers receive the Medicaid payments from a Medicaid managed care plan, or whether taxpayers themselves or another entity make redistribution payments using the very dollars received as Medicaid payments or with other provider funds that are replenished by the Medicaid payments, the taxpayers participating in these redistribution arrangements have a reasonable expectation that they will be held harmless for all or a portion of their tax amount.

We stated that the addition of the words "or indirectly" in the regulation indicates that the State itself need not be involved in the actual redistribution of Medicaid funds for the purpose of returning tax amounts to taxpayers in order for the arrangement to qualify as a hold harmless (73 FR 9694). We further explained in the same preamble that we used the term "reasonable expectation" because "State laws were rarely overt in requiring that State payments be used to hold taxpayers harmless" (73 FR 9694). Hold harmless arrangements need not be overtly established through State law or contracts, but can be based upon a reasonable expectation that certain actions will take place among participating entities to return to taxpaying providers all or any portion of their tax amounts. The redistribution arrangements detailed earlier constitute a hold harmless arrangement described in section 1903(w)(4) of the Act and implementing regulations in part 433. Such arrangements require a reduction of the State's medical assistance expenditures as specified by section 1903(w)(1)(A)(iii) of the Act and § 433.70(b).

Approving an SDP under which the State share is funded through an impermissible redistribution agreement would also be inconsistent with "proper and efficient administration" of the Medicaid program within the meaning of section 1902(a)(4) of the Act, as it would result in expenditures for which FFP would ultimately have to be disallowed, when it would be more efficient to not allow such expenditures to be made in the first place. We therefore also rely on our authority under section 1902(a)(4) of the Act to specify methods of administration that are necessary for proper and efficient administration in support of the authority we proposed to make explicit in § 438.6 to disapprove an SDP when we are aware the State share in the SDP would be based on an arrangement that violates section 1903(w) of the Act. We note that in addition to the foregoing, SDPs that are required by Medicaid managed care contracts must be limited to payments for services that are covered under the Medicaid managed care contract and meet the definition of medical assistance under section 1903(a) of the Act. Thus, to the extent the funds are not used for medical assistance, but diverted for another purpose, matching as medical assistance would not be permissible.

In the past, we have identified instances of impermissible redirection or redistribution of Medicaid payments and have taken action to enforce compliance with the statute. For example, the Board upheld our decision to disallow a payment redirection arrangement in a State under a FFS State plan amendment, citing section 1903(a)(1) of the Act, among other requirements (HHS, Board Decision No. 2103, July 31, 2007). Specifically, the Board found that written agreements among certain hospitals redirected Medicaid payments. The payments were not retained by the hospitals to offset their Medicaid costs, as required under the State plan. Instead, pre-arranged agreements redirected Medicaid payments to other entities to fund non-Medicaid costs. In its decision, the Board stated, "Hence, they were not authorized by the State plan or Medicaid statute[.]" When providers redistribute their Medicaid payments for purposes of holding taxpayers harmless or otherwise, in effect, the State's claim for FFP in these provider payments is not limited to the portion of the payment that the provider actually retains as payment for furnishing Medicaid-covered services, but also includes the portion that the provider diverts for a non-Medicaid activity ineligible for FFP (for example, holding other taxpayers harmless for their tax costs). This payment of FFP for non-qualifying activities also has the effect of impermissibly inflating the Federal matching rate that the State receives for qualifying Medicaid expenditures above the applicable, statutorily-specified matching rate (see, for example, sections 1903(a), 1905(b), 1905(y), and 1905(z) of the Act).

Ensuring permissible non-Federal share sources and ensuring that FFP is only paid to States for allowable Medicaid expenditures is critical to protecting Medicaid's sustainability through responsible stewardship of public funds. State use of impermissible non-Federal share sources often artificially inflates Federal Medicaid expenditures. Further, these arrangements reward providers based on their ability to fund the State share, and disconnect the Medicaid payment from Medicaid services, quality of care, health outcomes, or other Medicaid program goals. Of critical concern, it appears that the redistribution arrangements are specifically designed to redirect Medicaid payments away from Medicaid providers that serve a high

percentage of Medicaid beneficiaries to providers that do not participate in Medicaid or that have relatively lower Medicaid utilization.

States have cited challenges with identifying and providing details on redistribution arrangements when we have requested such information during the review of SDPs. The current lack of transparency prevents both CMS and States from having information necessary for reviewing both the proposed non-Federal share financing source and the proposed payment methodology to ensure they meet Federal requirements. Some States have also expressed concerns with ongoing oversight activities in which CMS is attempting to obtain information that may involve arrangements to which only private entities are a party. We are only interested in any business arrangements among private entities that could result in a violation of Federal statutory and regulatory requirements.

As noted above, we recognize that health care-related taxes can be critical tools for financing payments that support the Medicaid safety net, but they must be implemented in accordance with applicable statutory and regulatory requirements. This proposed rule would ensure that CMS and States have necessary information about any arrangements in place that would redistribute Medicaid payments and make clear that we have the authority to disapprove proposed SDPs if States identify the existence of such an arrangement or do not provide required information or ensure the attestations are made and available as required under proposed paragraph (c)(2)(ii)(H). The proposed new attestation requirement would help ensure appropriate transparency regarding the use of Medicaid payments and any relationship to the non-Federal share source(s), and aims to do so without interfering with providers' normal business arrangements.

All Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, apply regardless of delivery system, although currently, § 438.6(c) does not explicitly state that compliance with statutory requirements and regulations outside of part 438 related to the financing of the non-Federal share is required for

SDPs to be approvable or that CMS may deny written prior approval for an SDP based on a State's failure to demonstrate that the financing of the non-Federal share is fully compliant with applicable Federal law. The requirements applicable to health care-related taxes, bona fide provider related donations, and IGTs also apply to the non-Federal share of expenditures for payments under part 438. Currently, § 438.6(c)(1)(ii)(E) provides that a State must demonstrate to CMS, in writing, that an SDP does not condition provider participation in the SDP on the provider entering into or adhering to intergovernmental transfer agreement. We believe additional measures are necessary to ensure compliance with applicable Federal requirements for the source(s) of non-Federal share. We are concerned that the failure of the current regulations to explicitly condition written prior approval of an SDP on the State demonstrating compliance with applicable Federal requirements for the source(s) of non-Federal share potentially compromises our ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Given the growing number of SDPs that raise potential financing concerns, and the growing number of SDPs generally, we believe it is important to be explicit in the regulations governing SDPs that the same financing requirements governing the sources of the non-Federal share apply regardless of delivery system, and that CMS will scrutinize the source of the non-Federal share of SDPs during the preprint review process. We propose to revise § 438.6(c)(2)(ii) to add a new paragraph (c)(2)(ii)(G) that would explicitly require that an SDP comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, as part of the CMS review process.

We also propose to revise § 438.6(c)(2)(ii) to ensure transparency regarding the use of SDPs and to ensure that the non-Federal share of SDPs is funded with a permissible source. Under our proposal, States would be required to ensure that each participating provider in an SDP arrangement attests that it does not participate in any hold harmless arrangement with respect to any health care-related tax as specified in § 433.68(f)(3) in which the State or other

unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount. Such hold harmless arrangements include those that produce a reasonable expectation that taxpaying providers would be held harmless for all or a portion of their cost of a health care-related tax. States would be required to note in the preprint their compliance with this requirement prior to our written prior approval of any contractual payment arrangement directing how Medicaid managed care plans pay providers. States would comply with this proposed requirement by obtaining each provider's attestation or requiring the Medicaid managed care plan to obtain each provider's attestation. We also propose, at § 438.6(c)(2)(ii)(H) to require that the State ensure that such attestations are available upon CMS request.

Under this proposal, CMS may deny written prior approval of an SDP if it does not comply with any of the standards in § 438.6(c)(2), including the financing of the non-Federal share is not fully compliant with all Federal legal requirements for the financing of the non-Federal share and/or the State does not require an attestation from each provider receiving a payment based on the SDP that it does not participate in any hold harmless arrangement. As part of our proposed restructuring of § 438.6(c)(2), these provisions would apply to all SDPs, regardless of whether written prior approval is required. We rely on our authority in section 1902(a)(4) of the Act to require methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the Medicaid State Plan to propose these requirements for ensuring that the source of the non-Federal share of the financing for SDPs is consistent with section 1903(w) of the Act. It is consistent with the economic and efficient operation of the Medicaid State Plan to ensure that State expenditures are consistent with the requirements to obtain FFP, and thereby avoid the process of recouping FFP when provided inappropriately, which is needlessly burdensome for States and CMS. Given that all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, apply regardless

of delivery system, we also solicit public comment on whether the proposed changes in § 438.6(c)(2)(ii)(G) and (H) should be incorporated more broadly into 42 CFR part 438.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on these proposals.

h. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§ 438.6(c)(2)(vii))

A fundamental requirement of SDPs is that they are payments related to the delivery of services under the contract. In the 2016 final rule, we stated how we believe that actuarially sound payments, which are required under section 1903(m)(2)(A)(iii) for capitation payments to MCOs and under part 438 regulations for capitation payments to risk-based PIHPs and PAHPs, must be based on the provision of covered benefits and associated administrative obligations under the managed care contract (81 FR 27588). This requirement that SDPs be tied to the utilization and delivery of covered benefits differentiates SDPs from pass-through payments. We described the differences between pass-through payments and SDPs in the 2016 final rule and in the 2017 Pass-Through Payment Rule, where we noted, that pass-through payments are not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services (81 FR 27587 through 27592, 82 FR 5415).

The current regulations at § 438.6(c)(2)(ii)(A) require that States demonstrate in writing that SDPs that require prior written approval be based on the utilization and delivery of services to Medicaid enrollees covered under the managed care plan contract. We have interpreted this requirement to mean that SDPs must be conditioned upon the utilization or delivery of services during the rating period identified in the preprint for which the State is seeking written prior approval. Requiring SDPs to be based on the utilization and delivery of services is a fundamental and necessary requirement for ensuring the fiscal and program integrity of SDPs, but we believe further clarification is necessary due to the variety of payment mechanisms that States use in their SDP arrangements. In particular, ensuring that payments are based on the delivery of

services in SDPs that are fee schedule requirements described in § 438.6(c)(1)(iii) is relatively straightforward since fee schedules explicitly link a rate to each code (for example, CPT or HCPCS), compared to SDPs that are VBP initiatives described in § 438.6(c)(1)(i) and (ii). As discussed in further detail in the section I.B.2.i of this proposed rule, ensuring that payments in VBP initiatives are based on the delivery of services in ways that do not hinder States' ability to pursue VBP efforts is more difficult because, by their nature, VBP initiatives seek to move away from paying for volume in favor of paying for value and performance. We propose revising § 438.6(c) to address how different types of SDPs must be based on utilization and delivery of covered services; this section discusses these requirements for fee schedule arrangements and section I.B.2.i. of this proposed rule discusses the requirements for VBP initiatives.

For SDPs that are fee schedule requirements described in § 438.6(c)(1)(iii), the tie to utilization and delivery of services means that States require managed care plans to make payments when a particular service was delivered during the rating period for which the SDP was approved. Thus, the State could not, under our interpretation of the requirement, require managed care plans to make payments for services that were delivered outside of the approved rating period. However, in working with States, we found that this was not always understood. We therefore clarified this in SMDL #21-001,[95] and explained that SDPs need to be conditioned on the delivery and utilization of services covered under the managed care plan contract for the applicable rating period and that payment cannot be based solely on historical utilization.

We propose to codify this clarification in a new § 438.6(c)(2)(vii)(A) for SDPs described in § 438.6(c)(1)(iii) – that is, minimum fee schedules, maximum fee schedules, and uniform increases. As proposed, § 438.6(c)(2)(vii)(A) would require that any and all payments made under the SDP are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only. This would preclude States from making any

95 *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

SDP payment based on historical or any other basis that is not tied to the delivery of services to the rating period itself.

Our proposal also addresses SDPs that require reconciliation. In SMDL #21-001[96], we noted that in capitation rate development, States can use historical data to inform the capitation rates that will be paid to managed care plans for services under the rating period, and this is consistent with § 438.5(b)(1) and (c). However, in accordance with current requirements in § 438.6(c)(2)(ii)(A), payment to providers for an SDP must be made based on the delivery and utilization of covered services rendered to Medicaid beneficiaries during the rating period documented for the approved SDP. We have reviewed and approved SDPs, typically SDPs that establish uniform increases of a specific dollar amount, in which States require managed care plans to make interim payments based on historical utilization and then after the close of the rating period, reconcile the payments to actual utilization that occurred during the rating period approved in the SDP. For these SDPs, States will include the SDP in the rate certification and then once actual utilization for the current rating year is known, CMS has also seen in some instances, States have their actuaries submit an amendment to adjust the amount paid to plans (whether through a separate payment term or an adjustment to base rates) to account for this reconciliation. These amendments typically come near to or after the close of the rating period and are most common when the reconciliation would result in increased costs to the plan absent the adjustment. As a result, risk is essentially removed from the managed care plans participating in the SDP. We are concerned with this practice as we believe tying payments in an SDP, even interim payments, to utilization from a historical time period outside of the rating period approved for the SDP, is inconsistent with prospective risk-based capitation rates that are developed for the delivery of services in the rating period. Further, rate amendments that are submitted after the rating period concludes that adjust the capitation rates retroactively to reflect actual utilization under the SDP goes against the risk-based nature of managed care. To address

96 *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

this, we propose a new § 438.6(c)(2)(vii)(B) which would prohibit States from requiring managed care plans to make interim payments based on historical utilization and then to reconcile those interim payments to utilization and delivery of services covered under the contract after the end of the rating period for which the SDP was originally approved.

To illustrate our concern and need for the proposed regulatory requirement, we share the following example for a State that has an SDP approved to require a uniform increase to be paid for inpatient hospital services for CY 2020. During CY 2020, the State's contracted managed care plans pay the inpatient hospital claims at their negotiated rates for actual utilization and report that utilization to the State via encounter data. Concurrently, the State directs its managed care plans, via the SDP, to make a separate uniform increase in payment to the same inpatient hospital service providers, based on historical CY 2019 utilization. Under this example, the increase in January CY 2020 payment for the providers is made based on January CY 2019 data, the increase in February CY 2020 payment is based on February CY 2019 data, and so forth. This pattern of monthly payments continues throughout CY 2020. After the rating period ends in December 2020, and after a claims runout period that can be as long as 16 months, the State then in mid-CY 2021 or potentially early 2022, reconciles the amount of CY 2019-based uniform increase payments to the amount the payments should be based on CY 2020 claims. The State then requires its managed care plans to make additional payments to, or recoup payments from, the hospitals for under- or over-payment of the CY 2019-based uniform increase.

In the inpatient hospital uniform increase example above, the State may initially account for the SDP in the CY 2020 rate certification and, after the rating period is over, the State submits an amendment to their rate certification to revise the total dollar amount dedicated to the SDP and the capitation rates to reflect the SDP provider payments that were made based on actual utilization in the CY 2020 rating period – thereby, making the managed care plans "whole" and removing risk from the managed care plans participating in the SDP. We do not find these practices consistent with the nature of risk-based managed care.

Capitation rates must be actuarially sound as required by section 1903(m)(2)(A)(iii) of the Act[97] and in § 438.4. Specifically, § 438.4(a) requires that actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements outlined in § 438.4(b). "Rating Period" is defined at § 438.2 as a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a). We believe SDPs that make payments based on retrospective utilization and include reconciliations to reflect actual utilization, while eventually tying final payment to utilization and delivery of services during the rating period approved in the SDP, are contrary to the nature of risk-based managed care. SDPs must tie to the utilization and delivery of services to Medicaid enrollees covered under the contract for the rating period approved in the SDP.

We have previously issued regulations and guidance in response to payments we found to be inconsistent with the statute concerning actuarial soundness. In the 2016 rule we noted our belief that the statutory requirement that capitation payments to managed care plans be actuarially sound requires that payments under the managed care contract align with the provision of services under the contract. We further noted that based on our review of capitation rates, we found pass-through payments being directed to specific providers that generally were not directly linked to the delivered services or the outcomes of those services; thereby noting that pass-through payments are not consistent with actuarially sound rates and do not tie provider payments with the provision of services[98] These concerns led CMS to phase out the ability of States to utilize pass-through payments as outlined in § 438.6(d). We reach a similar conclusion in our review of SDP proposals which use reconciliation of historical to actual utilization; if

97 The actuarial soundness requirements apply statutorily to MCOs under section 1903(m)(2)(A)(ii) of the Act and were extended to PIHPs and PAHPs under our authority in section 1902(a)(4) of the Act in the 2002 final rule.
98 81 FR 27587 and 27588.

States are seeking to remove risk from managed care plans in connection with these types of SDPs, it is inconsistent with the nature of risk-based Medicaid managed care. As further noted in the 2016 rule, "[t]he underlying concept of managed care and actuarial soundness is that the [S]tate is transferring the risk of providing services to the MCO and is paying the MCO an amount that is reasonable, appropriate, and attainable compared to the costs associated with providing the services in a free market. Inherent in the transfer of risk to the MCO is the concept that the MCO has both the ability and the responsibility to utilize the funding under that contract to manage the contractual requirements for the delivery of services." [99]

States use retrospective reconciliations even though there are less administratively burdensome ways to ensure payment rates for specific services are at or above a certain level. States could accomplish this through the establishment of a minimum fee schedule, which we propose to define in § 438.6(a) as any contract requirement where the State requires a MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s). If a State's intent is to require that managed care plans pay an additional amount per service delivered, States could accomplish this through the establishment of a uniform increase, which we propose to define in § 438.6(a) as any contract requirement where the State requires a MCO, PIHP, or PAHP to pay the same amount (the same dollar or the same percentage increase) per covered service(s) in addition to the rates the managed care plan negotiated with providers. In addition to being less administratively burdensome, both options would provide more clarity to providers on payment rates and likely result in more timely payments than a retrospective reconciliation process. Both options would also allow States' actuaries to include the SDPs into the standard capitation rate development process using the same utilization projections used to develop the underlying capitation rates. States can require both minimum fee schedules and uniform increases under current regulations.

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99 81 FR 27588.

We believe requiring managed care plans to make interim payments based on historical utilization and then reconciling to actual utilization instead suggests an intent by State to ensure payment of a specific aggregate amount to certain providers or, in some cases, removal of all risk related to these SDPs from managed care plans. We believe prohibiting this practice and removing post-payment reconciliation processes as we propose in § 438.6(c)(2)(vii)(B) would alleviate actuarial and oversight concerns as well as restore program and fiscal integrity to these kinds of payment arrangements.

CMS is proposing to prohibit the use of post-payment reconciliation processes for SDPs; specifically, that States establishing fee schedules under § 438.6(c)(1)(iii) cannot require that plans pay providers using a post-payment reconciliation process. It is not uncommon for States to pair SDPs requiring plans to pay providers using a post-payment reconciliation process with a separate payment term described later in section I.B.2.l. However, post-payment reconciliation process and separate payment terms are not the same. Separate payment terms are payments made to the plan in addition to the capitation rates to account for any portion of the cost of complying with the SDP not already accounted for in the capitation rates. In contrast, the post-payment reconciliation process that we are proposing to prohibit here directs how the plans pay providers. In both cases, CMS has raised concerns about the removal of risk from the plan and their use by some States in ways that are contrary to the risk-based nature of Medicaid managed care. However, as discussed later, while CMS has a strong preference that SDPs be included as adjustments to the capitation rates since that method is most consistent with the nature of risk-based managed care, we believe separate payment terms can be a useful tool for States to be able to make targeted investments in response to acute concerns around access to care. In contrast, we do not see the same kind of benefit to the Medicaid program in allowing States to require that plans pay providers using a post-payment reconciliation process. We believe that there are methods for providing sufficient guardrails around the use of separate payment terms that lessen

the risks associated with the use of separate payment terms as we have proposed and described in section I.B.2.1. of this proposed rule.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

i. Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi))

We are also proposing several changes to § 438.6(c) to address how VBP initiatives, which include value-based purchasing, delivery system reform, and performance improvement initiatives as described in § 438.6(c)(1)(i) and (ii), can be tied to delivery of services under the Medicaid managed care contract as well as to remove barriers that prevent States from using SDPs to implement these initiatives. Currently § 438.6(c)(2)(ii)(A) requires SDPs to be based on the utilization and delivery of services, so SDPs that require use of VBP initiatives must base payment to providers on utilization and delivery of services. Further, § 438.6(c)(2)(iii)(A) requires States to demonstrate in writing that the SDP will make participation in the VBP initiative available, using the same terms of performance, to a class of providers providing services under the contract related to the initiative. Existing regulations at § 438.6(c)(1)(i) and (ii) allow States to direct Medicaid managed care plans to implement value-based purchasing models with providers or to participate in delivery system reform or performance improvement initiatives; these types of SDPs require written prior approval from CMS. These provisions were adopted as exceptions to the overall prohibition on States directing the payment arrangements used by Medicaid managed care plans to pay for covered services. Since the 2016 rule, States have used SDPs to strengthen their ability to use their managed care programs to promote innovative and cost-effective methods of delivering care to Medicaid enrollees, to incent managed care plans to engage in State activities that promote certain performance targets, and to identify strategies for VBP initiatives to link quality outcomes to provider reimbursement. As the number of SDPs for VBP initiatives continues to grow, we have found that the existing

requirements at § 438.6(c)(2)(iii) can pose unnecessary barriers to implementation of these initiatives in some cases. Revisions to § 438.6(c) would address such barriers. First, we propose to redesignate current paragraph (c)(2)(iii) as paragraph (c)(2)(vi) with a revision to remove the phrase "demonstrate in writing," and we propose to redesignate current paragraph (c)(2)(iii)(A) as paragraph (c)(2)(iv)(A).

In an effort to remove provisions that are barriers to implementation of VBP initiatives, add specificity to the types of arrangements that can be approved under § 438.6(c), and to strengthen the link between SDPs that are VBP initiatives and quality of care, we are proposing the following changes to the requirements that are specific to SDPs that involve VBP initiatives:

(1) Remove the existing requirements at § 438.6(c)(2)(iii)(C) that currently prohibit States from setting the amount or frequency of the plan's expenditures.

(2) Remove the existing requirements at § 438.6(c)(2)(iii)(D) that currently prohibit States from recouping unspent funds allocated for these SDPs.

(3) Redesignate § 438.6(c)(2)(iii)(B) with revisions and clarifications to § 438.6(c)(2)(vi)(B). The provision addresses how performance in these types of arrangements is measured for participating providers.

(4) Adopt a new § 438.6(c)(2)(vi)(C) to establish requirements for use of population-based and condition-based payments in these types of SDP arrangements.

As discussed in section I.B.2.f of this proposed rule, we are proposing to adopt requirements for provider payment rates used in SDP arrangements through revisions to § 438.6(c)(2)(iii).

Currently, § 438.6(c)(2)(iii)(C) prohibits States from setting the amount or frequency of expenditures in SDPs that are VBP initiatives. In the 2015 proposed rule[100], we reasoned that while capitation rates to the managed care plans would reflect an amount for incentive payments to providers for meeting performance targets, the plans should retain control over the amount and

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100 *https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered*.

frequency of payments. We believed that this approach balanced the need to have a health plan participate in a multi-payer or community-wide initiative, while giving the health plan a measure of control to participate as an equal collaborator with other payers and participants. However, VBP initiatives often include, by design, specific payment amounts at specific times. As States began to design and implement VBP initiatives, sometimes across delivery systems or focused on broad population health goals, many found that allowing plans to retain such discretion undermined the State's ability to implement meaningful initiatives with clear, consistent operational parameters necessary to drive provider performance improvement and achieve the goals of the State's program. Also, because some VBP initiatives provide funding to providers on a bases other than "per claim," these payment arrangements need to be designed and administered in a way that encourages providers to commit to meeting performance goals while trusting that they will receive the promised funding if they meet the performance targets. This is especially true for multi-delivery system arrangements or arrangements that do not make payments for long periods of time, such as annually. Inconsistencies in administration or payment can undermine providers' confidence in the arrangement. For example, States often direct their Medicaid managed care plans to distribute earned performance improvement payments to providers on a quarterly basis. Because these types of payment arrangements affect provider revenue differently than the usual per claim payment methodology, establishing strong parameters and operational details that define when and how providers will receive payment is critical for robust provider participation. While allowing States the flexibility to include the amount and frequency of payments when designing VBP and delivery system reform initiatives removes discretion from managed care plans, we believe this flexibility is necessary to ensure that States can achieve their quality goals and get value for the dollars and effort that they invest in these arrangements. Creating obstacles for States trying to implement VBP initiatives was not our intent in the 2016 final rule. Our goal then and now is to incent States to implement innovative initiatives that reward quality of care and improved health outcomes over volume of

services. To accomplish this, we need to refine our regulations; we propose to remove the existing text at § 438.6(c)(2)(iii)(C) that prohibits States from setting the amount and frequency of payment. We believe this would enable States to design more effective VBP initiatives using more robust quality measures to help ensure provider uptake, boost providers' confidence in the efficiency and effectiveness of the arrangement, and enable States to use VBP initiatives to achieve critical program goals.

Currently, § 438.6(c)(2)(iii)(D) prohibits States from recouping any unspent funds allocated for SDP arrangements from managed care plans when the SDP arrangement is for VBP, delivery system reform, or performance improvement initiatives. In the 2015 proposed rule, we explained that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds would remain with the MCO, PIHP, or PAHP. We believed this was important to ensure that the SDPs made to providers were associated with a value relative to innovation and Statewide reform goals and not simply an avenue for States to provide funding increases to specific providers. However, allowing managed care plans to retain unspent funds when providers fail to achieve performance targets can create perverse incentives for States and managed care plans. States have described to us that they are often not incentivized to establish VBP arrangements with ambitious performance or quality targets if those arrangements result in managed care plans profiting from weak provider performance. Although States attempt to balance setting performance targets high enough to improve care quality and health outcomes but not so high that providers are discouraged from participating or so low that they do not result in improved quality or outcomes, many States struggle due to of lack experience and robust data. And unfortunately, failed attempts to implement VBP arrangements discourage States, plans, and providers from trying to use the arrangements again. It was never our intent to discourage States from adopting innovative VBP initiatives, so we seek to address the unintended consequence created in the 2016 final rule by proposing to remove the regulation text at § 438.6(c)(2)(iii)(D) that prohibits States from

recouping unspent funds from the plans. We believe that removing this prohibition could enable States to reinvest these unspent funds to further promote VBP and delivery system innovation.

To expand the types of VBP initiatives that would be allowed under § 438.6(c)(1)(i) and (ii) and ensure a focus on value over volume, we are also proposing additional revisions in § 438.6(c)(2)(vi) to distinguish between performance-based payments and the use of proposed population-based or condition-based payments to providers.

The existing regulations at § 438.6(c)(1)(i) and (ii) were intended both to incent State activities that promote certain performance targets as well as to facilitate and support delivery system reform initiatives within the managed care environment to improve health care outcomes. We recognize that certain types of multi-payer or Medicaid-specific initiatives, such as patient-centered medical homes (PCMH), broad-based provider health information exchange projects, and delivery system reform projects to improve access to services, among others, may not lend themselves to being conditioned upon provider performance during the rating period.[101] Instead, these arrangements are conditioned upon other factors, such as the volume and characteristics of a provider's attributed population of patients or upon meeting a total cost of care (TCOC) benchmark, for example, through the provision of intense case management resulting in a reduction of chronic disease. Due to the diversity of VBP initiatives, we believe that the existing language at § 438.6(c)(2)(iii)(B), which requires that all SDPs that direct plan expenditures under § 438.6(c)(1)(i) and (ii) must use a common set of performance measures across all of the payers and providers, cannot be broadly applied to arrangements or initiatives under § 438.6(c)(1)(i) and (ii) that do not measure specific provider performance measures.

We believe the best way to address the limitations in current regulation text is to specify different requirements for VBP initiatives that condition payment upon performance from ones that are population or condition-based. Therefore, we propose to use new § 438.6(c)(2)(vi)(B) for requirements for SDPs that condition payment on performance. We are also proposing to adopt

101 *http://hcp-lan.org/workproducts/apm-framework-onepager.pdf*.

additional requirements in addition to redesignating the provision currently at § 438.6(c)(2)(iii)(B) to newly proposed § 438.6(c)(2)(vi)(B)(*2*). Additionally, we are proposing new requirements at new (c)(2)(vi)(B)(1) and (3) through (5) that are clarifications or extensions of the current requirement that SDPs use a common set of performance metrics.

We further propose to add new § 438.6(c)(2)(vi)(C) to describe the requirements for SDPs that are population-based payments and condition-based payments.

Performance-Based Payments. Under current § 438.6(c)(2)(ii)(A), SDPs that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) and (ii) must be based on the utilization and delivery of services. Therefore, we have required that SDPs that are VBP initiatives be based on performance tied to the delivery of covered services to Medicaid beneficiaries covered under the Medicaid managed care contract for the rating period. This means that we have not allowed these types of SDPs to be based on "pay-for-reporting" because the act of reporting, alone, is an administrative activity and not a covered service. Instead, when States seek to design SDPs that pay providers for administrative activities rather than provider performance, we have encouraged States to use provider reporting or participation in learning collaboratives as a condition of provider eligibility for the SDPs and then tie payment under the SDP to utilization under § 438.6(c)(1)(iii). At § 438.6(c)(2)(vi)(B)(*1*), we propose to codify our interpretation of this policy by requiring that payments to providers under SDPs that are based on performance not be conditioned upon administrative activities, such as the reporting of data, nor upon the participation in learning collaboratives or similar administrative activities. The proposed regulation explicitly states our policy so that States have a clear understanding of how to design their SDPs appropriately. We recognize and understand the importance of establishing provider reporting requirements, learning collaboratives, and similar activities to help further States' goals for performance and quality improvement and want to support these activities; however, while these activities can be used as eligibility criteria for the provider class receiving

payments, they cannot be the basis for receiving payment from the Medicaid managed care plan under an SDP described in § 438.6(c)(1)(i) or (ii) that is based on performance.

Currently, our policy is that the performance measurement period for SDPs that condition payment based upon performance must overlap with the rating period in which the payment for the SDP is made. However, we have found that States frequently experience delays in obtaining performance-based data due to claims run out time and the time needed for data analyses and validation of the data and the results. All of this can make it difficult, if not impossible, to comply with this requirement. Therefore, we propose to permit States to use a performance measurement period that precedes the start of the rating period in which payment is delivered by up to 12 months. Under this aspect of our proposal, States would be able to condition payment on performance measure data from time periods up to 12 months prior to the start of the rating period in which the SDP is paid to providers. We believe that this flexibility would allow States adequate time to collect and analyze performance data for use in the payment arrangement and may incentivize States to adopt more VBP initiatives. We solicit comment on whether 12 months is an appropriate time period to allow for claims runout and data analysis, or if the time period that the performance period may precede the rating period should be limited to 6 months or extended to 18 or 24 months, or if the performance period should remain consistent with the rating period. We also propose that the performance measurement period must not exceed the length of the rating period. We believe this would make it clear to States that although we propose to extend the length of time between provider performance and payment for administrative simplicity, we are not extending the performance measurement time. Finally, we are also proposing that all payments would need to be documented in the rate certification for the rating period in which the payment is delivered. We also believe identifying which rating period the payments should be reflected in is important since up to 2 rating periods may be involved between performance and payment, and we want States to document these payments consistently. Specifically, we propose, at § 438.6(c)(2)(vi)(B)(*3*), that a payment arrangement

that is based on performance must define and use a performance period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered.

In a December 2020 report[102], the OIG found that a quality improvement incentive SDP implemented in one State resulted in incentive payments paid to providers whose performance declined during the measurement period. Other interested parties, such as MACPAC, have noted concerns with performance improvement SDPs that continue even when there has been a decline in quality or access. In alignment with our proposed evaluation policies at § 438.6(c)(2)(iv) (see section I.B.2.j. of this proposed rule) that seek to better monitor the impact of SDPs on quality and access to care, and in an effort to establish guardrails against payment for declining performance in VBP SDPs, we propose to add § 438.6(c)(2)(vi)(B)(*4*) and (*5*). Measurable performance targets that demonstrate performance relative to a baseline allow States (and CMS) to assess whether or not a provider's performance has improved. Therefore, at § 438.6(c)(2)(vi)(B)(*4*), we propose to require that all SDPs that condition payment on performance include a baseline statistic for all metrics that are used to measure the performance that is the basis for payment from the plan to the provider; these are the metrics (including, per proposed paragraph (c)(2)(iv)(A)(*2*), at least one performance measure, as that term is proposed to be defined in § 438.6(a)) that are specified by the States in order to comply with proposed § 438.6(c)(2)(vi)(B)(*2*). At § 438.6(c)(2)(vi)(B)(*5*), we propose to require that all SDPs that condition payment on performance use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the payment arrangement applies, that demonstrate improvement over baseline data on all metrics selected in § 438.6(c)(2)(vi)(B)(*2*). We believe

102 U.S. Department of Health and Human Services Office of the Inspector General, "Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program," A-06-18-07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp*.

that these proposals would be consistent with how quality improvement is usually measured as well as be responsive to oversight bodies and help promote economy and efficiency in Medicaid managed care.

Population-Based Payments and Condition-Based Payments. As discussed previously in this preamble section, States often adopt VBP initiatives that are intended to further goals of improved population health and better care at lower cost. We support these efforts and encourage the use of methodologies or approaches to provider reimbursement that prioritize achieving improved health outcomes over volume of services. Therefore, we propose to add new § 438.6(c)(2)(vi)(C) to establish regulatory pathways for approval of VBP initiatives that may not be conditioned upon specific measures of performance.

We propose to define a "population-based payment" at § 438.6(a) as a prospective payment for a defined Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group. We propose to define a "condition-based payment" as a prospective payment for a defined set of Medicaid service(s), that are tied to a specific condition and delivered to Medicaid managed care enrollees. One example of a population-based payment would be an SDP that is a primary care medical home (PCMH) and directs managed care plans to pay prospective per member per month (PMPM) payments for care management to primary care providers, where care management is the service being delivered under the contract and covered by the PMPM. An attributed population could also be condition-based. For example, States could direct managed care plans to pay a provider or provider group a PMPM for Medicaid enrollees with a specific condition when the enrollee is attributed to the provider or provider group for treatment for that condition.

At § 438.6(c)(2)(vi)(C)(*1*), we propose to require that population-based and condition-based payments be conditioned upon either the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution to the provider of a covered enrollee for the rating period for treatment. This proposed requirement aligns with the

requirement, currently at § 438.6(c)(2)(ii)(A), that SDP arrangements base payments to providers on utilization and delivery of services under the Medicaid managed care contract. States, consistent with 1903(m)(2)(A)(xi), § 438.242(d), and 438.818, must collect, maintain, and submit to T-MSIS encounter data showing that covered service(s) have been delivered to the enrollees attributed to a provider that receives the population-based payment. Further, if the payment is conditioned upon the attribution of a covered enrollee to a provider, we propose § 438.6(c)(2)(vi)(C)(2) to require that the attribution methodology uses data that are no older than the 3 most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; accounts for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers.

We have seen States submit proposals for VBP initiatives that include prospective PMPM population-based payments with no direct tie to value or quality of care and paid in addition to the contractually negotiated rate. Because population-based payments should promote higher quality and coordination of care to result in improved health outcomes, we believe it is imperative that these type of PMPM payments are used to ensure that enrollees are receiving higher quality and coordinated services to increase the likelihood of enrollees experiencing better outcomes. Therefore, we propose to add § 438.6(c)(2)(vi)(C)(*3*) to require that population-based payments and condition-based payments replace the negotiated rate between a plan and providers for the Medicaid covered service(s) being delivered as a part of the SDP to prevent any duplicate payment(s) for the same service. Also, at § 438.6(c)(2)(vi)(C)(*2*), we propose to add a requirement that prevents payments from being made in addition to any other payments made by plans to the same provider on behalf of the same enrollee for the same services included in the population- or condition-based payment. We believe that the requirements in paragraph (c)(2)(vi)(C)(*2*) would prevent States from implementing SDPs under § 438.6(c)(2)(vi)(C) that

are PMPM add-on payments made in addition to negotiated rates with no further tie to quality or value.

We recognize the importance of providing a regulatory pathway for States to implement SDPs that are VBP initiatives designed to promote higher quality care in more effective and efficient ways at a lower cost. because quality of care and provider performance are integral and inherent to all types of VBP initiatives, we believe that SDPs under proposed § 438.6(c)(2)(vi)(C) that are designed to include population-based or condition-based payments must also include in their design and evaluation at least one performance measure and set the target for such a measure to demonstrate improvement over baseline at the provider class level for the provider class receiving the payment. As such, we propose new § 438.6(c)(2)(vi)(C)(*4*) to require that States include at least one performance measure that measures performance at the provider class level as a part of the evaluation plan outlined in proposed § 438.6(c)(2)(iv). We are also proposing that States would be required to set the target for such a performance measure to demonstrate improvement over baseline. We believe that this balances the need to provide States the flexibility to design VBP initiatives to meet their population health and other value-based care goals, while providing accountability by monitoring the effect of the initiatives on the performance of the provider class and the subsequent health outcomes of the enrollees.

Approval Period. In the 2020 Medicaid managed care rule, we finalized a revision to § 438.6(c)(2)(i) allowing that SDPs are VBP initiatives as defined in § 438.6(c)(1)(i) and (ii) meet additional criteria described in § 438.6(c)(3)(i)(A) through (C) would be eligible for multi-year approval if requested. Because of the tie to the managed care quality strategy, which in § 438.340 is required to be updated at least once every 3 years, CMS has never granted written prior approval of an SDP for more than 3 years. We are proposing to modify § 438.6(c)(3)(i) to add that a multi-year written prior approval may be for of up to three rating periods to codify our existing policy. Requiring States to renew multi-year SDPs every 3 years will allow us to monitor changes and ensure that SDPs remains aligned with States' most current managed care

quality strategy. We are also proposing minor revisions in paragraphs (c)(3)(i)(A) through (C) to use the term "State directed payment" as appropriate and to revise paragraph (c)(3)(ii) to specify it is about written prior approvals. Finally, we are proposing to redesignate paragraph (c)(2)(F) to new paragraph (c)(3)(iii) to explicitly provide that State directed payments are not automatically renewed.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on these proposals.

j. Quality and Evaluation (§ 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7))

We are proposing several changes to the SDP regulations in § 438.6(c) to support more robust quality improvement and evaluation. Existing regulations at § 438.6(c)(2)(ii)(C) and (D) specify that to receive written prior approval, States must demonstrate in writing, amongst other requirements, that the State expects the SDP to advance at least one of the goals and objectives in the State's managed care quality strategy and has an evaluation plan that measures the degree to which the SDP advances the identified goals and objectives. We issued guidance in November 2017[103] that provided further guidance on what evaluation plans should generally include: the identification of performance criteria which can be used to assess progress on the specified goal(s) and objective(s); baseline data for performance measure(s); and improvement targets for performance measure(s).

In order to monitor the extent to which an SDP advances the identified goals and objectives in a State's managed care quality strategy, we request that States submit their SDP evaluation results from prior rating periods to aid our review of preprint submissions that are renewals of an existing SDP. If an SDP proposal meets regulatory requirements but the State is unable to provide the requested evaluation results, we will usually approve a renewal of the SDP with a "condition of concurrence" that the State submit evaluation results with the following

103 *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf*.

year's preprint submission for renewal of the SDP for the following rating period. For example, one common condition of concurrence for year two preprints is the provision of SDP evaluation results data for year one of the SDP with the year three preprint submission.

In 2021, CMS conducted an internal analysis to assess the effectiveness of SDP evaluation plans in measuring progress toward States' managed care quality strategy goals and objectives and whether SDP evaluation findings provided us with sufficient information to analyze whether an SDP facilitated quality improvement. We analyzed data from 228 renewal preprints submitted by 33 States between April 2018 and February 2021. Over half (63 percent) of the evaluation plans submitted were incomplete, and only 43 percent of the renewal preprints included any evaluation results. Our analysis also found only a 35 percent compliance rate with conditions of concurrence requesting States submit SDP evaluation results with the preprint for the following rating period. Our policy goals in this area are frustrated by the lack of a regulation requiring submission of these evaluation results. By adopting requirements for submission of evaluation plans and reports, we intend to increase compliance and improve our oversight in this area.

As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, we recognize the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives, and recognize that meaningful evaluation results are critical for ensuring that these payments further improvements in quality of care. Moreover, consistent submission of evaluation results is important for transparency and for responsiveness to oversight bodies. Consistent with our internal findings, other entities, including MACPAC[104] and GAO[105], have noted concerns about the level of detail and quality of SDP evaluations. In MACPAC's June 2022 Report to Congress, the Commission noted concern about the lack of

104 Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

105 U.S. Government Accountability Office, "Medicaid: State Directed Payments in Managed Care," June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

availability of information on evaluation results for SDPs, even when the arrangements had been renewed multiple times. The report also noted that examples of when evaluation results showed a decline in quality or access but the SDPs were renewed without changes. MACPAC recommended in its report that CMS require more rigorous evaluation requirements for SDPs, particularly for arrangements that substantially increase provider payments above Medicaid FFS reimbursement. The report also suggests that CMS provide written guidance on the types of measures that States should use to evaluate progress towards meeting quality and access goals and noted that we should clarify the extent to which evaluation results are used to inform approval and renewal decisions.

We are proposing a number of regulatory changes to enhance CMS's ability to collect evaluations of SDPs and enhance the level of detail described in the evaluation. CMS' intent is to shine a spotlight on SDP evaluations and use evaluation results in determining future approvals of State directed payments. CMS also plans to issue additional technical assistance on this subject as well to assist States in the development of evaluation plans in alignment with the proposed regulatory requirements and preparing the subsequent evaluation reports.

In an effort to strengthen reporting and to better monitor the impact of SDPs on quality and access to care, we propose at § 438.6(c)(2)(iv) that the State must submit an evaluation plan for each SDP that requires written prior approval that includes four specific elements. We specify that our proposal is to establish minimum content requirements for SDP evaluation plans but is not intended to limit States in evaluating their SDP arrangements. Currently, § 438.6(c)(2)(ii)(D) requires that States develop an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the State's managed care quality strategy (which is required by § 438.340).

We propose at § 438.6(c)(2)(iv)(A) that the evaluation plan must identify at least two metrics that would be used to measure the effectiveness of the payment arrangement in advancing the identified goal(s) and objective(s) from the State's managed care quality strategy

on an annual basis. In addition, proposed paragraph (c)(2)(vi)(C)(*4*) further specifies that at least one of those metrics must measure performance at the provider class level for SDPs that are population- or condition-based payments. Under § 438.6(c)(2)(iv)(A)(*1*), we propose that the metrics must be specific to the SDP and attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the SDP applies, when practicable and relevant. We propose the standard "when practicable and relevant" to allow flexibility to account for situations in which contract or program level specificity may be either impossible to obtain or may be ineffective in measuring the identified quality goal(s) and objective(s). For example, States may implement a quality improvement initiative in both the Medicaid FFS program and Medicaid managed care program(s), but measuring the impact of that initiative on each program separately would not produce valid results due to the small sample sizes. Proposing this flexibility would allow States to produce an evaluation inclusive of both Medicaid managed care and FFS data and comprised of measures relevant to the approved SDP to demonstrate the effect the SDP arrangement is having on advancing the State's overall quality goals.

We propose at § 438.6(c)(2)(iv)(A)(*2*) to require that at least one of the selected metrics must be a performance measure, for which we propose a definition in § 438.6(a) as described in section I.B.2.i. of this proposed rule. We currently allow, and would continue to allow, States to select a metric with a goal of maintaining access to care when that is the goal of the SDP. While access metrics provide valuable information, they do not measure service delivery, quality of care, or outcomes, and they do not provide insight into the impact that these payment arrangements have on the quality of care delivered to Medicaid enrollees. Therefore, if a State elects to choose a metric that measures maintenance of access, our proposal would require States to choose at least one additional performance metric. Because we recognize that performance is a broad term and that the approach to evaluating quality in healthcare is evolving, and because we understand the importance of preserving States' flexibility to identify performance measure(s)

that are most appropriate for evaluating the specific SDP, we are not proposing additional requirements for the other minimum metric so as not to preclude innovation. However, we would strongly recommend that States use existing measure sets which are in wide use across Medicaid and CHIP, including the Medicaid and CHIP Child and Adult Core Sets[106] and the Home and Community-Based Services Quality Measure Set[107], to facilitate alignment and reduce administrative burden. In some cases, these existing measures may not be the most appropriate choice for States' Medicaid managed care goals; therefore, we will issue subregulatory guidance to provide best practices and recommendations for choosing appropriate performance measures when not using existing measure sets.

Concerns around access to primary care, maternal health, and behavioral health have been raised nationally. The current administration considers increasing access to care for these services to be a national priority. We encourage States to implement SDPs for these services and providers to improve access. We also encourage States to include measures that focus on primary care and behavioral health in their evaluation plans when relevant. This could include using existing measures from the Medicaid and CHIP Child and Adult Core Sets[108] or other standardized measure sets. CMS also expects that States consider examining parity in rates for primary care and behavioral health compared to other services, such as inpatient and outpatient hospital services, as part of their evaluation of SDPs.

It is crucial to monitor and evaluate the impact of SDP implementation, and as such we propose at § 438.6(c)(2)(iv)(B) to require States to include baseline performance statistics for all metrics that would be used in the evaluation since this data must be established in order to monitor changes in performance during the SDP performance period. We believe this proposal is

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106 Medicaid and CHIP Child Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html*, the Medicaid Adult Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html*).
107 *https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.*
108 Medicaid and CHIP Child Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html*, the Medicaid Adult Core Set (*https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html*).

particularly necessary since we found in our internal study that, among the SDP evaluation plan elements, a baseline statistic(s) was the most commonly missing element. We propose the requirements at § 438.6(c)(2)(iv)(B) in an effort to ensure that States' evaluation plans produce reliable results throughout the entirety of the SDP's implementation.

Measurable SDP evaluation performance targets that demonstrate performance relative to the baseline measurement allow States to determine whether the payment arrangement is having the intended effect and helping a State make progress toward its quality goals. Our internal analysis showed that nearly 20 percent of performance measures selected by States were not specific or measurable. Therefore, at § 438.6(c)(2)(iv)(C), we also propose to require that States include measurable performance targets relative to the baseline statistic for each of the selected measures in their evaluation plan.

Overall, we believe that the proposed regulations at § 438.6(c)(2)(iv) would ensure that States collect and use stronger data for developing and evaluating payment arrangements to meet the goals of their Medicaid programs and would also be responsive to recommendations for more clarity for SDP evaluation plans. However, we recognize and share the concerns raised by oversight bodies regarding the limited availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care. While we ask States for evaluation results as part of the review process for SDP renewals, current regulations do not explicitly require submission of completed evaluation reports and results or use by CMS of prior evaluation reports and results in reviewing current SDPs for renewal or new SDPs. As a result, because most States do not comply with our request for evaluation data, we are proposing to revise § 438.6(c)(2) to ensure that SDPs further the goals and objectives identified in the State's managed care quality strategy. We propose at § 438.6(c)(2)(iv)(D) that States must provide commitment to submit an evaluation report in accordance with proposed § 438.6(c)(2)(v), which is discussed in the next paragraph of this section, if the final State directed payment cost percentage exceeds 1.5 percent.

Finally, we are proposing to amend § 438.6(c)(2)(ii)(D) to further require the evaluation plan include all the elements outlined in paragraph (c)(2)(iv). These proposed changes in § 438.6(c)(2)(ii)(D) and the new proposed requirements in § 438.6(c)(2)(iv) would further identify the necessary components of a State's evaluation plans for SDPs and make clear that we have the authority to disapprove proposed SDPs if States fail to provide in writing evaluation plans for their SDPs that comply with these regulatory requirements.

Section 1902(a)(6) of the Act requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Our proposal to add new § 438.6(c)(2)(v) to require that States submit to CMS, for specified types of SDPs that have a final State directed payment cost percentage that exceeds 1.5 percent, an evaluation report using the evaluation plan the State outlined under proposed § 438.6(c)(2)(iv). As proposed in § 438.6(c)(2)(v), the proposed evaluation reporting requirement is limited to States with SDPs that require prior approval. We recognize that submitting an evaluation report would impose some additional burden on States, so we propose this risk-based approach to identify when an evaluation report must be submitted to CMS based on the actual total amount that is paid as a separate payment term described in § 438.6(c)(6) or portion of the actual total portion of capitation payments attributable to the SDP, as a percentage of the State's total Medicaid managed care program costs for each managed care program. This approach would allow States and CMS to focus resources on payment arrangements with the highest financial risk. We have selected the 1.5 percent as it aligns with existing Medicaid managed care policy for when rate amendments are necessary (often referred to as a *de minimis* threshold or *de minimis* changes) and with proposed policies for in lieu of services (see section I.B.3. of this proposed rule).

We propose to define "final State directed payment cost percentage" in § 438.6(a) as the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment and each managed care program. In § 438.6(c)(7)(iii)(A), we propose for SDPs requiring prior approval that the final SDP cost percentage numerator be calculated as the

portion of the total capitation payments that is attributable to the State directed payment and, actual total amount that is paid as a separate payment term described in § 438.6(c)(6), for each managed care program. In § 438.6(c)(7)(iii)(B), we propose the final SDP cost percentage denominator be calculated as the actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total amount of State directed payments that are paid as a separate payment term as described in paragraph (c)(6). To calculate the numerator for a minimum or maximum fee schedule type of SDP that is incorporated into capitation rates as an adjustment to base capitation rates, an actuary should calculate the absolute change that the SDP has on base capitation rates. Over time, as the SDP is reflected in the base data and incorporated into base capitation rates, it is possible that the absolute effect may decrease or no longer be apparent, and the numerator may decrease to zero. We solicit comment on whether the numerator for a minimum or maximum fee schedule SDP that is incorporated into capitation rates as an adjustment to base capitation rates should be calculated in a different manner (for example, estimating a portion of the capitation rates resulting from the SDP.) We do not believe that it is necessary to propose regulation text to codify this approach as we intend to issue additional guidance in the Medicaid Managed Care Rate Development Guide in accordance with § 438.7(e). We also solicit comment on whether we should codify this in regulation text. We believe this proposed numerator and denominator would provide an accurate measurement of the final expenditures associated with a SDP and total program costs in each managed care program in a risk-based contract.

We believe the final SDP cost percentage should be measured distinctly for each managed care program and SDP, as reflected in the definition proposed for this term. This is appropriate because capitation rates are typically developed by program, SDPs may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types. For example, one State may have

a behavioral health program that covers care to most Medicaid beneficiaries through PIHPs, a physical health program that covers physical health care to children and pregnant women through MCOs, and a program that covers physical health and MLTSS to adults with a disability through MCOs. Another State may have several different managed care programs that serve similar populations and provide similar benefits through MCOs, but the delivery model and geographic areas served by the managed care programs vary. We addressed managed care program variability within the 2016 final rule when we noted that "This clarification in the regulatory text to reference "managed care program" in the regulatory text is to recognize that States may have more than one Medicaid managed care program – for example physical health and behavioral health…" (81 FR 27571). Therefore, we believe it would be contrary to our intent if States were to develop a final SDP cost percentage by aggregating data from more than one managed care program since that would be inconsistent with rate development, the unique elements of separate managed care programs, and the SDPs that vary by managed care program. We note here that we intend to use this application of managed care program in other parts of this section of this proposed rule, including, but not limited to, the discussion of calculating the total payment rate in section I.B.2.f. of this proposed rule, measurement of performance for certain VBP arrangements discussed in section I.B.2.i. of this proposed rule and separate payment terms in section I.B.2.i. of this proposed rule.

With § 438.6(c)(7)(i), we propose that the final State directed payment cost percentage be calculated on an annual basis and recalculated annually to ensure consistent application across all States and managed care programs. To ensure that final State directed payment cost percentage would be developed in a consistent manner with how the State directed payment costs would be included in rate development, we propose at § 438.6(c)(7)(ii) to require that the final SDP cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. An "actuary" is defined in § 438.2 as an individual who meets the qualification standards established

by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board, and who is acting on behalf of the State to develop and certify capitation rates.

Although all States would be required to develop and document evaluation plans in compliance with the provisions proposed in § 438.6(c)(2)(iv), the proposed regulation at § 438.6(c)(2)(v) requires submission of the evaluation report for an SDP based on whether the SDP results in a final SDP cost percentage greater than 1.5 percent. In recognition that the final SDP cost percentage report represents additional State burden and that many States may choose to evaluate their SDPs regardless of the final SDP cost percentage, we propose § 438.6(c)(7) which requires States to submit the final SDP cost percentage report, only if a State wishes to demonstrate that it is below 1.5 percent. With this proposed reporting requirement, States would be required to provide the final SDP cost percentage report to demonstrate that an SDP is exempt from the proposed evaluation report requirement. For SDP arrangements that do not exceed the threshold, States would not be required to submit evaluation results under proposed new paragraph § 438.6(c)(2)(v), but we would encourage States to monitor the evaluation results of all of their SDPs. We recognize that in order to monitor the 1.5 percent threshold, we would need a reporting mechanism by which States would be required to calculate and provide the final SDP cost percentage to CMS. Therefore, we propose a requirement (at new § 438.6(c)(7)(iv)) that the State submit the final State directed payment cost percentage annually to CMS for review, when the final State directed payment cost percentage does not exceed 1.5 percent and the State has not voluntarily submitted the evaluation report, as a separate report concurrent with the rate certification submission required in § 438.7(a) no later than 2 years after the completion of each 12-month rating period that included a State directed payment. We believe that it is appropriate for States' actuaries to develop a separate report to document that the final State directed payment cost percentage does not exceed 1.5 percent, rather than including it in a rate certification, because the final State directed payment cost percentage may require alternate data

compared to the base data that were used for prospective rate development, given the timing of base data requirements as outlined in § 438.5(c)(2). We note that this proposal is similar to the concurrent submission for the proposed MLR reporting at § 438.74 and proposed ILOS projected and final cost percentage reporting at § 438.16(c). We considered proposing that States submit the final SDP report to CMS upon completion of the report, separately and apart from the rate certification. However, we believe there should be consistency across States for when this report is submitted to CMS for review, and we believe receiving this report and the rate certification at the same time would enable CMS to review them concurrently.

As the proposed denominator for the final SDP cost percentage would be based on the actual total capitation payments and the actual total State directed payments paid as a separate payment term (see section I.B.2.l. of this proposed rule for details on this proposal for separate payment terms) paid by States to managed care plans, we recognize that calculating the final SDP cost percentage would take States and actuaries some time. For example, changes to the eligibility file and revised rate certifications for rate amendments may impact the final capitation payments that are a component of the calculation. Given these factors, we believe that 2 years is an adequate amount of time to accurately perform the calculation. Under this proposal, for example, the final SDP cost percentage report for a managed care program that uses a calendar year 2024 rating period would be submitted to CMS with the calendar year 2027 rate certification.

For the evaluation reports, we propose to adopt three requirements in § 438.6 (c)(2)(v)(A). First, in § 438.6(c)(2)(v)(A)(*1*), we propose that evaluation reports must include all of the elements approved in the evaluation plan required in § 438.6(c)(2)(iv). In § 438.6(c)(2)(v)(A)(*2*), we propose to require that States include the 3 most recent and complete years of annual results for each metric as required in § 438.6(c)(2)(iv)(A). Lastly, at § 438.6(c)(2)(v)(A)(*3*), in acknowledgement of MACPAC's recommendation to enhance

transparency of the use and effectiveness of SDP arrangements, we propose to require that States publish their evaluation reports on their public facing website as required under § 438.10(c)(3).

States consistently have difficulty providing evaluation results in the first few years after implementation of an SDP due to the time required for complete data collection. Our internal analysis found that States' ability to provide evaluation results improved over time. Although only 21 percent of proposals included evaluation results in year two, 55 percent of proposals included results data in year three, and 66 percent of year 4 proposals included the results of the evaluation. For this reason, we considered but ultimately did not propose that States submit an annual evaluation. Therefore, we propose at § 438.6(c)(2)(v)(B) to require States to submit the first evaluation report no later than 2 years after the conclusion of the 3-year evaluation period and that subsequent evaluation reports would have to be submitted to CMS every 3 years after.

In § 438.6(c)(2)(v)(A)(*2*), we propose to require that evaluation reports include the 3 most recent and complete years of annual results for each metric as approved under the evaluation plan approved as part of the preprint review. Therefore, the first evaluation report would be due no later than with the submission of the preprint for the sixth rating period after the applicability date for the evaluation plan; this evaluation plan would contain results from the first 3 years after the applicability date for the evaluation plan. We believe that this approach to implementation would allow adequate time for States to obtain final and validated encounter data and performance measurement data to compile and publish the first evaluation report. We also considered a 5 and 10-year period evaluation period, but we concluded that seemed to be an unreasonably long time to obtain actionable evaluation results. We concluded that a 3-year period would provide sufficient time to collect complete data and demonstrate evaluation trends over a period of time.

After submission of the initial evaluation report, States would be required to submit subsequent evaluation reports every 3 years. This means that States would submit the second evaluation report with the SDP preprint submission for the first rating period beginning 9 years

after the applicability date for the evaluation plan; this evaluation report would contain results from years four through six after the applicability date for the evaluation plan . States would be required to continue submitting evaluation reports with this frequency as long as the SDP is implemented. We acknowledge that some SDPs will have been operational for multiple years when these proposed regulations take effect. We are not proposing a different implementation timeline for SDP arrangements that predate the compliance deadline for this proposal. For these mature payment arrangements, States would be required to submit an evaluation report in the fifth year after the compliance date that includes the 3 most recent and complete years of annual results for the SDP. However, because these types of long-standing payment arrangements have been collecting evaluation data since implementation, we would expect States to include the evaluation history in the report in order to provide the most accurate picture.

We recognize and share the concerns that oversight bodies have expressed regarding the extent to which CMS uses evaluation results to inform SDP written prior approval decisions. In response to these concerns and as a part of the proposed revisions to § 438.6(c)(2)(ii), which include the standards that all SDPs must meet, we are proposing a new standard at § 438.6(c)(2)(ii)(F) requiring that all SDPs must result in achievement of the stated goals and objectives in alignment with the State's evaluation plan. We believe that the proposed changes would help us to better monitor the impact of SDPs on quality and access to care and would help standardize our review of SDP proposal submissions under § 438.6(c) while allowing us to disapprove SDPs that do not meet their stated quality goals and objectives.

We are also making a concurrent proposal at § 438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which would give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs. We believe this proposed optional activity would reduce burden associated with these new requirements and is discussed in more detail in section I.B.5.c.3 of this proposed rule. we are considering, and invite public comment on, requiring that States procure an independent evaluator for SDP evaluations

in the final rule based on comments received. In consideration of the myriad of new proposed requirements within this proposed rule, we weighed the value of independent evaluation with increased State burden. We are concerned that it would be overly burdensome for States to procure independent evaluators for SDPs due, in part, to the timing of the final SDP cost percentage submission. In section I.B.2. of this proposed rule, we are proposing that the final SDP cost percentage be submitted 2 years following completion of the applicable rating period, and we propose here that if the final SDP cost percentage exceeds the 1.5 percent, States would be required to submit an evaluation. While we encourage all States to evaluate their SDPs, it could be difficult and time consuming to procure an independent evaluator in a timely manner solely for the purpose of the SDP evaluation since States would not know definitely whether an evaluation is required until 2 years following the rating period. We solicit comment on whether we should consider a requirement that States use an independent evaluator for SDP evaluations.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals and the alternatives under consideration.

k. Contract Term Requirements (§ 438.6(c)(5))

SDPs are contractual obligations in which States direct Medicaid managed care plans on how or how much to pay specified provider classes for certain Medicaid-covered services. The current heading for § 438.6(c) describes paragraph (c) as being about delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts. Further, the regulation refers to SDPs throughout as provisions in the contract between the MCO, PIHP or PAHP and the State that direct expenditures by the managed care plan (that is, payments made by the managed care plan to providers). SDPs are to be included in a State's managed care rate certification per § 438.7(b)(6) and final capitation rates for each MCO, PIHP, and PAHP must be identified in the applicable contract submitted for CMS review and approval per § 438.3(c)(1)(i). Thus, every SDP must be documented in the managed care contract and actuarial rate

certification.

Previous guidance issued to States, including in the January 2022 State Guide to CMS Criteria for Medicaid Managed Care Contract Review and Approval (State Guide), indicates that contractual requirements for SDPs should be sufficiently detailed for managed care plans to operationalize each payment arrangement in alignment with the approved preprint(s).[109] The State Guide includes examples of information that States could consider including in their managed care contracts for SDPs.[110] However, despite this guidance, there is a wide variety of ways States include these requirements into their contracts, many of which lack critical details to ensure that plans implement the contractual requirement consistent with the approved SDP. For example, some States have sought to include a broad contractual requirement that their plans must comply with all SDPs approved under § 438.6(c) with no further details in the contract to describe the specific payment arrangements that the State is directing the managed care plan to implement and follow. Other States have relied on broad contract requirements stating that plans must comply with all applicable State laws as a method of requiring compliance with State legislation requiring plans to pay no less than a particular fee schedule for some services. These types of vague contractual provisions represent significant oversight risk for both States and CMS.

To reduce this risk and improve the clarity of SDPs for managed care plans, we propose to codify at § 438.6(c)(5) minimum requirements for the content of a Medicaid managed care contract that includes one or more SDP contractual requirement(s). We believe these minimum requirements for SDP contract terms would assist States when developing their contracts, ensure that managed care plans receive necessary information on the State's intent and direction for the SDP, facilitate CMS' review of managed care contracts, and ensure compliance with the approved SDP preprint. At § 438.6(c)(5)(i) through (v), we propose to specify the information

109 *https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf.*
110 *https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf.*

that must be documented in the managed care contract for each SDP. Proposed § 438.6(c)(5)(i) would require the State to identify the start date and, if applicable, the end date within the applicable rating period. While most SDPs, particularly long-standing contractual requirements, are in effect throughout the entire rating period, some SDPs begin in the middle of the rating period or are for a limited period of time within a rating period. This requirement would ensure that the time period for which the SDP applies is clear to the managed care plans.

Proposed § 438.6(c)(5)(ii) would require the managed care contract to describe the provider class eligible for the payment arrangement and all eligibility requirements. This would ensure compliance with the scope of the written prior approval issued by CMS because we have implemented paragraph (c)(2)(ii)(B) by requiring States to provide a description of the class of providers eligible to participate and the eligibility criteria. In addition, a clear contract term will provide clear direction to plans regarding the provider class that is eligible for the SDPs.

Proposed § 438.6(c)(5)(iii) would require the State to include a description of each payment arrangement in the managed care contract. This will ensure compliance with the written prior approval issued by CMS and provide clear direction to plans while also assisting CMS in its review and approval of Medicaid managed care contracts. For each type of payment arrangement, we are proposing to require that specific elements be included in the contract at a minimum. For SDPs that are minimum fee schedule arrangements, we propose that the contract must include: in § 438.6(c)(5)(iii)(A)(1), the fee schedule the plan must ensure payments are at or above; in paragraph (c)(5)(iii)(A)(2), the procedure and diagnosis codes to which the fee schedule applies; and in paragraph (c)(5)(iii)(A)(3), the applicable dates of service within the rating period for which the fee schedule applies. We are proposing the requirement at paragraph (c)(5)(iii)(A)(3) so that it is clear that payment can only be triggered based on service delivery within the applicable rating period.

For minimum fee schedules set at the State plan approved rate as described in § 438.6(c)(1)(iii)(A), we propose to require at § 438.6(c)(5)(iii)(A)(*4*) that the contract reference

the applicable State plan page, the date it was approved, and a link to where the currently approved State plan page is posted online when possible. For minimum fee schedules set at the Medicare rate as described in § 438.6(c)(1)(iii)(B), we propose to require at § 438.6(c)(5)(iii)(A)(*5*), that the contract include the Medicare fee schedule and any specific information necessary for implementing the payment arrangement. For example, Medicare updates their fee schedules annually using a calendar year but Medicaid managed care contracts may not be based on a calendar year, such as those that use a State fiscal year. Therefore, States would have to identify the publication year of the Medicare fee schedule being required by the SDP. As another example, the Medicare physician fee schedule includes factors for different geographic areas of the State to reflect higher cost areas; the Medicaid managed care contract would have to specify if the plans are required to apply those factors or use an average of those factors and pay the same rate irrespective of the provider's geographic region.

For uniform increases as described in paragraph (c)(1)(iii)(D), we propose at § 438.6(c)(5)(iii)(B)(*1*) through (5) to require the contract to include: (1) whether the uniform increase will be a specific dollar amount or a specific percentage increase over negotiated rates; (2) the procedure and diagnosis codes to which the uniform increase will be applied; (3) the specific dollar amount of the increase or percent of increase, or the methodology to establish the specific dollar amount or percentage increase; (4) the applicable dates of service within the rating period for which the uniform increase applies; and (5) the roles and responsibilities of the State and the plan, as well as the timing of payment(s), and any other significant relevant information.

For maximum fee schedules as described in paragraph (c)(1)(iii)(E), we propose at § 438.6(c)(5)(iii)(C)(*1*) through (*4)* to require the contract to include: (1) the maximum fee schedule the plan must ensure payments are below; (2) the procedure and diagnosis codes to which the fee schedule applies; (3) the applicable dates of service within the rating period for which the fee schedule applies; and (4) details of the State's exemption process for plans and providers to follow if they are under contract obligations that result in the need to pay more than

the maximum fee schedule. We believe an exemption process is necessary for payment arrangements that limit how much a managed care plan can pay a provider to ensure that the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

For contractual obligations described in paragraph (c)(1)(i) and (ii) that condition payment based upon performance, we propose at § 438.6(c)(5)(iii)(D)(*1*) through (6) to require that managed care plan contracts must include a description of the following elements approved in the SDP arrangement: (1) the performance measures that payment will be conditioned upon; (2) the measurement period for those metrics; (3) the baseline statistics against which performance will be based; (4) the performance targets that must be achieved on each metric for the provider to obtain the performance-based payment; (5) the methodology to determine if the provider qualifies for the performance-based payment as well as the amount of the payment; and (6) the roles and responsibilities of the State and the plan, the timing of payment(s), what to do with any unearned payments if applicable, and other significant relevant information. Some States perform the calculations to determine if a provider has achieved the performance targets necessary to earn performance-based payments, while others delegate that function to their managed care plans. Adding this specificity to the contract would ensure clarity for both the States and the managed care plans.

For contractual obligations described in paragraphs (c)(1)(i) and (ii) that are population or condition-based payments as defined in § 438.6(a), we propose at § 438.6(c)(5)(iii)(E) to require the contract to describe: (1) the Medicaid covered service(s) that the population or condition-based payment is made for; (2) the time period that the population-based or condition-based payment covers; (3) when the population-based or condition-based payment is to be made and how frequently; (4) a description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how that attribution model will be communicated to providers; and

(5) the roles and responsibilities of the State and the plan in operationalizing the attribution methodology if an attribution methodology is used.

Proposed § 438.6(c)(5)(iv) would require that the State include in the managed care contract any encounter reporting and separate reporting requirements that the State needs in order to audit the SDP and report provider-level payment amounts to CMS as required in § 438.6(c)(4).

Proposed § 438.6(c)(5)(v) would require that the State indicate in the contract whether the State would be using a separate payment term as defined in § 438.6(a) to implement the SDP. This information would provide additional clarity for oversight purposes for both States and CMS.

Finally, we propose to require in § 438.6(c)(5)(vi) that all SDPs must be specifically described and documented in MCO, PIHP, and PAHP contracts no later than 120 days after the start of the SDP or approval of the SDP under § 438.6(c)(2)(i), whichever is later. This timeframe is consistent with the timeframe being proposed for documenting separate payment terms in the managed care contract under § 438.6(c)(6)(v). We believe that proposing to require States to document the SDP within these timeframes is reasonable given that the contract would only have to document the SDP and the contract action could be submitted to CMS in draft form so long as it included all of the required elements in § 438.6(c)(5)(i) through (v), as applicable. CMS would not require a final signed copy of the contract amendment within this proposed 120-day timeframe; however, States would still be required to submit a final signed contract action prior to CMS' approval of the managed care contract.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comments on our proposals.

l. Including SDPs in rate certifications and separate payment terms (§§ 438.6(c)(2)(ii)(J), (c)(6) and 438.7(f))

Including SDPs in rate certifications. Under current regulations, all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). As part of our proposed amendment and redesignation of current § 438.6(c)(2)(i), we are proposing to re-designate the existing regulatory requirement at § 438.6(c)(2)(i) as § 438.6(c)(2)(ii)(J) to require that each SDP must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. We are also proposing to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices. We are proposing this edit because inclusion of the language "generally accepted actuarial principles and practices" is duplicative of the language included in § 438.4. establishment of SDPs is a State decision. We are concerned that inclusion of the duplicative language that SDPs must be developed in accordance with generally accepted actuarial principles and practices could be interpreted as a requirement for an actuary to be involved in the development of the SDP arrangement and adherence to actuarial standards of practice (ASOPs), potentially creating unnecessary State administrative burden associated with the preprint development process. However, we note the proposed rule maintains the existing requirement that SDPs must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. While we believe that an actuary, as defined in § 438.2, must develop the capitation rates to ensure they are actuarially sound and account for all SDPs when doing so, but we believe States should have the flexibility to determine if they wish to involve actuaries in the development of each specific SDP arrangement. Because actuaries must account for all SDPs approved by CMS and included in the State's approved managed care contract in the applicable rate certifications, providing all documentation required by CMS, we do recommend that States consult with and keep actuaries apprised of SDPs to facilitate their development of actuarially sound capitation rates. We also believe that for certain SDPs, specifically bundled payments, episode-based payments, population-based payments and accountable care organizations, it would be beneficial for actuaries to assist States in the

development of these arrangements.

In accordance with § 438.4(a), actuarially sound capitation rates are projected to provide for all reasonable, appropriate and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract, and capitation rates are developed in accordance with the requirements in § 438.4(b) to be approved by CMS. This includes the requirement in § 438.4(b)(1) that the capitation rates must be developed with generally accepted actuarial principles and practices and in § 438.4(b)(7) they must meet any applicable special contract provisions as specified in § 438.6, to ensure that all SDPs, which are contractual arrangements, are considered as the actuary develops actuarially sound capitation rates. (Similarly, withhold and incentive arrangements and pass-through payments must be taken into account when capitation rates are developed.) We are not proposing changes to the requirements for actuarially sound capitation rates; therefore, we will retain and reaffirm here applicability of the requirements of that SDPs must be developed in such a way as to ensure compliance with § 438.4 and the standards specified in § 438.5 and specify further that SDPs must also be developed in such a way to ensure compliance with § 438.7 and § 438.8.

We solicit public comments on our proposal.

Separate Payment Terms. Under current regulations, all SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) as noted in § 438.7(b)(6). As part of the Medicaid Managed Care Rate Development Guide, CMS has historically provided guidance on two ways that States could make payment to cover SDP obligations in Medicaid managed care contracts: through adjustments to the base capitation rates[111] in alignment with the standards described in § 438.5(f) or through a "separate payment

111 As defined in § 438.2, capitation payments are a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan.

term"[112] which was described in guidance applicable to rating periods beginning between July 1, 2019 and June 30, 2021. Separate payment terms are unique to Medicaid managed care SDPs. CMS has not previously formally defined separate payment terms in regulation.

The most common structure for separate payment terms is a State first establishes a finite and predetermined pool of funding that is paid by the State to the plan(s) separately and in addition to the capitation payments for a specific SDP. The pool of funds is then disbursed regularly throughout the rating period (for example, quarterly) based on the services provided in that portion of the rating period (for example, quarter) to increase total provider payments or reach a specific payment rate target. Typically, States divide the dedicated funding pool into equal allotments (for example, four if making quarterly payments to their plans). They then review the encounter data for the service(s) and provider class identified in the approved preprint for the quarter that has just ended and divide the allotment by the total service utilization across all providers in the defined class (for example, inpatient discharges for all rural hospitals) to determine a uniform dollar amount to be paid in addition to the initial payment by the managed care plan for rendered services. The State will then pay the quarterly allotment to the managed care plans, separate from the capitation rate payment, and direct them to use that allotment for additional retroactive payments to providers for the utilization that occurred in the quarter that just ended. The State will repeat this process each quarter, with the uniform increase changing for each quarter depending on utilization but being paid uniformly to providers in the defined class for the services within that quarter (for example, inpatient discharges for rural hospitals). Other States have chosen to make payments semi-annually, annually, or monthly. States have also utilized separate payment terms for SDPs that are performance-based payments rather than uniform increases (for example, pay for performance under which payment is conditioned upon provider performance).

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112 This guidance has appeared in the Medicaid Managed Care Rate Development Guide for rating periods starting between July 1, 2019 and June 30, 2021. Medicaid Managed Care Rate Development Guides for every rating period are located at *https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html*.

As noted earlier, separate payment terms are paid separate and apart from capitation rate payments; they are not included in capitation rates. The development of the separate payment term is frequently done by the State rather than the State's actuaries; CMS has never required actuaries to certify the reasonableness of the amount of the separate payment term, but only that the separate payment term is consistent with what was approved in the SDP preprint. However, CMS has always required that separate payment terms be documented in the State's rate certification and that SDPs, including those that utilize separate payment terms, must be developed in accordance with § 438.4 and the standards in §§ 438.5, 438.7 and 438.8. CMS has asked actuaries to document the separate payment terms in the State's rate certification because they are required payments for services under the risk-based contract.

Depending on the size and scope of the SDP and the provider payment rates assumed in the capitation rate development, separate payment terms can have a significant impact on the assessment of the actuarial soundness of the rates. In some cases, capitation rates may not be sufficient without taking separate payment terms into account. When examined in conjunction with the capitation rates, CMS has found that amounts included in separate payment terms can, when combined with capitation payment amounts, represent a significant portion of the total payment made under the Medicaid managed care contract. For example, in one State, the separate payment term for an SDP for inpatient hospital services represented 40 percent of the total amount paid in certain rate cells.

In some cases, the provider payment rates assumed in the development of the capitation rates, absent the SDP paid through a separate payment term to the plan(s), are so low that the capitation rates would likely not be actuarially sound. In the example above, considering how low the payment rates were absent the SDP paid to the plans through a separate payment term in this State, it would be difficult for an actuary to determine that the capitation rates are actuarially sound. However, the additional payments made as part of the SDP for these providers raise the effective provider payment rates, and after considering all payments made to the plan (the base

capitation rates and the separate payment term payments for the SDP) the actuary may be able to determine that the capitation rates are actuarially sound. This is not the case for all States and for all SDPs; however, this example highlights the need to account for the impact of separate payment terms on the assessment of the actuarial soundness of the capitation rates. Additionally, since the contract requires that the managed care plans pay the SDP to providers, the separate payment term must be included within the actuarial certification for the rates to be considered actuarially sound as defined in § 438.4(a). For this reason, we consider separate payment terms part of the contract with the managed care plans that is subject to the requirements of section 1903(m)(2)(A) of the Act, and a necessary part of certifying the actuarial soundness of capitation rates under this provision. As such, we propose to regulate them under this authority.

Over time, the number of SDPs approved by CMS using separate payment terms has increased substantially. According to our internal analysis, 41.5 percent of all SDPs that CMS has reviewed and approved from May 2016 through March 2022 were included in the State's rate certification submission as a separate payment term. While there has been some fluctuation over time in this trend, the share of SDPs that use separate payment terms has increased from 42 percent of all SDPs that began in calendar year 2020 to 55 percent of all SDPs that began in calendar year 2021.[113]

In our January 2021 SMDL, we published additional guidance on SDPs, and expressed our growing concern with the increased use of separate payment terms.[114] We noted, "[a]s CMS has reviewed State directed payments and the related rate certifications, CMS has identified a number of concerns around the use of separate payment terms. Frequently, while there is risk for the providers, there is often little or no risk for the plans related to the directed payment, which is contrary to the nature of risk-based managed care. This can also result in perverse incentives for

113 Our internal analysis examines trends based upon when a payment arrangement began. Since States have different rating periods, this can refer to different time frames for different States. For example, payment arrangements that began in calendar year 2020 would include payment arrangements that were in effect for CY 2020 rating periods, which operated between January 1, 2020 through December 31, 2020, as well as SFY 2021 rating periods, which for most States were operated between July 1, 2020 through June 30, 2021.
114 *https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.*

plans that can result in shifting utilization to providers in ways that are not consistent with Medicaid program goals."

To better understand why States choose to pay plans for their SDPs through a separate payment term, we started collecting information from States as part of the revised preprint form published in January 2021. States were required to start using this revised preprint for SDP requests for rating periods beginning on or after July 1, 2021. In the revised preprint form, States must identify if any portion of the SDP would be included in the rate certification as a separate payment term and if so, to provide additional justification as to why this is necessary and what precludes the State from covering the costs of SDPs as an adjustment to the capitation rates paid to managed care plans.

From the data we have collected as well as discussions with States, we have noted that there are a number of reasons why States use separate payment terms. For example, States have noted particular challenges with including VBP arrangements in capitation rates. They have asserted that it is difficult to project individual provider level performance in a way that lends itself to inclusion in standard rate development practices. Additionally, performance measurement often does not align with States' rating periods, further complicating the standard rate development process.

Several States also noted that even for fee schedule-based SDPs, such as uniform payment increases, incorporation into standard rate development practices presents challenges. States assert that using a separate payment term offers administrative simplicity to the State agency in administering the SDPs because distributing a pre-determined amount of funding among the plans is much easier than relying on actuarial projections. Further, the use of a separate payment term also promotes the ease of tracking and verification of accurate payment to providers from the managed care plans required under the SDP. This is particularly important when States are implementing legislative directives that require an appropriation of funding be dedicated to a specific purpose. State legislatures, in some instances, have identified a specific

dollar amount that they want to invest in increasing reimbursement for a particular service, potentially to respond to an acute concern around access. Incorporating this funding into the State's capitation rates through standard rate development would not ensure that plans did not use this funding, or portions of this funding, for other purposes. Additionally, even with the proper tracking, States would have to specify a particular minimum fee schedule or uniform increase at the start of the rating period to include in rate development and ensure it went to the appropriate providers for the appropriate services. While such a methodology is permissible and used effectively by a number of States today, some States have noted challenges in utilizing such an approach, particularly if the SDP is targeting a narrow set of providers.

States have also noted that utilization often cannot be predicted adequately; thus, including dedicated funding into base rates may not always result in the funding being distributed as intended by the legislature. Absent the ability to use separate payment terms, States are likely to resort to requiring plans to make interim payments based on historical utilization and then reconciling to current utilization, often after the end of the rating period, to ensure that all of the funding was used as directed by the legislature. As noted in section I.B.2.h. of this proposed rule, we have significant concerns with this practice in States that already require plans to make interim payments based on historical utilization and then reconcile to current utilization. As part of this proposed rulemaking, we have proposed to prohibit such payment methodologies in § 438.6(c)(2)(vii).

States also stated that separate payment terms reduce the burden on managed care plans by limiting the need to update claims systems. In fact, one State noted that they shifted from incorporating a particular SDP as an adjustment to capitation rates to implementing the SDP through a separate payment term because their managed care plans did not have the ability to update or modify their claims payment systems in a manner that would ensure accurate payment of the increases required under the State's SDP if the funding was built into the capitation

payment. The State noted that the managed care plans had dedicated significant technical resources and still could not implement the changes needed accurately.

As noted earlier, CMS has a strong preference that SDPs be included as adjustments to the capitation rates since that method is most consistent with the nature of risk-based managed care. However, we recognize that States believe there is utility in the use of separate payment terms for specific programmatic or policy goals. We believe separate payment terms are one tool for States to be able to make targeted investments in response to acute concerns around access to care. However, we continue to believe that, while separate payment terms often retain risk for the providers as opposed to guaranteeing them payment irrespective of the Medicaid services they deliver to Medicaid managed care enrollees, there is often little or no risk for the plans related to separate payment terms under an SDP, which is contrary to the nature of risk-based managed care.

Therefore, we believe that it is necessary to establish regulatory requirements regarding the use of separate payment terms to fulfill our obligations for fiscal and programmatic oversight. Because the use of separate payment terms is limited to SDPs that must be tied to utilization and delivery of services to Medicaid enrollees under the managed care contract and the potential impact of separate payment terms on the assessment of actuarial soundness and certification of capitation rates, we consider separate payment terms part of the contract with the a managed care plan that is subject to 1903(m)(2)(A) requirements, and we propose to regulate them under this authority. States are generally not permitted to direct the expenditures of a Medicaid managed care plan under the contract between the State and the plan or to make payments to providers for services covered under the contract between the State and the plan (§§ 438.6 and 438.60) unless SDP requirements are satisfied.

Proposed Regulatory Changes – Contract Requirements

First, we propose to amend § 438.6(a) to define "separate payment term" as a pre-determined and finite funding pool that the State establishes and documents in the Medicaid

managed care contract for a specific SDP for which the State has received written prior approval. Payments made from this funding pool are made by the State to the MCOs, PIHPs or PAHPs exclusively for SDPs for which the State has received written prior approval and are made separately and in addition to the capitation rates identified in the contract as required under § 438.3(c)(1)(i).

CMS recognizes that some separate payment terms in the past may not have fit this definition. For example, one State makes one payment monthly that is inclusive of both the capitation payment and the separate payment term. The State then contractually requires the managed care plans to hold a portion of the monthly payment in a reserve that the State later directs the plans how to pay to providers under an approved SDP. In this example, the State initially indicated to CMS that the SDP was accounted for through adjustments to base data in capitation rates. However, the State later agreed with CMS that the contractual requirement to hold a portion of the monthly payment in a reserve that the State later directed was more in alignment with separate payment terms. To be clear, such a practice would not be considered an adjustment to base rates or part of capitation rate development under this proposed rule; instead it would, under our proposed rule, fall under the proposed definition of a separate payment term and would have to comply with all proposed requirements for SDPs and separate payment terms in the proposed revisions to § 438.6(c).

We propose a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms. First, we propose a new § 438.6(c)(6)(i) to require that all separate payment terms are reviewed and approved as part of the review of the SDP in § 438.6(c)(2). This is effectively current practice today; when a State indicates that an SDP is included in the applicable rate certification(s) through a separate payment term, the approved preprint is checked to ensure that it also indicates that the SDP utilizes a separate payment term. This requirement would codify this operational practice. We believe reviewing and approving the separate payment term as part of the SDP review and approval process would be mutually beneficial for

CMS and States because they are inextricably linked given the proposed definition of a separate payment term. We believe this would also enable us to track of the use of separate payment terms more quickly and accurately.

Because we are proposing to require that separate payment terms are approved as part of the review and approval of the SDPs in § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)), we believe we should explicitly address those SDPs that do not require written prior approval to ensure clarity for States. Therefore, we propose a new requirement at § 438.6(c)(6)(ii) that would expressly prohibit States from using separate payment terms to fund SDPs that are exempted from the written prior approval process – specifically, minimum fee schedules using State plan approved rates in § 438.6(c)(1)(iii)(A) and minimum fee schedules using approved Medicare fee schedules, as proposed in § 438.6(c)(1)(iii)(B). Such payment arrangements must be included as an adjustment to the capitation rates identified in the contract, as required under § 438.3(c)(1)(i).

At § 438.6(c)(6)(iii), we propose to require that each separate payment term be specific to both an individual SDP approved under § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)) and to each Medicaid managed care program to provide clarity in the contract for the plan and facilitate State and Federal oversight of such terms. SDPs approved under § 438.6(c)(2) can apply to more than one Medicaid managed care program. Requiring that each separate payment term be specific to both the SDP approved under § 438.6(c)(2)(i) (redesignated from 438.6(c)(2)(ii)) and each Medicaid managed care program would facilitate monitoring and oversight help ensure clarity and consistency between the approval of the separate payment term and the SDP, the managed care plan contract, and the rate certification.

Additionally, we are proposing a new requirement at § 438.6(c)(6)(iv) that the separate payment term would not exceed the total amount documented in the written prior approval for each SDP for which we have granted written prior approval. Under current practice, the total dollar amount for the separate payment term has acted as a threshold to ensure alignment between the rate certification and the SDP; States that documented more for the separate

payment term in the rate certification(s) than the total dollars documented in the preprint under current practice have to either revise the rate amendment so that the total dollars for the separate payment term does not exceed what was captured in the preprint or submit an amendment to the preprint. If States choose to amend the preprint under current practice, the State is required to explain the cause of the increase (for example, a change in payment methodology, or expansion of the provider class); and then verify that the payment analysis has not changed or if it has, then update the payment analysis to ensure that the total payment rate is still reasonable, appropriate and attainable.[115] This proposed requirement would strengthen this practice by requiring that the amount included in both the rate certification(s) and contract(s) for each separate payment term cannot exceed the amount documented as part of the SDP review and approval. The total dollar amount documented in the written prior approval for the State directed payment would instead act as a maximum that could not be exceeded in the Medicaid managed care contract(s) and rate certification(s) that include the SDP without first obtaining written CMS approval of an amendment to the SDP as noted below. We emphasize that we currently review rate certifications to verify that the total dollars across all applicable Medicaid managed care programs do not exceed the total dollars identified in the State directed payment documentation approved by CMS. If the total dollars included in rate certifications exceed the total dollars identified in the State directed payment documentation, the State then has to either reduce the total dollars included in the rate certification for the separate payment term or, most commonly, submit an amendment to the preprint for review and approval by CMS. This process causes significant delays and administrative burden for both the State and the Federal government, and therefore, we believe a regulation prohibiting States from exceeding the total dollars for the

115 As noted in section I.B.2.f. of this proposed rule, CMS requires States to demonstrate that SDPs result in provider payment rates that are reasonable, appropriate, and attainable as part of the preprint review process in alignment with the guidance published in State Medicaid Director Letter #21-001 published on January 8, 2021. We are proposing to codify this requirement in § 438.6(c)(2(ii)(I).

separate payment term identified in the State directed payment documentation is appropriate and important.

We have also considered requiring that the separate payment term must equal exactly the total amount documented for each SDP for which we have granted written prior approval. Instead of acting as a maximum, the total dollar amount for the separate payment term would act as both a minimum and a maximum; the State's contract and rate certifications would have to include exactly the total dollar amount identified in the SDP approved by CMS. We did not propose this alternative as we are concerned that requiring the total amount for the separate payment term to act as both a minimum and maximum could be too administratively burdensome; however, we solicit comments on both our proposal to require that the total dollars documented in the SDP approved by CMS under (c)(2) would act as a maximum as well as this alternative option of the total dollars documented in the SDP approved by CMS under (c)(2)(i) as both a minimum and a maximum.

Historically, separate payment terms have only been documented in the State's preprint review and in the State's rate certifications; the details of when and how these payments would be made by the State to the plans was often not clear to CMS or the plans. This lack of clarity presents significant oversight concerns for these separate payment terms because it makes tracking the payments made from the State to the plan difficult to identify, particularly on the CMS-64 form on which States claim FFP. It also presents challenges for ensuring timely payment to plans and, ultimately, providers. CMS believes that just as the final capitation rates must be specifically identified in the applicable contract submitted for CMS review and approval, so too should separate payment terms associated with SDPs.

As previously noted in this section, CMS maintains that while there is risk for the providers as opposed to guaranteeing them payment irrespective of the Medicaid services they deliver to Medicaid managed care enrollees, there is often little or no risk for the plans related to the SDP to the extent it is included in contracts as a separate payment term, which is contrary to

the nature of risk-based managed care. This becomes even more concerning when States retroactively amend the separate payment term, sometimes even after the end of the rating period.

To illustrate this, we provide the following examples. Example 1: States that include SDPs into their contracts and rate certifications through separate payment terms must have the total dollars for the separate payment term certified in the rate certification(s). The State would then look at the utilization over a defined period, for example, one quarter, and divide one-fourth of the total dollars certified in the separate payment term by the utilization during that quarter to determine a uniform dollar amount increase. Example 1 illustrates a common practice for SDPs that use separate payment terms: it allows the uniform dollar amount applied to utilization to vary from one quarter to another, but it ensures that the total dollars dedicated to the State directed payment are fully expended.

Example 2: Some States have used this same methodology in example 1, but instead of having their actuaries certify the total dollar amount prospectively, they would have their actuaries certify an estimate of the total dollars and then have their actuaries recertify a higher amount later, often after all the payments under the separate payment term have been made.

Example 2 not only removes all risk from the plans for the SDP, but also removes all risk from the providers when the actuary recertifies a total dollar amount later, often after all the payments under the separate payment term have been made. Such practices are contradictory to the prospective nature of risk-based managed care. In our experience, such payment arrangements are not driven by furthering particular goals and objectives identified in the State's managed care quality strategy, but rather by the underlying financing of the non-Federal share associated with the SDPs. We note financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, fee-for-service, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c) or not.

To curtail these concerning practices, we propose to require as part of § 438.6(c)(6)(v) that States must document the separate payment term in the State's managed care contracts no later than 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later. We believe that proposing to require States to document the separate payment term within these timeframes is reasonable given that the contract amendment would only have to document the separate payment term and the related SDP; the contract action could be submitted to CMS in draft form so long as it included all of the required elements. CMS would not require a final signed copy of the amendment within this proposed 120-day timeframe; however, States would still be required to submit a final signed contract action prior to CMS' approval of the managed care contract.

To further the fiscal and programmatic integrity of separate payment terms, we propose in § 438.6(c)(6)(v)(A) to prohibit States from amending the separate payment term after CMS approval except to account for an amendment to the payment methodology that is first approved by CMS as an amendment to the approved State directed payment. We recognize that a change in payment methodology would potentially result in the need to amend the separate payment term as it could impact the total dollar amount. However, to avoid the current practice where States include a total dollar amount in the rate certification(s) other than what is in the approved SDP preprint, CMS is proposing to require that CMS first approve the amendment to the preprint before the separate payment term can be amended. We believe this proposal would also ensure that some level of risk is maintained and that States do not retroactively add additional funding with the goal of removing all risk from the SDP arrangement. Such actions do not align with the fundamental principles of Medicaid managed care.

Alternatively, we are also considering including a proposal to permit amendments to the separate payment term to account for a change in the total aggregate dollars to be paid by the State to the plan where there is no change in the non-Federal portion of the total aggregate dollars. We are considering this alternative in recognition that the Federal portion of the total

aggregate dollars may fluctuate due to Federal statute changes that are outside the State's control. We acknowledge that due to this, the total dollars, which includes the Federal share, cannot be perfectly predicted by States at the start of a State's rating period. We did not include this alternative proposal out of concern that it may have negative unintended consequences. We solicit comment on both the exception we are proposing and this alternative additional exception that we are considering.

To improve transparency of States' use of separate payment terms and to ensure that managed care plans have clear information on the contractual requirements associated to State directed payments linked to a separate payment term, in § 438.6(c)(6)(v)(B)(*1*) through (*4*), we propose four pieces of information that would be documented in the State's Medicaid managed care plan contracts: (1) the total dollars that the State would pay to the plans for the individual SDP that CMS gave written prior approval; (2) the timing and frequency of payments that would be made under the separate payment term from the State to the plans; (3) a description or reference to the contract requirement for the specific SDP for which the separate payment term would be used; and (4) any reporting that the State requires to ensure appropriate reporting of the separate payment term for purposes of MLR reporting under § 438.8.

Proposed Regulatory Changes – Rate Certification for Separate Payment Terms

To reflect our proposals discussed above that would require States to document separate payment terms in their managed care rate certifications, we propose changes to § 438.7. Specifically, we propose to add a new § 438.7(f) that would require the State, through its actuary, to certify the total dollar amount for each separate payment term as detailed in the State's Medicaid managed care contract, consistent with the requirements of § 438.6(c)(6). Requiring that all separate payment terms be included in the rate certification to plans is also current practice today and provides a complete picture of all payments made by States to plans under risk contracts.

We also propose to codify many existing practices that we currently employ when reviewing State directed payments that use separate payment terms. In § 438.7(f)(1), we propose that the State may pay each MCO, PIHP, or PAHP a different amount under the separate payment term compared to other MCOs, PIHPs, or PAHPs so long as the aggregate total dollars paid to all MCOs, PIHPs, and PAHPs does not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract. In § 438.7(f)(2), we propose that the State, through its actuary, would have to provide an estimate of the impact of the separate payment term on a rate cell basis, as paid out per the SDP approved by CMS under § 438.6(c)(2)(i). Both of these proposed regulatory requirements are part of current operational practice today as documented in the Medicaid Managed Care Rate Development Guide.[116] Having the estimated impact of the separate payment term on a rate cell basis helps to evaluate the actuarial soundness of the capitation rates. In § 438.7(f)(3), we propose that no later than 12 months following the end of the rating period, the State would have to submit documentation to CMS that includes the total amount of the separate payment term in the rate certification consistent with the distribution methodology described in the State directed payment for which the State obtained written prior approval to facilitate oversight and monitoring of the separate payment term.

Finally, we are proposing at § 438.7(f)(4) to require States to submit a rate certification or rate certification amendment incorporating the separate payment term within 120 days of either the start of the payment arrangement or written prior approval of the SDP, whichever is later. This proposal is aligned with the proposed contract requirement in § 438.6(c)(6)(v).

As previously noted we strongly prefer that SDPs be included as adjustments to capitation rates since that method is most consistent with the nature of risk-based managed care. Our proposals to amend § 438.6(a) to add a new definition for separate payment term, the

116 Medicaid Managed Care Rate Development Guides for every rating period are located at *https://www.medicaid.gov/medicaid/managed-care/guidance/rate-review-and-rate-guides/index.html.*

addition of §§ 438.6(c)(6) and 438.7(f) are intended to maintain the State's ability to use separate payment terms while implementing necessary guardrails for fiscal and programmatic oversight. However, given our longstanding concern with separate payment terms, CMS is considering, and invites comment on, requiring all SDPs to be included only through risk-based adjustments to capitation rates and eliminate the State's ability to use separate payment terms altogether in the final rule based on comments received. Prohibiting the use of separate payment terms would align with CMS' stated preference and would be most consistent with the nature of risk-based managed care. However, many States currently use separate payment terms for existing SDPs; prohibiting their use could cause some disruptions for States.

Another alternative CMS is considering, and invites comment on, is further prohibiting the use of separate payment terms not only to SDPs described in paragraphs (c)(1)(iii)(A) and (B), but to all SDPs described in paragraph (c)(1)(iii). Under this alternative, States would only be able to use separate payment terms for value-based initiatives described in paragraphs (c)(1)(i) and (ii). This alternative would still allow States to use separate payment terms for some payment arrangements and could incentivize States to consider quality-based payment models that can better improve health outcomes for Medicaid managed care enrollees. this proposal recognizes the difficulties that States and their actuaries may face in incorporating some value-based payment initiatives into capitation rate development as compared to fee schedules as described in paragraph (c)(1)(iii).

For each of these two alternatives, we acknowledge that some States currently use separate payment terms. Therefore, these alternative proposals could cause some disruptions as States evaluate changes to SDPs. If CMS adopts one of the alternatives for a total payment rate limit on SDP expenditures in the final rule, we also seek public comment on whether or not CMS should consider a transition period in order to mitigate any disruptions.

We seek public comment on whether either of these alternative approaches we are considering should be adopted in the final rule, as well as comments on our proposals.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comment on our proposals.

m. SDPs Included through Adjustments to Base Capitation Rates (§ 438.7(c)(4) through (6))

We also propose three additional changes to § 438.7(c) to address adjustments to managed care capitation rates that are used for SDPs. Specifically, we propose to add a new regulatory requirement at § 438.7(c)(5) specifying that retroactive adjustments to capitation rates resulting from an SDP must be the result of an approved SDP being added to the contract, an amendment to an already approved SDP, a State directed payment described in § 438.6(c)(1)(iii)(A) or (B), or a material error in the data, assumptions, or methodologies used to develop the initial rate adjustment such that modifications are necessary to correct the error. This requirement would align with the proposed requirement at § 438.6(c)(6)(v)(A). We believe this proposed regulatory requirement is necessary to ensure the fiscal integrity of SDPs and their impact on rate development. While not as frequent, we have also observed States, through their actuaries, submitting amendments to rates for SDPs included through adjustments to base rates that do not reflect changes in payment methodology, changes in benefit design, or general actuarial practices, but instead appear to be related to financing of the non-Federal share. We do not view such actions as consistent with the prospective and risk-based nature of Medicaid managed care. It also creates significant administrative burden for both States and the Federal government, by delaying review of associated rate certifications.

Additionally, we propose a new regulatory requirement at § 438.7(c)(4) that States must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under § 438.7(a) for any special contract provisions related to payment in § 438.6 not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell. States are permitted the flexibility under § 438.7(c)(3) to increase or decrease the capitation rate per rate cell up to 1.5 percent during the rating period without submitting a

revised rate certification for rate changes unrelated to special contract provisions, including SDPs, and ILOSs as proposed in section I.B.4.e. of this proposed rule. We believe that providing this same flexibility for changes to rates for special contract provisions, including SDPs, is incongruent with the existing requirement at § 438.7(b)(6) that the rate certification include a description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract. In addition, we believe it is also inconsistent with ensuring appropriate program integrity, such as the 105 percent threshold in 438.6(b)(2) and existing and proposed SDP standards. Therefore, our proposal here addresses and clarifies this requirement.

Finally, we propose a new regulatory requirement at § 438.7(c)(6) to require that States must submit the required rate certification documentation for SDPs incorporated through adjustments to base rates (either the initial rate certification or a revised rate certification) no later than 120 days after either the start date of the SDP approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) or 120 days after the date CMS issued written prior approval of the SDP, whichever is later.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comment on our proposals.

n. Appeals (§ 430.3(d))

As outlined under § 438.6(c), SDPs are arrangements that allow States to require managed care plans to make specified payments to healthcare providers when the payments support overall Medicaid program goals and objectives (for example, funding to ensure certain minimum payments are made to safety net providers to ensure access or quality payments to ensure providers are appropriately rewarded for meeting certain program goals). Section 438.6(c) was issued by CMS because this type of State direction of managed care payment goes against the general premise of managed care in which a contracted organization assumes risk from the State for the delivery of care to its beneficiaries. As a result, we established a process whereby

States must submit a "preprint" form to CMS to document how the SDP complies with the Federal requirements outlined in § 438.6(c). If the proposal does comply, we issue written prior approval. Subsequent to written prior approval, the SDP is permitted to be included in the relevant managed care organization contract and rate certification documents. This process is required by CMS for most SDPs.

As discussed throughout this proposed rule, the volume of State requests for written approval to implement State directed payment arrangements has grown significantly in both number and total dollars included in managed care plan capitation rates since § 438.6(c) was promulgated in the 2016 final rule.

Based on our review of SDP prior approval requests, we have observed that States use SDPs not only as routine payment mechanisms, such as to set minimum fee schedules or provide uniform increases, but also for more complex payment arrangements, such as to implement Total Cost of Care (TCOC) programs, and multi-metric and multi-year VBPs. CMS provides technical assistance to States at all stages of SDP development to help States develop SDP arrangements that meet their programmatic goals and comply with § 438.6(c). This technical assistance can involve both verbal and written assistance, as well as the exchange of CMS-generated question sets and State responses. The State responses are shared internally with Federal review partners who provide subject matter expertise, which may include those representing managed care policy and operations, quality, and actuarial science, which is then shared with the State to inform SDP revisions and ensure compliance with the regulations.

Providing this technical assistance has become increasingly challenging as the number and complexity of States' SDP requests has increased. To date, when CMS and States have found themselves unable to reach agreement on an SDP proposal and we are unable to issue prior written approval, States have agreed to withdraw the submission. However, as SDPs have matured as a State tool, they have outgrown this informal process of State rescission. The

proposals in this rule would further specify and strengthen the SDP regulations and we believe it is appropriate to begin formally disapproving proposals that cannot comply with the regulations.

A disapproval for an SDP could be issued for many reasons, including impermissible financing of the non-Federal share, failure to show improvement in the proposed quality evaluation report in the timeframe required, or non-compliance with the controlling regulations in part 438. To be consistent with other CMS processes which issue formal disapprovals, such as those for SPA submissions and disallowances of State Medicaid claims, there should be a formal process for States to appeal should CMS issue disapproval of written prior approval for a State's SDP proposal. The alternative is that a State may seek redress in the courts, which can be costly and slow for both CMS and the States. We believe that States will benefit from and appreciate an established, consistent administrative process with which they are familiar.

Under our authority under section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid, we propose to add a new § 430.3(d) that would explicitly permit disputes that pertain to written disapprovals of SDPs under § 438.6(c) to be heard by the Health and Human Services (HHS) Department Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16. As described in that section, the Board is comprised of members appointed by the HHS Secretary it conducts *de novo* review of certain agency decisions under the procedures at 45 CFR part 16 and its corresponding appendix A. The Board has a robust administrative adjudication process as well experience resolving disputes between CMS and States involving the Medicaid program, as it already reviews Medicaid disallowances under Title XIX of the Act using the procedures set forth at 45 CFR part 16.

Applying those procedures to CMS's decision to deny a State's SDP request, the State would have 30 days to appeal to the Board after an appellant receives a final written decision from CMS communicating a disapproval of a State directed payment. The case would then be assigned a presiding Board member who would preside over procedural matters and conduct record development in the case. Within 10 days of receiving the notice of appeal, the Board

would assess the filing for completeness and jurisdiction. If it is found to be appropriately filed, the Board would acknowledge the notice and outline the next steps in the case. Under existing 45 CFR 16.16, the Board may even allow additional parties to participate if there is a "clearly identifiable and substantial interest in the outcome of the dispute" in the discretion of the Board. The State would then have 30 days to file its appeal brief, which would contain its argument for why the final decision of CMS was in error, and its appeal file, which would include the documents on which its arguments are based. Then, CMS would have 30 days to submit its brief in response to the State's brief as well as any additional supporting documentation not already contained in the record. The State would be given fifteen days to submit its optional reply.

Under the Board's process, parties would be encouraged to work cooperatively to develop a joint appeal file and stipulate to facts alleviating the need to submit documentation. At any time, the Board may request additional documentation or information, request additional briefings, hold conferences, set schedules, issue orders to show cause, and take other steps as appropriate to "develop a prompt, sound decision" per existing 45 CFR 16.9. Although there is no general right to a hearing in cases heard under 45 CFR part 16, States appealing a CMS disapproval of a proposed State directed payment under this proposed process could request a hearing or oral argument, or the Board may call for one *sua sponte* should it determine its decision-making would be enhanced by such proceedings. Generally, the Board's proceedings are held in Washington, DC, but may be held in an HHS Regional Office or "other convenient facility near the appellant." Decisions are issued by the Board in three-member panels. Under 45 CFR 16.23, the Board has established general goals for its consideration of cases within 6 to 9 months; however, the paramount concern of the Board is to take the time needed to review a record fairly and adequately in order to produce a sound decision. Mediation may be used under 45 CFR 16.18 as an alternative or preliminary process to resolve the issues between the parties.

As an alternative to our proposal described above to use the Board for such decisions, we also considered permitting appeals of SDP written disapprovals to be heard by the CMS Offices

of Hearings and Inquiries (OHI) and the CMS Administrator for final agency action, as governed by part 430, subpart D. The current jurisdiction of OHI stems from section 1902 of the Act, under which it hears appeals arising from decisions to disapprove Medicaid State Plan material under § 430.18 or to withhold Federal funds under § 430.35 for noncompliance of a State Plan. The OHI process is overseen by a presiding officer who makes a recommendation to the Administrator, who issues the final decision. The process is initiated upon issuance of a written disapproval.

If we were to use this process for disapproval of SDPs, the hearing officer would mail the State a notice of hearing or opportunity for hearing related to an SDP disapproval that is also published in the **Federal Register**. The hearing would be scheduled either in the CMS Regional Office or another place designated by the hearing officer for convenience and necessity of the parties between 30 and 60 days after notice. Before the hearing, issues may be added, removed, or modified, to also be published in the Federal Register and with twenty days' notice to the State before the hearing, unless all issues have been resolved, in which case the hearing is terminated.

Under this process, the State and CMS would be given 15 days to provide comment and information regarding the removal of an issue. Before the hearing, other individuals or groups would be able to petition to join the matter as a party within 15 days after notice is posted in the **Federal Register**. The State and CMS would be able to file comments on these petitions within five days from receipt. The presiding officer would determine whether to recognize additional parties. Alternatively, any person or organization would be able to file an *amicus curiae* (friend of the court) as a non-party, should their petition to do so be granted. The parties would have the right to conduct discovery before the hearing under § 430.86 and to participate in prehearing conferences under § 430.83.

At the hearing, parties would make opening statements, submit evidence, present and cross-examine witnesses, and present oral arguments.[117] The transcript of the hearing along with stipulations, briefs, and memoranda would be filed with CMS and may be inspected and copied in the office of the CMS Docket Clerk. After the expiration of the period for post hearing brief, the presiding officer would certify the record and recommendation to the Administrator. The Administrator would serve a copy to the parties who have 20 days to file exceptions or support to the recommendation. The Administrator would then issue its final decision within 60 days. The decision of the Administrator under this section is the final decision of the Secretary and constitutes "final agency action" within the meaning of 5 U.S.C. 704 and a "final determination" within the meaning of section 1116(a)(3) of the Act and § 430.38. Should the Administrator preside directly, they will issue a decision within 60 days after expiration of the period for submission of post hearing briefs. Hearings using this CMS/OHI and Administrator review process most often take over 1 year to reach final resolution.

We believe the Board would be the most appropriate entity to hear appeals of disapprovals of SDPs proposals for the following reasons. Foremost, while both the Board's and OHI's processes can resolve disputes, we believe the Board's shorter goal resolution time of 6 to 9 months would better facilitate timely approval of managed care plan contracts and the payment of capitation payments. Medicaid managed care uses a prospective payment system of capitation payments and anything that delays approval of the managed care plans' contracts can have a significant adverse impact on a State's managed care program. Additionally, the Board's processes have the added flexibilities of allowing for mediation under 45 CFR 16.18, as well as not requiring, but allowing, a hearing, as described in 45 CFR 16.11. These differences in the Board regulations give additional options and possible efficiencies to the parties. Therefore, while we believe both processes would be adequate for appeals of any disapproval of a State

117 42 CFR 430.83

directed payment, for the reasons described above, we believe the processes under the Board would be the most appropriate proposal for inclusion in § 430.3(d).

We seek public comment on whether the Board or OHI appeals processes would best serve the purposes of resolving disputes fairly and efficiently.

o. Reporting Requirements to Support Oversight (§ 438.6(c)(4))

Many States with managed care programs are using the authority in § 438.6(c) to direct managed care plans' payments to certain providers. States' increasing use of these arrangements has been cited as a key area of oversight risk for CMS. Several oversight bodies, including MACPAC, OIG, and GAO, have authored reports focused on CMS oversight of SDPs.[118,119,120] Both GAO and MACPAC have recommended that we collect and make available provider-specific information about Medicaid payments to providers, including SDPs.

As discussed in section I.B.3. of this proposed rule, CMS' current review and approval process for SDPs is prospective; that is, we do not consistently nor systematically review the actual amounts that States provide to managed care plans for these SDPs[121] nor the actual amounts that managed care plans pay to providers. CMS published a revised preprint form in January 2021 that requires States to provide an estimated total dollar amount that will be included in the capitation rates for the SDP arrangement[122]; however, States are not required to report to CMS on the actual expenditures associated with these arrangements in any separate or identifiable way. On a limited basis, we perform in-depth State-level medical loss ratio (MLR)

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118 Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.

119 U.S. Department of Health and Human Services Office of the Inspector General, "Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program," A-06-18-07001, December 21, 2020, available at *https://oig.hhs.gov/oas/reports/region6/61807001.asp*.

120 U.S. Government Accountability Office, "Medicaid: State Directed Payments in Managed Care," June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

121 Consistent with the requirements for separate payment terms outlined in the Medicaid managed care rate guide, CMS requires States to (1) submit documentation to CMS includes the total amount of the payment into the rate certification's rate cells consistent with the distribution methodology included in the approved State directed payment preprint, as if the payment information had been known when the rates were initially developed; and (2) submit a rate amendment to CMS if the total amount of the payment or distribution methodology is changed from the initial rate certification.

122 *https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf.*

reviews and Financial Management Reviews (FMRs) that include the actual amounts paid through SDPs. But without the systematic collection of actual payment amounts, we cannot determine exactly how much is being paid under these arrangements, to what extent actual expenditures differ from the estimated dollar amounts approved by CMS under a State's proposal, and whether Federal funds are at risk for impermissible or inappropriate payments.

We concur with the oversight bodies that it is important that we gain more information and insight into actual SDP spending to help us fulfill our oversight and monitoring obligations. We propose two approaches, one near term and one longer term, for collecting both aggregate and provider-level information. The first proposal would use existing MLR reporting as a vehicle to collect actual expenditure data associated with SDPs. Specifically, in § 438.8(k), we propose to require that managed care plans include SDPs and associated revenue as separate lines in their MLR reports to States; specifically, the amount of payments to providers made under SDPs that direct the managed care plan's expenditures as specified in § 438.6(c) and the payments from the State to the managed care plans for expenditures related to these SDPs. In turn, we propose to require that managed care plan-level SDP expenditure reporting be explicitly reflected in States' annual summary MLR reporting to CMS, as required under § 438.74. See section I.B.3. of this proposed rule for more information about these proposals.

We also propose to establish a new requirement at § 438.6(c)(4) for States to annually submit data, no later than 180 days after each rating period, to CMS' Transformed Medicaid Statistical Information System (T-MSIS), and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs that were in effect for the rating period, including amounts paid to individual providers. The purpose of this reporting would be to gain more information and insight into actual SDP spending at the individual provider-level. As MACPAC noted in their June 2022 Report to Congress, "[State directed payments] are a large and rapidly growing form of Medicaid payments to providers, but we do not have provider-level data on how billions of dollars in directed payments are being

spent".[123] The Commission noted that SDPs are larger than Disproportionate Share Hospital (DSH) and Upper Payment Limit (UPL) supplemental payments, but there is much less data on who is receiving them.[124] Currently, States must provide CMS with specific information for FFS supplemental payments that are made to individual providers; however, there is no such requirement for States or managed care plans to provide this type of quantitative, provider-specific data separately for SDPs. We believe implementing a provider-level SDP reporting requirement would facilitate our understanding of provider-level Medicaid reimbursement across delivery systems.

We propose to develop and provide the form through which the reporting would occur so that there would be one uniform template for all States to use. We propose in § 438.6(c)(4) the minimum data fields that would need to be collected to provide the data needed to perform proper oversight of SDPs. Proposed § 438.6(c)(4)(i) through (v) outlines the minimum data fields: provider identifiers, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, and allowed, billed, and paid amounts. Paid amounts would include the amount that represents the managed care plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. When contemplating the FFS supplemental payment reporting, we considered how States should have the information being requested readily available, "[i]ncluding the provider-specific payment amounts when approved supplemental payments are actually made and claimed for FFP, as the aggregate expenditures reported on the CMS-64 comprise the individual, provider-specific payment amounts".[125] Similarly, we believe States and their managed care plans already collect provider-level SDP

123 Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.
124 Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-2-Oversight-of-Managed-Care-Directed-Payments-1.pdf*.
125 *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

data, including the negotiated rate between the plan and provider and any additional SDPs (or pass-through payments specified at § 438.6(d)) that are made to the provider. We seek comment on whether these are the appropriate minimum data fields to require and what provider-level SDP data States currently collect as part of their monitoring and oversight of SDPs.

We recognize that there are existing data collection processes and systems established between CMS and States that could likely support this SDP reporting, and would like to rely on these systems to the extent they could help minimize additional or duplicative reporting by States. For instance, we considered the existing system and reporting structure that States are using for FFS supplemental payment reporting. The Consolidated Appropriations Act (CAA) of 2021 established new reporting requirements for Medicaid FFS supplemental payments under both State plan or demonstration authorities consistent with section 1902(a)(30)(A) of the Act.[126,127] We issued guidance in December 2021 outlining the information that States must report to CMS as a condition of approval for a State plan or SPA that would provide for a supplemental payment, beginning with supplemental payments data about payments made on or after October 1, 2021.

Under these FFS requirements, each quarter, each State must submit reports on supplemental payment data through the Medicaid Budget and Expenditure System (MBES), as a requirement for a State plan or State plan amendment that would provide for a supplemental payment. The data collection involves both narrative information, as well as quantitative, provider-specific data on supplemental payments. The narrative information includes descriptions of the supplemental payment methodology, determination of eligible providers, description of the timing of the payments, and justification for compliance with section 1902(a)(30)(A) of the Act. The quantitative, provider-specific data collection includes detailed

126 The CAA included Division CC, Title II, Section 202 (section 202), which added section 1903(bb) of the Act to specify new supplemental payment reporting requirements.

127 Demonstration authority includes uncompensated care (UC) pool payments, delivery system reform incentive payments (DSRIP), and possibly designated State health program (DSHP) payments to the extent that such payments meet the definition of supplemental payment as specified in section 1903(bb)(2) of the Act.

provider-specific accounting of supplemental payments made within the quarter, including: provider name, provider ID number, and other provider identifiers; Medicaid authority (FFS or demonstration authority); Medicaid service category for the supplemental payments; aggregate base payments made to the provider; and aggregate supplemental payments made to the provider, which will reflect the State's claim for Federal financial participation.

This supplemental payment reporting is included in the MBES to capture the entire set of data reporting elements required in section 1903(bb)(1)(B) of the Act in one central location. MBES is familiar to States, in part because of State's quarterly expenditure reporting on the CMS-64 form. We can view additional reporting of provider-specific base and supplemental FFS payment amount information in MBES in the context of actual State expenditures for Medicaid. We could consider taking a similar approach for SDPs by adding reporting in MBES to capture provider-specific SDP data.

As another option, we considered encounter data reported through T-MSIS as the method for collecting SDP provider-specific payment amounts. Specifically, T-MSIS could work well for SDPs that are specifically tied to an encounter or claim, such as minimum fee schedules or uniform dollar or percentage increases. Current regulations at § 438.242(c)(3) require States to submit all enrollee encounter data, including the allowed amount and paid amounts, and these paid amounts should be inclusive of State directed payments that are tied to an encounter or claim. We could build additional data fields in T-MSIS to capture more details about the paid amount, including the amount that was the managed care plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total payment amount paid to the provider. This level of detail would provide the information we need for analysis and oversight of SDP spending, and it would be consistent with the managed care plan payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this proposed rule). There are various fields currently captured in T-MSIS via monthly encounter submissions (for example, national provider

identifier, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, billed, allowed, and paid amounts) that could help us determine provider-specific SDP reimbursement. We believe utilizing T-MSIS in this manner would substantially reduce unnecessary or duplicative reporting from States, would be an effective method to collect the data with minimal additional burden on managed care plans and States, and it would enable comprehensive analyses since the data would be included with all other T-MSIS data.

Lastly, we considered whether to utilize a separate reporting mechanism for this new reporting of SDP provider-level data. For example, we could explore building a new reporting portal, similar to the one developed for the submission of the Managed Care Program Annual Report. However, this would take considerable time and resources to develop and would be separate and distinct from all other SDP data, making it more difficult to perform comprehensive analyses. We also considered whether to permit States to submit the proposed reporting using a Word or Excel template sent to a CMS mailbox. While this would be the fastest way to collect the data, it too presents challenges for integrating the data with other data collected by CMS for analyses.

Because we believe T-MSIS to be the most efficient option, we propose in § 438.6(c)(4) to require States to submit data to T-MSIS as the method for collecting provider-specific payment amounts under SDPs. As specified in proposed § 438.6(c)(4)(i)(E), provider-specific paid amounts would include a plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. States would submit this data to CMS no later than 180 days after each rating period. We believe 180 days permits adequate time for claims run out, submission of the necessary data to the State, and for the State to format the data for submission to CMS. We also propose in § 438.6(c)(4) that States would have to comply with this new reporting requirement after the rating period that begins after we release reporting instructions for submitting the information required by this proposal. We seek public comment

on our proposal to use T-MSIS for this new reporting, or whether another reporting vehicle such as MBES, or other alternatives described in this proposed rulemaking would be better suited for SDP reporting. We also seek comment on how T-MSIS or another reporting vehicle could support capturing value-based payment arrangements in which payment is not triggered by an encounter or claim.

We also propose a conforming requirement at § 438.6(c)(5)(iv) to align with the proposal in § 438.6(c)(4); proposed paragraph (c)(5)(iv) would require States to document any reporting requirements necessary to comply with § 438.6(c)(4) in their managed care contracts.

We consider these data reporting proposals to be a two-prong approach, with the MLR proposed requirements explained in section I.B.3. of this proposed rule serving as a short-term step and the provider-specific data reporting proposed here being a longer-term initiative. We believe this would ensure the appropriate content and reporting while also giving States sufficient time to prepare for each proposal based on the level of new burden. While some managed care plans and States may assert that these proposals increase administrative burden unnecessarily, we believe that the increased transparency associated with these enhanced standards would benefit both State and Federal government oversight of SDPs. Implementing these proposals for State and managed care plan reporting of actual SDP expenditures would provide CMS more complete information when evaluating, developing, and implementing possible changes to Medicaid payment policy and fiscal integrity policy.

For discussion on the proposed applicability dates for the proposals outlined in this section, see section I.B.2.p. of this proposed rule.

We solicit public comment on these proposals.

p. Applicability and Compliance Dates (§§ 438.6(c)(4) and (c)(8), and 438.7(g)(2))

We propose that States and managed care plans would have to comply with § 438.6(a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) through (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv), and 438.7(c)(4), (c)(5), and (f)(1) through (3) upon

the effective date of the final rule, as these proposals are either technical corrections or clarifications of existing policies and standards. We propose that States and managed care plans would have to comply with § 438.6(c)(2)(iii), (vi)(B), (vi)(C)(*1*) and (*2*) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as these newly proposed requirements will provide States with increased flexibility and not require States to make changes to existing arrangements. We propose that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(H), (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(vii), (c)(2)(viii) and (ix), and (c)(5)(i) through (v) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after the effective date of the final rule. We believe this is a reasonable timeframe for compliance because it allows States sufficient time to operationalize the timelines and requirements for preprint submissions that are newly established in these proposals while balancing the need to strengthen CMS oversight.

We further propose that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(D), (F), (c)(2)(iv), (c)(2)(v), and (c)(7) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of the final rule as we believe States will need a sufficient period of time to address the policy elements within these proposals and operationalize them via various reporting, documentation and submission processes. For § 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7), we are considering requiring compliance for the first rating period beginning on or after 1 year, or 2 years after the effective date of the final rule, but we are proposing the first rating period beginning on or after 3 years after the effective date of the final rule because we believe it strikes a balance between the work States would need to do to comply with these proposals and the urgency with which we believe these proposals should be implemented in order to strengthen and ensure appropriate and efficient operation of the Medicaid program. We solicit comment on the proposal and alternatives.

We propose that States and managed care plans would have to comply with §§ 438.6 (c)(5)(vi), and (c)(6)(v), and 438.7(c)(6) and (f)(4) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after the effective date of the final rule. Because these proposals establish new submission timelines and new requirements for contract and rate certification documentation, and because States could view the new requirements as substantial changes to the SDP process, we are proposing a longer timeline for compliance. We are considering requiring compliance no later than the first rating period beginning on or after 3 years after effective date of the final rule to align with the compliance dates in the proposals described in the paragraph above; however, to provide States adequate time to implement strong policies and procedures to address the newly proposed requirements before submitting the relevant contract and rate certification documentation, we are proposing the longer period for States to adjust and come into compliance. We solicit comment on the proposal and alternative.

Finally, as outlined in proposed § 438.6(c)(4), States would be required to submit the initial TMSIS report subsequent to the first rating period following the release of CMS guidance on the content and form of the report.

We have proposed these applicability dates in §§ 438.6(c)(4) and (c)(8), and 438.7(g).

We solicit public comment on these proposals.

3. Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.3, and 457.1203)

In the 2016 final rule, we finalized Medicaid and CHIP managed care regulations in §§ 438.8(k) and 457.1203(f) respectively, that require managed care plans to annually submit reports of their MLR to States, and, at §§ 438.74 and 457.1203(e) respectively, we require States to submit annually a summary of those reports to CMS. These sections were issued based on our authority under sections 1903(m)(2)(A)(iii), 1902(a)(4), and 2101(a) of the Act based on the rationale that actuarially sound capitation rates must be utilized for MCOs, PIHPs, and PAHPs. Additionally, actuarial soundness requires that capitation payments cover reasonable,

appropriate, and attainable costs in providing covered services to enrollees in Medicaid managed care programs. We propose to amend our requirements under the same authority and rationale that we describe below.

Medical loss ratios are one tool that CMS and States can use to assess whether capitation rates are appropriately set by generally illustrating how capitation funds are spent on claims and quality improvement activities as compared to administrative expenses. More specifically, MLR calculation and reporting can be used to demonstrate that adequate amounts of the capitation payments are spent on services for enrollees. With MLR reporting, States have more information to understand how the capitation payments made for enrollees in managed care programs are expended, resulting in responsible fiscal stewardship of total Medicaid and CHIP expenditures.

Medicaid and CHIP managed care MLR reporting requirements align, generally, with Marketplace standards for Qualified Health Plans (QHPs) and Medicare Advantage standards for Medicare Advantage organizations (MAOs). As we noted in the preamble to the 2015 managed care proposed rule[128], alignment with Marketplace or Medicare Advantage standards supports administrative simplicity for States and health plans to manage health care delivery across different product lines and eases the administrative burden on issuers and regulators that work in all of those contexts and markets (80 FR 31101). We also noted that a consistent methodology across multiple markets (private, Medicare, Medicaid, and CHIP) would allow for administrative efficiency for the States in their roles regulating insurance and Medicaid/CHIP, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports. In addition, a consistent standard would allow comparison of MLR outcomes consistently from State to State and among commercial, Medicare, and Medicaid/CHIP managed care plans (80 FR 31107).

In general, Medicaid and CHIP managed care MLR reporting requirements have remained aligned over time with the Marketplace MLR requirements; however, CMS finalized

128 *https://www.govinfo.gov/content/pkg/FR-2015-06-01/pdf/2015-12965.pdf.*

some regulatory changes for QHP MLR reporting in 45 CFR 158.140, 158.150, and 158.170 effective July 1, 2022.[129] To keep the Medicaid and CHIP managed care regulations aligned with these new Marketplace provisions, we propose several revisions to our requirements in the following areas:

- Requirements for clinical or quality improvement standards for provider incentive arrangements;
- Prohibited administrative costs in quality improvement activity (QIA) reporting; and
- Additional requirements for expense allocation methodology reporting.

In addition, we propose changes to specify timing of updates to credibility adjustment factors; when Medicaid and CHIP managed care plans are required to resubmit MLR reports to the State; the level of data aggregation required for State MLR summary reports to CMS; contract requirements related to reporting of overpayments; and new reporting requirements for SDPs.

a. Standards for Provider Incentives (§§ 438.3(i), 438.8(e)(2), 457.1201, and 457.1203)

We are revising standards for provider incentives to remain consistent with our goals of alignment with the Marketplace when appropriate, and to ensure that capitation rates are actuarially sound and based on reasonable expenditures for covered services under the contract. Under section 1903(m)(2)(A)(iii) of the Act and implementing regulations, FFP is not available for State expenditures incurred for payment (as determined under a prepaid capitation basis or under any other risk basis) for services provided by a managed care plan unless the prepaid payments are made on an actuarially sound basis. This requirement is made applicable to PIHPs and PAHPs under authority in section 1902(a)(4) of the Act. As specified in current regulations at § 438.4(a), actuarially sound Medicaid capitation rates are projected to provide for all reasonable, appropriate, and attainable costs as well as the operation of the MCO, PIHP, or

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129 *https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023.*

PAHP required under the terms of the contract.

While Medicaid managed care plans are required to calculate and report an MLR to the State, States are not required to establish a minimum MLR requirement; although under current regulations at § 438.4(b)(9), capitation rates must be developed in a way that the managed care plan would reasonably achieve an MLR of at least 85 percent. Under current regulations at § 438.8(c), if a State elects to require that their managed care plans meet a minimum MLR requirement, the minimum must be set to at least 85 percent. Further, under § 438.8(j), States may establish a remittance arrangement based on an MLR requirement of 85 percent or higher. As a general matter, remittance arrangements based on minimum MLRs may provide value to States by requiring managed care plans to remit a portion of their capitation payments to States when spending on covered services and QIAs is less than the minimum MLR requirements.

At existing §§ 438.3(i)(1) and 457.1201(h), respectively, Medicaid and CHIP managed care plan contracts must require compliance with the provider plan incentive requirements in §§ 422.208 and 422.210.[130] In this section, we refer to the term "incentive" to mean both incentive and bonus payments to providers. Under § 422.208(c), managed care plans may enter into a physician incentive plan with a health care provider, but plans must meet requirements applicable to those arrangements in § 422.208(c) through (g), and under § 422.208(c)(1) plans cannot make a payment, directly or indirectly, as an inducement to reduce or limit medically necessary services. A Medicaid and CHIP managed care plan may make incentive payments to a provider if the provider agrees to participate in the plan's provider network. These payment arrangements may be based solely on an amount negotiated between the plan and the provider. Medicaid and CHIP managed care plans can implement provider incentive arrangements that are not based on quality improvement standards or metrics; however, provider incentive payments must be included as incurred claims when managed care plans calculate their MLR, per

130 As specified in § 438.3(i)(2), in applying the provisions of §§ 422.208 and 422.210 of this chapter, references to "MA organization," "CMS," and "Medicare beneficiaries" must be read as references to "MCO, PIHP, or PAHP," "State," and "Medicaid beneficiaries," respectively.

§§ 438.8(e)(2)(iii)(A) and 457.1203(c) respectively. Further, provider incentive payments may influence the development of future capitation rates, and Medicaid managed care plans may have a financial incentive to inappropriately pay provider incentives when the plans are unlikely to meet minimum MLR requirements. Additionally, these payments may inappropriately inflate the numerator of the MLR calculation and reduce or eliminate remittances, if applicable. Additionally, including such data in the base data used for rate development may inappropriately inflate future capitation rates.

Vulnerabilities with Managed Care Plans' Provider Incentive Contracting Practices

As part of our Medicaid managed care program integrity oversight efforts, CMS recently conducted several in-depth reviews of States' oversight of managed care plan MLR reporting. These reviews included examinations of the contract language for provider incentive arrangements between managed care plans and network providers. As part of these reviews, CMS identified several examples of managed care plan practices that could make an incentive payment inappropriate to include in the numerator. For example, there were inconsistent documentation and contracting practices for incentive payments in contracts between some Medicaid managed care plans and their network providers, including State acceptance of attestations of these arrangements from senior managed care plan leadership when contract documentation was lacking. These reviews also noted that many managed care plans' contracts with network providers did not base the incentive payments on a requirement for the providers to meet quantitative clinical or quality improvement standards or metrics. In fact, examination of these contracts between managed care plans and their network providers revealed that some managed care plans did not require a provider to improve their performance in any way to receive an incentive payment. Additionally, many of the incentive arrangements were not developed prospectively with clear expectations for provider performance. Finally, we identified provider incentive performance periods that did not align with the MLR reporting period and provider incentive contracts that were signed after the performance period ended.

Contract Requirements for Provider Incentive Payment Arrangements

Based on these reviews, we are concerned that if a provider incentive arrangement is not based on basic core contracting practices (including sufficient supporting documentation and clear, prospective quantitative quality or performance metrics), it may create an opportunity for a managed care plan to more easily pay network providers solely to expend excess funds to increase their MLR numerator under the guise of paying incentives. This potential loophole could also be used to help managed care plans avoid paying remittances. Also, this practice could artificially inflate future capitation rates. To address these concerns, we are proposing additional requirements on provider incentive arrangements in § 438.3(i).

In a new § 438.3(i)(3) and (4) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1201(h), we propose to require that the State, through its contract(s) with a managed care plan, must include specific provisions related to provider incentive contracts. Specifically, the proposed changes would require in § 438.3(i)(3)(i) and (ii) that incentive payment contracts between managed care plans and network providers have a defined performance period that can be tied to the applicable MLR reporting period(s), and such contracts must be signed and dated by all appropriate parties before the commencement of the applicable performance period. We also propose, in § 438.3(i)(3)(iii), that all incentive payment contracts must include well-defined quality improvement or performance metrics that the provider must meet to receive the incentive payment. In addition, in § 438.3(i)(3)(iv), we propose that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of these metrics as well as a date of payment. We note that managed care plans would continue to have flexibility to determine the appropriate quality improvement or quantitative performance metrics to include in the incentive payment contracts. In addition, the proposed changes would also require in § 438.3(i)(4)(i) that the State's contracts must define the documentation that the managed care plan must maintain to support these arrangements. In § 438.3(i)(4)(ii), we propose that the State must prohibit managed care plans from using

attestations as documentation to support the provider incentive payments. In § 438.3(i)(4)(iii), we propose that the State's contracts require that managed care plans must make the incentive payment contracts and supporting documentation available to the State both upon request and at any routine frequency that the State establishes. Finally, we propose that States and managed care plans would have to comply with § 438.3(i)(3) and (4) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. Therefore, we have proposed this applicability date in § 438.3(v) for Medicaid, and through a proposed cross-reference at § 457.1200(d) for separate CHIPs, and we seek public comment on this proposal. Other changes proposed to § 438.3(v) are outlined in section I.B.4.i. of this proposed rule.

We also propose to amend § 438.608 to cross-reference these requirements in the program integrity contract requirements section. Specifically, we propose to add a new § 438.608(e) that notes the requirements for provider incentives in § 438.3(i)(3) and (4). This proposed requirement is equally applicable for separate CHIPs through an existing cross-reference at § 457.1285.

Alignment with Marketplace Regulations for Provider Incentive Arrangements[131]

Effective July 1, 2022, the Marketplace regulations at 45 CFR 158.140(b)(2)(iii) were revised to require issuers to tie provider bonuses and incentives payments to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards for these costs to qualify as expenditures in the MLR numerator. In contrast, current Medicaid and CHIP managed care regulations for provider incentive arrangements do not require these payments to be based on quality or performance metrics. This inconsistency hinders the comparison of MLR data between the Marketplace issuers and Medicaid and CHIP managed care plans, which is important given the high number of health plans that are both sold in the

131 *https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023*.

Marketplace and Medicaid managed care plans as well as the frequent churn of individuals between Marketplace, Medicaid, and CHIP coverage. To address the potential for inappropriate inflation of the MLR numerator as well as facilitate data comparability, we propose in § 438.8(e)(2)(iii)(A) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to require that for a provider bonus or incentive payment to be included in the MLR numerator, the provider bonus or incentive arrangement would have to require providers to meet clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards to receive the bonus or incentive payment. This change would prohibit Medicaid and CHIP managed care plans from including provider bonus or incentive payments that are not based on clinical or quality improvement standards in their MLR numerator, which would improve the accuracy of their MLR, as well as other components of managed care programs that rely on reported MLRs, such as capitation rate development and remittances. Further, a consistent methodology across multiple markets would allow for administrative efficiency for the States as they monitor their Medicaid and CHIP programs, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports.

We believe that by requiring States' contracts with managed care plans to specify how provider bonus or incentive payment arrangements would be structured in managed care plans' provider contracts, transparency around these arrangements would improve. In addition, by requiring the contracts to include more specific documentation requirements, CMS and States would be better able to ensure that provider bonus or incentive payments are not being used either to inappropriately increase the MLR to avoid paying potential remittances, inflate future capitation rates, or to simply move funds from a Medicaid managed care plan to an affiliated company. The proposals would increase transparency into provider bonuses and incentives, improve the quality of care provided by ensuring that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care, and protect Medicaid and CHIP

programs against fraud and other improper payments. We are seeking comment on these proposed requirements, including whether any additional documentation requirements should be specified in regulation. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough. We seek comment on this proposal.

b. Prohibited Costs in Quality Improvement Activities (§§ 438.8(e)(3) and 457.1203(c))

The preamble to the Marketplace regulations that took effect on July 1, 2022 indicated that examinations of MLR reporting of issuers found "wide discrepancies in the types of expenses that issuers include in QIA expenses" and that inconsistency "creates an unequal playing field among issuers" (87 FR 692). Therefore, to provide further clarity on the types of costs that may be included in MLR calculations in the future, CMS modified Marketplace regulations for QIA expenditures in 45 CFR 158.150(a), effective July 1, 2022, to prohibit the inclusion of indirect or overhead expenses that do not directly improve health care quality when reporting QIAs.

In Medicaid and separate CHIP regulations at §§ 438.8(e)(3) and 457.1203(c) respectively, we included QIA activities that meet the Marketplace MLR requirements, but we did not explicitly include a prohibition on managed care plans including indirect or overhead expenses when reporting QIA costs in the MLR because the commercial regulations did not have this exclusion at the time. As a result, the current Medicaid MLR regulations do not require managed care plans to exclude indirect or overhead QIA expenditures. For example, expenditures for facility maintenance, utilities, or marketing may be included in the MLR even though these expenses do not directly improve health care quality. As a result, Medicaid or CHIP managed care plans may include these types of costs as QIA costs in the MLR numerator, which

could result in inappropriately inflated MLRs, and a different standard existing in the Marketplace and Medicaid and CHIP markets. This difference in standards could pose a potential administrative burden for managed care plans that participate in both Medicaid and CHIP and the Marketplace because managed care plans may include different types of expenses in reporting QIA.

To align Medicaid and CHIP MLR QIA reporting requirements with the Marketplace requirements and to improve clarity on the types of QIA expenditures that should be included in the MLR numerator, we propose to amend § 438.8(e)(3)(i) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to add a reference to the Marketplace regulation that prohibits the inclusion of overhead or indirect expenses that are not directly related to health care quality improvement. This change would provide States with more detailed QIA information to improve MLR reporting consistency, allow for better MLR data comparisons between the Marketplace and Medicaid and CHIP markets, and reduce administrative burden for managed care plans that participate in both Medicaid and CHIP and the Marketplace. We propose that these requirements would be effective 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough. We seek comment on the applicability date for these proposals.

c. Additional Requirements for Expense Allocation Methodology (§§ 438.8(k)(1)(vii) and 457.1203(f))

As specified in current regulations at §§ 438.8(k)(1)(vii) and 457.1203(f) respectively, Medicaid and CHIP managed care plans must provide a report of the methodology or methodologies that they used to allocate certain types of expenditures for calculating their MLR. Examples of these types of expenditures include overhead expenses such as facility costs or

direct expenses such as employee salaries. If a plan operates multiple lines of business, for example in both Medicaid and the Marketplace, it must indicate in the Medicaid MLR report how the share of certain types of costs were attributed to the Medicaid line of business. However, the Medicaid MLR regulations in § 438.8(g) and (k)(1)(vii) do not require managed care plans to submit information about the types of expenditures allocated to the Medicaid line of business and do not require managed care plans to specify how each type of expenditure was allocated to the Medicaid MLR.

Recent CMS State-level Medicaid MLR reviews noted a lack of expense allocation information in managed care plans' MLR reports to States. Specifically, CMS determined that several plans operated in multiple markets, for example, Medicaid and Medicare Advantage, and failed to adequately describe how certain costs that may apply across multiple lines of business were allocated to the Medicaid MLR report. Examples of these expenses include: quality improvement expenses, taxes, licensing or regulatory fees, and non-claims costs. The impact of this lack of transparency is that it may be impossible for a State to determine if the managed care plan's allocation of the applicable expenses to the Medicaid line of business was reasonable. For example, if a managed care plan operating in multiple markets does not provide information on how quality improvement activity expenses were allocated to the Medicaid MLR, the State will be unable to determine if the MLR numerator is inappropriately inflated.

The Marketplace regulations in 45 CFR 158.170(b) require significantly more detail for expense allocation in QHPs' MLR reporting. Specifically, § 158.170(b) requires a description of the types of expenditures that were allocated, how the expenses met the criteria for inclusion in the MLR, and the method(s) used to aggregate these expenses. We propose to require in § 438.8(k)(1)(vii) for Medicaid, which is included in CHIP regulations through an existing cross-reference at § 457.1203(f), that managed care plans must include information that reflects the same information required under Marketplace requirements in the MLR report that they submit to the State. Specifically, in § 438.8(k)(1)(vii), we propose to add to the existing text that plans'

descriptions of their methodology must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described § 158.170(b). These revisions would improve State MLR oversight by providing States with more detailed information to ensure the appropriateness of managed care plans' expense allocation. These proposed requirements would align with Marketplace regulations and reduce administrative burden for managed care plans. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned that is not soon enough. We seek comment on this proposal.

d. Credibility Factor Adjustment to Publication Frequency (§§ 438.8(h)(4) and 457.1203(c))

Section 2718(c) of the Public Health Service Act charged the National Association of Insurance Commissioners (NAIC) with developing uniform methodologies for calculating measures of the expenditures that make up the MLR calculation, and to address the special circumstances of smaller plans. The NAIC model regulation allows smaller plans to adjust their MLR calculations by applying a "credibility adjustment." Under §§ 438.8(h) and 457.1203(c) respectively, Medicaid and CHIP managed care calculated MLRs may be adjusted using credibility factors to account for potential variability in claims due to random statistical variation. These factors are applied to plans with fewer enrollees to adjust for the higher impact of claims variability on smaller plans. As stated in § 438.8(h)(4), CMS is responsible for developing and publishing these factors annually for States and managed care plans to use when reporting MLRs for plans with fewer enrollees. In the 2015 Medicaid and CHIP managed care proposed rule (80 FR 31111), we proposed adopting a credibility adjustment methodology along with assurances to monitor and reevaluate credibility factors "in light of developing experience with the Affordable

Care Act reforms." In the 2015 proposed rule (80 FR 31111), we also proposed to update the credibility adjustment method within the parameters of the methodology proposed in that proposed rule. We finalized this proposal without revision in the 2016 final rule (81 FR 27864). The Medicaid managed care credibility adjustment factors were published on July 31, 2017 at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib073117.pdf*.

Since this publication of the credibility adjustment factors in 2017, the factors have not changed. The factors were originally developed using a statistical model applying the Central Limit Theorem (80 FR 31111). This model produced credibility factors that were not expected to change annually. Therefore, we believe that annual updates to these factors are not required, and we propose to modify § 438.8(h)(4) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(c), to remove "On an annual basis." If we determine that the factors need to be updated, we would use the methodology specified at § 438.8(h)(4)(i) through (vi). We are not proposing any revisions to § 438.8(h)(4)(i) through (vi) in this rule. We propose that these changes would be effective 60 days after the effective date of this final rule as we believe this timeframe is reasonable. We seek comment on this proposal.

e. MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (§§ 438.8(m) and 457.1203(f))

Medicaid and CHIP managed care plans are required to resubmit MLR reports to States under certain circumstances. In the 2015 managed care proposed rule preamble, we noted that States may make retroactive changes to capitation rates that could affect the MLR calculation for a given MLR reporting year and that when that occurred, the MCO, PIHP, or PAHP would need to recalculate the MLR and provide a new report with the updated figures (80 FR 31113). We also indicated that "In any instance where a State makes a retroactive change to the capitation payments for an MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by

the change and submit a new report meeting the requirements in paragraph (k) of this section." This regulation was finalized in 2016 without changes (81 FR 27864). However, the reference in the regulation to changes to capitation "payments" rather than "rates" has caused confusion about when managed care plans should resubmit MLR reports to the State, and has contributed to additional administrative burden by requiring plans to resubmit MLR reports to the State and by requiring States to review multiple MLR report submissions from managed care plans.

As part of our Medicaid MLR report compliance reviews, we have heard from several States that MLR reports from MCOs, PIHPs, or PAHPs are often resubmitted to the State. These resubmissions usually resulted from payments the State made to the managed care plan as part of the retroactive eligibility review process. As part of this process in these States, the State reviews beneficiary eligibility records to determine if an individual qualifies for retroactive eligibility. If an enrollee qualifies for retroactive eligibility, the State modifies the number of capitation payments that were made to a plan; however, the State does not retroactively modify the capitation rate for a group of members. When a State modifies the number of payments, but not the rate of payment to a managed care plan, we believe that it is unnecessary for a plan to resubmit the MLR to the State. For separate payment terms, only used for SDPs, the proposed regulation changes would require the State to document in the managed care plan contracts the total dollars that the State would pay to the plans for the individual State directed payment; the timing and frequency of payments that would be made under the separate payment term from the State to the plans; a description or reference to the contract requirement for the specific State directed payment for which the separate payment term would be used; and any reporting that the State requires to ensure appropriate reporting of the separate payment term for purposes of MLR reporting under § 438.8. If the State modifies a separate payment term, the MLR would need to be resubmitted to the State. See further details in section I.B.2.l. of this proposed rule.

We propose to amend § 438.8(m) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(f), to specify that an MCO, PIHP,

or PAHP would only be required to resubmit an MLR report to the State when the State makes a retroactive change to capitation rates. Specifically, we propose to replace "payments" with "rates" and to insert "retroactive rate" before the word "change." These changes would decrease administrative burden for both managed care plans and States by reducing the number of MLR report submissions while retaining our original intent. We propose that these changes would be effective 60 days after the effective date of this final rule as we believe this timeframe is reasonable to alleviate State and plan administrative burden. We considered an alternative effective date no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we do not believe additional time is necessary. We seek comment on this proposal.

f. Level of MLR Data Aggregation (§§ 438.74 and 457.1203(e))

As specified in existing requirements at §§ 438.8(k) and 457.1203(f) respectively, Medicaid and CHIP managed care plans are required to submit detailed MLR reports to States, and States, as required in § 438.74 for Medicaid and § 457.1203(e) for separate CHIP, must submit a summary description of those reports to CMS. In the preamble to the 2015 managed care proposed rule (80 FR 31113), we described the term "summary" as meaning an abbreviated version of the more detailed reports required from managed care plans in § 438.8(k), but did not refer to a Statewide aggregation of data across managed care plans. The proposed regulatory text for § 438.74 did not include the words "for each" and was finalized as proposed. In our compliance reviews of State summary MLR reports, several States provided MLR data aggregated over the entire State and neglected to provide the abbreviated MLR report for each plan. These submissions of MLR summary reports that omitted information by plan indicate States' confusion with what is required for these reports.

To correct this issue, we propose to amend § 438.74(a) for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1203(e), to note explicitly that State MLR summary reports must include the required elements for each MCO, PIHP, or

PAHP that is contracted with the State. To specify that the MLR information would have to be reported for each managed care plan, we propose in § 438.74(a)(1) to replace "the" with "each" before "report(s)." In addition, in § 438.74(a)(2), we propose to add language to specify that the information listed as required in the summary description must be provided for each MCO, PIHP, or PAHP under contract with the State. These changes would specify that States must provide MLR information for each managed care plan in their annual summary reports to CMS. We propose that States and managed care plans would be required to comply with these changes 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative compliance date of no later than the rating period for MCO, PIHP and PAHP contracts beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough. We seek comment on this proposal.

g. Contract Requirements for Overpayments (§§ 438.608(a)(2) and(d)(3), and 457.1285)

In the 2016 final rule, we aimed to strengthen State and Medicaid and CHIP managed care plan responsibilities to protect against fraud and other overpayments in State Medicaid and CHIP programs, in part, by enhancing reporting requirements to support actuarial soundness payment provisions and program integrity efforts (81 FR 27606). Overpayments are defined in § 438.2 as any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled under Title XIX of the Act. These overpayments may be the result of fraud, waste, abuse, or other billing errors. Regardless of cause, overpayments should be excluded from the capitation rate because they do not represent reasonable, appropriate, or attainable costs.

The 2016 final rule also enhanced the integrity of capitation payments, in part, by requiring at § 438.608(d)(3) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1285, that State contracts with managed care plans include

provisions specifying that managed care plans must report the recoveries of overpayments annually. This reporting to the State is critical to the actuarial soundness of capitation rates because managed care plans must exclude overpayments from their incurred claims, which is also a key element in the numerator of the MLR calculation. As required in § 438.5(b)(5), States must consider Medicaid managed care plans' past reported MLR and the projected MLR in the development of capitation rates. If a managed care plan's MLR numerator does not exclude overpayments, the MLR may be inappropriately inflated. Section 438.608(d)(4) requires that the State use the results of the information and documentation collected under § 438.608(d)(3) for setting actuarially sound Medicaid capitation rates consistent with the requirements in § 438.4.

This proposed rule seeks to modify § 438.608(a)(2), which requires managed care plan contracts to include a provision for the prompt reporting of all overpayments identified or recovered (specifying those due to potential fraud) to the State; and § 438.608(d)(3), which requires managed care plan contracts to include annual reports on plan recoveries of overpayments. Both proposed changes are included in separate CHIP regulations through an existing cross-reference at § 457.1285. The proposed changes aim to ensure that Medicaid and CHIP managed care plans report comprehensive overpayment data to States in a timely manner, which would better position States to execute program integrity efforts and develop actuarially sound capitation rates.

Defining "Prompt" Reporting (§§ 438.608(a)(2) and 457.1285))

Current regulations at § 438.608(a)(2) require that States include a provision in their contracts with managed care plans for the prompt reporting to the State of all overpayments identified or recovered, specifying the overpayments due to potential fraud. However, the term "prompt" is not defined. Although a time period is not defined, prompt reporting of identified or recovered overpayments is important because it can enable a State to expeditiously take action against a provider to prevent further inappropriate activity, including potential fraud. With prompt reporting of managed care plan overpayments, the State is better equipped to identify

similar overpayments and prevent future overpayments across its networks and managed care programs.

CMS' oversight efforts and other program integrity reviews have revealed that States interpret the promptness requirement under § 438.608(a)(2) inconsistently. For example, some States do not define "prompt" in managed care plan contracts, instead deferring to managed care plans' interpretation of the timeframe to report overpayments; this lack of definition can result in inconsistent overpayment reporting among managed care plans and States. Our reviews also revealed that some States do not use a consistent timeframe across managed care plan contracts when requiring the reporting of overpayments. As a result, managed care plans may not report identified or recovered overpayments within a timeframe that enables States to effectively and swiftly investigate and take appropriate administrative action against providers that may be committing fraudulent activities across networks and managed care programs.

We believe that establishing a uniform definition of the term "prompt" would provide clarity to States and managed care plans, thereby enhancing ongoing communication between managed care plans and States, particularly as it relates to program integrity practices. Therefore, we propose to amend § 438.608(a)(2) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1285, to define "prompt" as within 10 business days of identifying or recovering an overpayment. We believe 10 business days would provide a managed care plan sufficient time to investigate overpayments and determine whether they are due to potential fraud or other causes, such as billing errors, and also quickly provide the State with awareness to mitigate other potential overpayments across its networks and managed care programs. With a clear and consistent overpayment reporting requirement, States would be better equipped to: direct managed care plans to look for specific network provider issues, identify and recover managed care plan and fee-for-service claims that are known to be unallowable, take corrective actions to correct erroneous billing practices, or consider a potential law enforcement referral. We are seeking public comment on the proposed 10 business day timeframe and

whether reporting should be from date of identification or recovery, or instead on a routine basis, such as monthly. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we do not believe additional time is necessary. We seek comment on this proposal.

Identifying Overpayment Reporting Requirements (§§ 438.608(d)(3) and 457.1285)

The overpayment reporting provisions in 42 CFR part 438, subpart H require managed care plans to recover the overpayments they identify, and in turn, report those identified overpayments to the State for purpose of setting actuarially sound capitation rates. In the 2015 proposed rule, we stated that "MCOs, PIHPs, and PAHPs must report improper payments and recover overpayments they identify from network providers. States must take such recoveries into account when developing capitation rates. Therefore, capitation rates that include the amount of improper payments recovered by an MCO, PIHP, or PAHP as projected costs would not be considered actuarially sound." (80 FR 31119). It was our expectation that "such recoveries" include recoveries of all identified overpayments. This intent is also reflected in § 438.608(a)(2), which states that managed care plans must report both "identified or recovered" overpayments to the State. However, the words "identified or" were omitted from the related regulatory text at § 438.608(d)(3). Program integrity reviews and investigations conducted since the 2016 final rule have found that language in § 438.608(d)(3) providing that managed care plans only report "recovered overpayments" has created an unintentional effect of managed care plans' reporting partial overpayment data for capitation rate calculations. This omission may have also disincentivized managed care plans from investing in the resources necessary to recover identified overpayments in the interest of maintaining a higher MLR. For example, we have identified instances in which managed care plans identified an overpayment, but did not

recover the entire overpayment from the provider due to negotiating or settling the overpayment to a lesser amount. In other cases, managed care plans identified an overpayment that was resolved by applying an offset to future payments to the provider instead of recovering the full overpayment in the impacted rating period. These situations resulted in the managed care plans only reporting a relatively small or no overpayment recovery amount to the State in the impacted rating period, instead of the full amount of the identified overpayment. This inconsistent reporting does not reflect our original intent in imposing the current requirements in § 438.608(d)(3), and prevents the State from accounting for the full amount of the identified overpayment in the impacted rating period when developing capitation rates as required under § 438.608(d)(4).

To address these issues, we propose to revise § 438.608(d)(3) for Medicaid and separate CHIP regulations through an existing cross-reference at § 457.1285, to specify our original intent that any overpayment (whether identified or recovered) must be reported by Medicaid or CHIP managed care plans to the State. Through this proposed change, we believe that managed care plans and States would have more consistency in the overpayment reporting requirements at § 438.608(a)(2) and (d)(3) by requiring reporting to the State all overpayments, whether identified or recovered. By ensuring that both identified and recovered overpayments are reported, States and CMS would be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the contract. We propose that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule as we believe these proposals are critical for fiscal integrity in Medicaid and CHIP. We considered an alternative effective date no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned that is not soon enough. We seek comment on this proposal.

h. Reporting of SDPs in the Medical Loss Ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), 438.74,

457.1203(e) and (f))

Many States are using the authority in § 438.6(c) to direct Medicaid managed care plans' payments to certain providers. See section I.B.2.e. of this proposed rule for more information. States' increasing use of SDP arrangements has been cited as a key area of oversight risk for CMS. Several advisory and oversight bodies, including MACPAC, the HHS OIG, and GAO, have authored reports focused on CMS oversight of SDPs.[132,133,134] The scope, size, and complexity of the SDP arrangements being submitted by States for approval has also grown steadily and quickly. For calendar year 2022, CMS received 298 preprints from States. In total, as of December 2022, CMS has reviewed more than 1,100 SDP proposals and approved 993 proposals since the 2016 final rule was issued.

SDPs also represent a notable amount of spending. MACPAC reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than $25 billion for SDPs through 2020. [135] GAO also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 proposals.[136]

Under our current review and approval process for SDPs we ask States to estimate projected SDP expenditures, but we do not review the actual amounts that States provide to Medicaid managed care plans for these payment arrangements, and we do not review the actual amounts that Medicaid managed care plans pay to providers. We retrospectively review SDP actual amounts as part of State-level MLR reviews and in-depth reviews of State expenditures where Federal dollars are at risk, known as Financial Management Reviews; however, these reviews are limited to only a few States each year. We do not conduct other formal retrospective reviews of actual SDP expenditures. Thus, we rarely confirm with States that SDP actual

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132 *https://www.macpac.gov/publication/june-2022-report-to-congress-on-medicaid-and-chip/ June 2022 Report to Congress on Medicaid and CHIP, Chapter 2.*
133 *https://oig.hhs.gov/oas/reports/region6/61807001.asp.*
134 *https://www.gao.gov/products/gao-22-105731.*
135 *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf.*
136 *https://www.gao.gov/assets/gao-22-105731.pdf.*

spending amounts were reasonably consistent with the CMS-approved estimated amounts. Instead, we require States to provide the estimated total payment amounts for these arrangements as part of the current approval process. We are also aware that some States are permitting managed care plans to retain a portion of SDPs for administrative costs when plans make these payments to providers. Because States are not required to provide the actual expenditures associated with these arrangements in any separate or identifiable way, we cannot determine exactly how much is being paid under these arrangements and whether Federal funds are at risk for impermissible or inappropriate payment.

We propose new reporting requirements for Medicaid SDPs in §§ 438.8 and 438.74 to align with the reporting that is currently required for Medicaid FFS supplemental payments. CMS FFS supplemental payment guidance notes that "[i]nformation about all supplemental payments under the State plan and under demonstration is necessary to provide a full picture of Medicaid payments."[137] While States must provide CMS with the amounts for FFS supplemental payments, there is no requirement for States or managed care plans to provide actual payment data separately for SDPs. Implementing a new requirement for both State and managed care plan reporting of actual SDP expenditures would support CMS oversight activities to better understand provider-based payments across delivery systems.

To address the need for additional information on the actual amounts paid as SDPs, we propose to require Medicaid managed care plans to include SDPs and associated revenue as separate lines in the MLR reports required at § 438.8(k). The managed care MLR reporting requirements at § 438.8(k) were codified in the 2016 final rule, and States have substantial experience in obtaining and reviewing MLR reports from their managed care plans. To date, our MLR guidance has not addressed the inclusion of SDPs in the MLR; this proposal would specify these requirements by amending § 438.8(k) to ensure that Medicaid SDPs would be separately identified in annual MLR reporting.

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137 *https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.*

Specifically, at § 438.8(e)(2)(iii)(C), we propose to require that managed care plan expenditures to providers that are directed by the State under § 438.6(c), including those that do and do not require prior CMS approval, must be included in the MLR numerator. In § 438.8(f)(2)(vii), we propose to require that State payments made to Medicaid MCOs, PIHPs, or PAHPs for approved arrangements under § 438.6(c) be included in the MLR denominator as premium revenue. We propose that States and managed care plans are required to comply with these changes in § 438.8(e)(2)(iii)(C) and (f)(2)(vii) 60 days after the effective date of the final rule as we believe these proposals are critical for fiscal integrity in Medicaid. We considered an alternative compliance date of no later than the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following the effective date of the final rule; however, we are concerned this is not soon enough, given the fiscal integrity risks that are involved. We seek comment on this proposal.

We also propose to require that the managed care plans' MLR reports to States as required in § 438.8(k) include two additional line items. The first item at § 438.8(k)(1)(xiv) requires reporting of Medicaid managed care plan expenditures to providers that are directed by the State under § 438.6(c). The second item at § 438.8(k)(1)(xv) requires reporting of Medicaid managed care plan revenue from the State to make these payments. We propose, in § 438.8(k)(xvi), that States and managed care plans would be required to comply with § 438.8(k)(1)(xiv) and (xv) no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after the effective date of the final rule. We considered an alternative effective date where States and plan would comply with these requirements 60 days after the effective date of this final rule. However, we were concerned this may not be a reasonable timeframe for compliance as the new reporting requirements may require State and managed care plans to make changes to financial reporting systems and processes. We seek public comment on this proposal.

For separate CHIPs, we do not propose to adopt the new reporting requirements at §

438.8(k)(1)(xiv) and (xv) because SDPs are not applicable to separate CHIP managed care plans. For this reason, we propose to amend § 457.1203(f) to exclude any references to SDPs for managed care plan MLR reporting. For clarity, we also propose to make a technical change at § 457.1203(f) to include the word "in" before the cross-reference to § 438.8.

To assist in CMS oversight of these arrangements, the plan-level SDP expenditure reporting should be reflected in States' annual summary MLR reports to CMS. As part of States' annual summary MLR reporting that is required under § 438.74, we propose to require two additional line items. The first item at § 438.74(a)(3)(i) requires State reporting of the amount of payments made to providers that direct Medicaid MCO, PIHP, or PAHP expenditures under § 438.6(c). The second item at § 438.74(a)(3)(ii) requires State reporting of the amount of payments, including amounts included in capitation payments, that the State makes to Medicaid MCOs, PIHPs, or PAHPs for approved SDPs under § 438.6(c). We propose, in § 438.74(a)(4), that States would be required to comply with § 438.74(a)(3) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We considered an alternative effective date where States would comply with the new requirement 60 days after the effective date of this final rule. However, we were concerned this may not be a reasonable timeline for compliance as these changes may require States to make changes to financial reporting systems and processes. We seek public comment on this proposal.

We do not propose to adopt the new SDP reporting requirements for separate CHIPs at § 438.74 since expenditures under § 438.6(c) are not applicable to separate CHIP managed care plans. However, since existing separate CHIP regulations at § 457.1203(e) currently cross-reference to the reporting requirements at § 438.74, we propose to amend § 457.1203(e) to exclude any references to SDPs in State MLR reporting.

While some managed care plans and States may oppose these proposals as increasing administrative burden, we believe that the increased transparency associated with these enhanced

standards would benefit both State and Federal government oversight of SDPs. Implementing these new requirements for both State and managed care plan reporting of actual SDP expenditures would support CMS' understanding of provider-based payment across delivery systems.

4. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.7, 438.16, 438.66, 457.1201, 457.1207)

a. Overview of ILOS requirements (§§ 438.2, 438.3(e), 438.16, 457.1201(e))

In the 2016 final rule, we finalized § 438.3(e) for Medicaid, which was included in separate CHIP regulations through cross-reference at § 457.1201(e), and specified in § 438.3(e)(2) that managed care plans have flexibility under risk contracts to provide a substitute service or setting for a service or setting covered under the State plan, when medically appropriate and cost effective, to enrollees at the managed care plan and enrollee option (81 FR 27538 and 27539). A substitute service or setting provided in lieu of a covered State plan service or setting under these parameters is known as an "in lieu of service or setting" (ILOS). In the 2015 notice of proposed rulemaking, we stated that, under risk contracts, managed care plans have historically had the flexibility to offer an ILOS that meets an enrollee's needs (80 FR 31116). Within the 2016 final rule, we clarified that this ILOS authority continues to exist for States and managed care plans, subject to § 438.3(e)(2). We believe ILOS authority is inherent in a risk contract in accordance with section 1903(m)(2)(A) of the Act which addresses risk-based capitation payments, which are defined in § 438.2. Additionally, we rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid with respect to PIHPs and PAHPs. ILOSs are incorporated into the applicable States' contracts with its managed care plans and associated capitation rates, and are subject to CMS review and approval in accordance with § 438.3(a) and § 438.7(a) respectively.

ILOSs are utilized by States and their managed care plans to strengthen access to, and availability of, covered services and settings, or reduce or prevent the need for covered services

and settings. As outlined in the guidance issued on January 7, 2021[138] and January 4, 2023[139] respectively, ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address social determinants of health (SDOHs) and health-related social needs (HRSNs). The use of ILOSs can also improve population health, reduce health inequities, and lower overall health care costs in Medicaid. We further believe that ILOSs can be used, at the option of the managed care plan and the enrollee, as immediate or longer term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize the State plan-covered services and settings. The investments and interventions implemented through ILOSs may also offset potential future acute and institutional care, and improve quality, health outcomes, and enrollee experience. For example, offering medically tailored meals as an ILOS may improve health outcomes and facilitate greater access to care to HCBS, thereby preventing or delaying enrollees' need for nursing facility care. We encourage managed care plans to leverage existing State and community level resources, including through contracting with community-based organizations and other providers that are already providing such services and settings and that have expertise working with Medicaid and CHIP enrollees. We believe there is a great deal of State and managed care plan interest in utilizing ILOSs to help address many of the unmet physical, behavioral, developmental, long-term care, and other needs of Medicaid and CHIP enrollees. We expect that States' and managed care plans' use of ILOSs, as well as associated Federal expenditures for these services and settings, will continue to increase. We acknowledge that ILOSs can offer many benefits for enrollees, but we also believe it is necessary to ensure adequate assessment of these substitute services and settings prior to approval, and ongoing monitoring for appropriate utilization of ILOSs and beneficiary protections. Additionally, we believe there must be appropriate fiscal protections and accountability of expenditures on these

138 *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*
139 *https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.*

ILOSs which are alternative services and settings not covered in the State plan. Therefore, we propose to revise the regulatory requirements for ILOSs to specify the nature of the ILOSs that can be offered and ensure appropriate and efficient use of Medicaid and CHIP resources, and that these investments advance the objectives of the Medicaid and CHIP programs.

To ensure clarity on the use of the term "in lieu of service or setting" and the associated acronym "ILOS," we propose to add a definition in § 438.2 for Medicaid to define an "in lieu of service or setting (ILOS)" as a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2) and acknowledge that an ILOS can be used as an immediate or longer term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize State plan-covered service or setting. For separate CHIP, we propose to align by adding "In lieu of service or setting (ILOS) is defined as provided in § 438.2 of this chapter" to the definitions at § 457.10. Given this proposed definition and associated acronym, we also propose several conforming changes in § 438.3(e)(2). We propose to revise § 438.3(e)(2) to remove "services or settings that are in lieu of services or settings covered under the State plan" and replace it with "an ILOS". We propose to revise § 438.3(e)(2)(i) and (ii) to remove "alternative service or setting" and replace it with "ILOS." In § 438.3(e)(2)(iii), we propose to remove "in lieu of services" and replace it with "ILOS is", and remove the "and" at the end of this requirement given new requirements that will be proposed. We propose to revise § 438.3(e)(2)(iv) to remove "in lieu of services are" and replace it with "the ILOS is, and add the term "and settings" after "covered State plan covered services" to accurately reflect that ILOSs are substitute services and settings for State plan services and settings. Additionally, we added an "and" at the end of this requirement given a new proposed addition of § 438.3(e)(2)(v) that is described later in this section. The proposed changes at § 438.3(e) are equally applicable to separate CHIP managed care plan contract requirements through the existing cross-reference at § 457.1201(e).

Because we are making numerous proposals related to ILOSs, we believe adding a cross reference in § 438.3(e)(2)(v) to a new section would make it easier for readers to locate all of the provisions in one place and the designation flexibility of a new section would enable us to better organize the provisions for readability. To do this, we propose to create a new § 438.16 titled *ILOS requirements* for Medicaid, and we propose to amend § 457.1201(c) and (e) to include cross-references to § 438.16 to adopt for separate CHIP. Our proposals in § 438.16 would be based on several key principles, described in further detail in sections I.B.4.b. through I.B.4.h. of this proposed rule. These principles include that ILOSs would have to: (1) meet general parameters; (2) be provided in a manner that preserves enrollee rights and protections; (3) be medically appropriate and cost effective substitutes for State plan services and settings, (4) be subject to monitoring and oversight; and (5) undergo a retrospective evaluation, when applicable. We also propose parameters and limitations for ILOSs, including our proposed requirements for ILOSs to be appropriately documented in managed care plan contracts and considered in the development of capitation rates, and our proposed risk-based approach for State documentation and evaluation requirements of any managed care plan contracts that include ILOSs. CMS intends to continue our review of ILOSs as part of our review of the States' managed care plan contracts in accordance with § 438.3(a), and associated capitation rates in accordance with § 438.7(a). CMS has the authority to deny approval of any ILOS that does not meet standards in regulatory requirements, and thereby does not advance the objectives of the Medicaid program, as part of our review of the associated Medicaid managed care plan contracts and capitation rates.

We acknowledge that one of the most commonly utilized ILOSs is inpatient mental health or substance use disorder treatment provided during a short term stay (no more than 15 days during the period of the monthly capitation payment) in an institution for mental diseases (IMD). Due to the statutory limitation on coverage of services provided in an IMD in accordance with language in section 1905(a) of the Act following section 1905(a)(30) of the Act, our ability

to permit States to make a monthly Medicaid capitation payment for an enrollee who receives services in an IMD is limited as outlined in § 438.6(e), and uniquely based on the nature of risk-based payment (see 80 FR 31116 for further details on this policy). Other than as an ILOS, in accordance with §§ 438.3(e)(2) and 438.6(e), FFP is not available for any medical assistance under Title XIX for services provided to an individual, ages 21 to 64, who is a patient in an IMD facility. We are not proposing changes regarding the coverage of short term stays in an IMD as an ILOS, or payments to MCOs and PIHPs for enrollees who are a patient in an IMD in § 438.6(e) (see 81 FR 27555 through 27563 for further details on the existing policy). In acknowledgement of the unique parameters necessary for coverage of services provided in IMDs as an ILOS, given the statutory limitations, we do not believe § 438.16 should apply to a short term IMD stay as an ILOS. For example, a short term stay in an IMD as an ILOS is excluded from the calculation for an ILOS cost percentage, described in further detail in section I.B.4.b. of this proposed rule, as the costs of a short term IMD stay must not be used in rate development given the statutory limitation, and instead States must use the unit costs of providers delivering the same services included in the State plan as required in § 438.6(e). Additionally, as described in § 438.6(e), States may only make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21 to 64 receiving inpatient treatment in an IMD when the length of stay in an IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. Therefore, we propose to add § 438.3(e)(2)(v) to explicitly provide an exception from the applicability of § 438.16 for short term stays, as specified in § 438.6(e), for inpatient mental health or substance use disorder treatment in an IMD. This proposal does not replace or alter existing Federal requirements and limitations regarding the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to MCOs and PIHPs for enrollees who utilize an IMD.

We do not propose to adopt the IMD exclusion for separate CHIP since there are no similar payment restrictions for stays in an IMD in separate CHIP. As long as a child is not

applying for or renewing their separate CHIP coverage while a resident of an IMD, the child remains eligible for separate CHIP and any covered State plan services or ILOSs while in an IMD consistent with the requirements of § 457.310(c)(2)(ii). For this reason, we propose to amend § 457.1201(e) to exclude references to IMDs in the cross-reference to § 438.3(e).

States and managed care plans will continue to be obligated to comply with other applicable Federal requirements for all ILOS, including short term IMD stays. This includes, but is not limited to, those requirements outlined in §§ 438.3(e)(2), 438.6(e), and 438.66. As required in § 438.66(a) through (c), States must establish a system to monitor performance of their managed care programs. When ILOSs are included in a managed care plan's contract, they too must be part of the State's monitoring activities. As part of such monitoring, States must ensure that all ILOSs, including short term stays in an IMD, are medically appropriate, cost effective, and at the option of the enrollee and managed care plan.

b. ILOS general parameters (§§ 438.16(a) through (d), 457.1201(c) and (e))

We believe ILOSs can give States and managed care plans opportunities to strengthen access to care, address unmet needs of Medicaid and CHIP enrollees, and improve the health of Medicaid and CHIP beneficiaries. However, we believe it is necessary to implement appropriate Federal protections to ensure the effective and efficient use of Medicaid and CHIP resources, particularly since these services and settings are not State plan-covered services and settings furnished under managed care plan contracts, and we rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP respectively. Therefore, to ensure States and managed care plans utilize ILOSs effectively and in a manner that best meets the needs of the enrollees as well as that related Federal expenditures are reasonable and appropriate, we propose several key requirements in § 438.16.

We believe that a limitation on the types of substitute services or settings that can be offered as an ILOS would be a key protection to ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources, and we believe this is a reasonable method to ensure

proper and effective operations in Medicaid and CHIP in accordance with authority in sections 1902(a)(4) and 2101(a) of the Act, respectively. We believe that the services and settings that could be provided as an ILOS should be consistent with the services and settings that could be authorized under the Medicaid or CHIP State plan or a program authorized through a waiver under section 1915(c) of the Act. As further described in section I.B.4.a. of this proposed rule, we believe the only Medicaid exception should be a short term stay in an IMD for the provision of inpatient mental health or substance use disorder treatment, which already has appropriate safeguards per requirements outlined in § 438.6(e). Therefore, we propose to require in § 438.16(b) that an ILOS must be approvable as a service or setting through a State plan amendment, including sections 1905(a), 1915(i), or 1915(k) of the Act, or a waiver under section 1915(c) of the Act. For example, personal care homemaker services are approvable as a covered service in a waiver under section 1915(c) of the Act, and would be an approvable ILOS if it is a medically appropriate and cost effective substitute for a service or setting covered under the State plan.

For separate CHIP, we similarly propose that ILOSs must be consistent with services and settings approvable under sections 2103(a) through (c), 2105(a)(1)(D)(ii), and 2110(a) of the Act as well as the services and settings identified in § 438.16(b). For this reason, we propose to adopt the requirements proposed at § 438.16(b) by amending § 457.1201(e) to include a new cross-reference to § 438.16(b). We also remind States that the use of an ILOS does not absolve States and managed care plans of their responsibility to comply with other Federal requirements. States must ensure that contracts with managed care plans comply with all applicable Federal and State laws and regulations in accordance with §§ 438.3(f) and 457.1201(f). For example, with the exception of short term IMD stays as described in section I.B.4.a. of this proposed rule, ILOSs must adhere to general prohibitions on payment for room and board under Title XIX of the Act. Additionally, States and managed care plans must ensure access to emergency services in accordance with the Emergency Medical Treatment and Labor Act and compliance with the

Americans with Disabilities Act and Section 504 of the Rehabilitation Act. Moreover, consistent with § 438.208(c)(3), States must comply with person-center planning requirements as applicable.

Because ILOSs are provided as substitutes for State plan-covered services and settings, we believe that we have an obligation to ensure appropriate fiscal protections for Medicaid and CHIP investments in ILOSs, and that there should be a limit on the amount of expenditures for ILOSs to increase accountability, reduce inequities in the services and settings available to beneficiaries across managed care and fee-for-service delivery systems, and ensure enrollees receive State plan-covered services and settings. We rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and efficient operations in Medicaid and section 2101(a) of the Act for establishing efficient and effective health assistance in CHIP. To determine a reasonable limit on expenditures for ILOSs, we propose to limit allowable ILOS costs to a portion of the total costs for each managed care program that includes ILOS(s), hereinafter referred to as an ILOS cost percentage. States claim FFP for the capitation payments they make to managed care plans. Capitation payments are based on the actuarially sound capitation rates as defined in § 438.2, for Medicaid, and rates are developed with "actuarially sound principles" as required for separate CHIP at § 457.1203(a). The utilization and cost associated with ILOSs are accounted for in the development of Medicaid and separate CHIP capitation rates in accordance with §§ 438.3(e)(2)(iv) and 457.1201(e) respectively. Therefore, we propose in § 438.16(c), that the ILOS cost percentage must be calculated based on capitation rates and capitation payments as outlined in further detail in this section. In section I.B.2.l. of this proposed rule, CMS proposes requirements for State directed payments as a separate payment term, and we also believe these costs should be accounted for in the denominator of the ILOS cost percentage as these are payments made by the State to the managed care plans. The reporting requirements in this proposal are authorized by sections 1902(a)(6) and 2107(b)(1) of

the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require.

Given that actuarially sound capitation rates are developed prospectively based on historical utilization and cost experience, as further defined in § 438.5, we believe that an ILOS cost percentage and associated expenditure limit should be measured both on a projected basis when capitation rates are developed and on a final basis after capitation payments are made by States to the managed care plans. Therefore, we propose to define both a "projected ILOS cost percentage" and "final ILOS cost percentage" in § 438.16(a) as the amounts for each managed care program that includes ILOS(s) using the calculations proposed in § 438.16(c)(2) and (3), respectively. Additional details on these percentages are provided later in this section. We also believe the projected ILOS cost percentage and final ILOS cost percentage should be measured distinctly for each managed care program as capitation rates are typically developed by program, ILOSs available may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types. For example, one State may have a behavioral health program that covers care to most Medicaid beneficiaries through PIHPs, a physical health program that covers physical health care to children and pregnant women through MCOs, and a program that covers physical health and MLTSS to adults with a disability through MCOs. Another State may have several different managed care programs that serve similar populations and provide similar benefits through MCOs, but the delivery model and geographic areas served by the managed care programs vary. We addressed managed care program variability within the 2016 final rule when we noted that "This clarification in the regulatory text to reference "managed care program" in the regulatory text is to recognize that States may have more than one Medicaid managed care program – for example physical health and behavioral health…" (81 FR 27571). Therefore, we do not believe it would be consistent with our intent to develop an ILOS cost percentage by aggregating data from more than one managed care program since that would be inconsistent with rate development,

the unique elements of separate managed care programs, and the ILOSs elements (target populations, allowable provider types, etc.) that vary by managed care program. Developing the ILOS cost percentage by managed care program would further ensure appropriate fiscal safeguards for each managed care program that includes ILOS(s). We believe 5 percent is a reasonable limit on ILOS expenditures because it is high enough to ensure that ILOSs would be used effectively to achieve their intended purpose, but still low enough to ensure appropriate fiscal safeguards. This proposed 5 percent limit would be similar to incentive arrangements at § 438.6(b), which limits total payment under contracts with incentive arrangements to 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. In § 438.6(b)(2), we note that total payments in excess of 105 percent will not be actuarially sound. We believe this existing limitation for incentive arrangements allows States to design and motivate quality and outcome-based initiatives while also maintaining fiscal integrity. We believe a similar threshold would be necessary and appropriate for ILOSs. Therefore, we propose, at § 438.16(c)(1)(i), to require that the projected ILOS cost percentage could not exceed 5 percent and the final ILOS cost percentage could not exceed 5 percent.

For separate CHIP, we require States at § 457.1203(a) to develop capitation rates consistent with actuarially sound principles, but at § 457.1203(b) we allow for States to establish higher capitation rates if necessary to ensure sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services. While we do not impose a similar limit for incentive arrangements in separate CHIP capitation rates as we do for Medicaid capitation rates, we wish to align with Medicaid in limiting projected and final ILOS cost percentages to 5 percent of capitation payments for separate CHIPs. For this reason, we propose to amend § 457.1203(b) to adopt 5 percent ILOS cost percentage limits by amending § 457.1201(c) to include a new cross-reference to § 438.16(c)(1).

We also propose, in § 438.16(c)(1)(ii), that the State's actuary would have to calculate the projected ILOS cost percentage and final ILOS cost percentage on an annual basis and recalculate these projections annually to ensure consistent application across all States and managed care programs. Furthermore, to ensure that the projected ILOS cost percentage and final ILOS cost percentage would be developed in a consistent manner with how the associated ILOS costs would be included in rate development, we propose at § 438.16(c)(1)(iii) to require that the projected ILOS cost percentage and the final ILOS cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. An "actuary" is defined in § 438.2 as an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board, and who is acting on behalf of the State to develop and certify capitation rates. Therefore, we believe that the actuary that would certify the projected and final ILOS cost percentages should be the same actuary that developed and certified the capitation rates that included ILOS(s). For separate CHIP, we do not require actuarial certification of capitation rates and are not adopting the requirement at § 438(c)(1)(iii). We propose to amend § 457.1201(c) to exclude requirements for certification by an actuary. However, we remind States that separate CHIP rates must be developed using "actuarially sound principles" in accordance with § 457.1203(a).

We propose at § 438.16(c)(2), that the projected ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that would be attributable to all ILOSs, excluding short term stays in an IMD as specified in § 438.6(e), for each managed care program (numerator) by the projected total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the projected total State directed payments that are paid as a separate payment term as described in § 438.6(c)(6) (denominator). We also propose, at

§ 438.16(c)(3), that the final ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program (numerator) by the actual total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total State directed payments that are paid as a separate payment term as described in § 438.6(c)(6) (denominator). We believe these proposed numerators and denominators for the projected and final ILOS cost percentages would be an accurate measurement of the projected and final expenditures associated with ILOSs and total program costs in each managed care program in a risk-based contract. For separate CHIP, we propose to align with the projected and final ILOS cost percentage calculations by amending § 457.1201(c) to include cross-references to § 438.16(c)(2) through (3). However, since pass-through payments and State directed payments are not applicable to separate CHIP, we propose to exclude all references to pass-through payments and State directed payments at § 457.1201(c).

We considered proposing that the actual expenditures of the managed care plans for ILOSs and total managed care program costs, tied to actual paid amounts in encounter data, be the numerator and denominator for the final ILOS cost percentage. However, we determined this would be inconsistent with how States claim FFP for capitation payments in a risk contract (based on the actuarially sound capitation rates as defined in § 438.2 for each managed care program, rather than on the actual plan costs for delivering ILOSs based on claims and encounter data submitted). Consistent with all services and settings covered under the terms of the managed care plans' contracts, we acknowledge the actual plan experience will inform prospective rate development in the future, but it is an inconsistent measure for limiting ILOS expenditures associated with FFP retroactively. We believe expenditures for short term stays in an IMD would have to be excluded from the numerator of these calculations as they are excluded from the proposed requirements outlined in § 438.16. We also believe the denominator of these

calculations should include all State directed payments and pass-through payments that are included into capitation rates as outlined in § 438.6(c) and (a) respectively. It is necessary to include these State directed payments and pass-through payments to ensure that the projected and final expenditures would accurately reflect total capitation payments.

We believe the projected ILOS cost percentage should be included in the rate certification for each managed care program that includes ILOS(s) and any subsequent revised rate certification (for example, rate amendment) as applicable, such as those that change the ILOSs offered, capitation rates, pass-through payments and/or State directed payments. As previously described in this section, we propose at § 438.16(c)(1)(iii) that the actuary who certifies the projected ILOS cost percentage would have to be the same actuary who develops and certifies the associated Medicaid capitation rates and the State directed payments paid as a separate payment term (see section I.B.2.l. of this proposed rule for details on this proposal for separate payment terms). We also believe that including this percentage within the rate certification would reduce administrative burden for States and actuaries while also ensuring consistency between how this percentage would be calculated and how ILOS costs would be accounted for in rate development. Therefore, we propose to require, at § 438.16(c)(5)(i), that States annually submit to CMS for review the projected ILOS cost percentage for each managed care program as part of the Medicaid rate certification required in § 438.7(a). For separate CHIP, we do not require actuarial certification of capitation rates or review by CMS, and for this reason we do not adopt the new requirement proposed at § 438.16(c)(5)(i) for separate CHIP.

As the proposed denominator for the final ILOS cost percentage, in § 438.16(c)(3)(i), would be based on the actual total capitation payments and the State directed payments paid as a separate payment term (see section I.B.2.l. of this proposed rule for details on this proposal for separate payment terms) paid by States to managed care plans, we recognize that calculating the final ILOS cost percentage would take States and actuaries some time. For example, changes to the eligibility file and revised rate certifications for rate amendments may impact the final

capitation payments that are a component of the calculation. We also believe documentation of the final ILOS cost percentage is a vital component of our monitoring and oversight as it would ensure that the expenditures for ILOSs comply with the proposed 5 percent limit; and therefore, must be submitted timely. Given these factors, we believe that 2 years is an adequate amount of time to accurately perform the calculation. Therefore, we propose, at § 438.16(c)(5)(ii), to require that States must submit the final ILOS cost percentage report to CMS with the rate certification for the rating period beginning 2 years after the completion of each 12-month rating period that included an ILOS(s). Under this proposal, for example, the final ILOS cost percentage report for a managed care program that uses a calendar year 2024 rating period would be submitted to CMS with the calendar year 2027 rate certification. For separate CHIP, we do not require review of capitation rates by CMS and do not propose to adopt the requirements at § 438.16(c)(5)(ii) for separate CHIP.

We considered requiring the final ILOS cost percentage be submitted to CMS within 1 year after the completion of the rating period that included ILOS(s) to receive this data in a more timely fashion. However, we were concerned this may not be adequate time for States and actuaries given the multitude of factors described previously in this section. We request comment on whether our assumption that 1 year is inadequate is correct.

We also believe that it is appropriate for States' actuaries to develop a separate report to document the final ILOS cost percentage, rather than including it in a rate certification, because the final ILOS cost percentage may require alternate data compared to the base data that were used for prospective rate development, given the timing of base data requirements as outlined in § 438.5(c)(2). However, this final ILOS cost percentage could provide details that should inform prospective rate development, such as through an adjustment outlined in § 438.5(b)(4), so we believe it should be submitted along with the rate certification. We note that this proposal is similar to the concurrent submission necessary for the MLR reporting at § 438.74. We considered proposing that States submit this report separately to CMS upon completion.

However, we believe there should be consistency across States for when this report is submitted to CMS for review, and we believe receiving this report and the rate certification at the same time would enable CMS to review them concurrently. For these reasons, we propose, at § 438.16(c)(5)(ii), to require that States submit the final ILOS cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a). We intend to issue additional guidance on the standards and documentation requirements for this report. For separate CHIP, we do not require review of capitation rates by CMS and do not propose to adopt the requirements at § 438.16(c)(5)(ii) for separate CHIP.

We believe there must be appropriate transparency on the managed care plan costs associated with delivering ILOSs to aid State oversight and monitoring of ILOSs, and to ensure proper and effective operations in Medicaid in accordance with authority in section 1902(a)(4) of the Act. Therefore, we propose, in § 438.16(c)(4), that States provide to CMS a summary report of the actual managed care plan costs for delivering ILOSs based on claims and encounter data provided by the managed care plans to States. We also believe this summary report should be developed concurrently and consistently with the final ILOS cost percentage to ensure appropriate fiscal safeguards for each managed care program that includes ILOS(s). We believe this summary report should be developed for each managed care program consistent with the rationale described in section I.B.4.b. of this proposed rule for developing the ILOS cost percentage for each managed care program. Therefore, in § 438.16(a), we propose to define a "summary report for actual MCO, PIHP and PAHP ILOS costs" and propose that this summary report be calculated for each managed care program that includes ILOSs. We also propose, in § 438.16(c)(1)(ii), that this summary report be calculated on an annual basis and recalculated annually. We propose, in § 438.16(c)(1)(iii), that this summary report be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. Finally, we propose, in § 438.16(c)(5)(ii), that this summary report be submitted to CMS for review within the actuarial report that includes the final ILOS

cost percentage. For separate CHIP, we do not require similar actuarial reports and do not propose to adopt the annual ILOS cost report requirements by excluding references to them at § 457.1201(c).

To balance States' administrative burden with ensuring fiscal safeguards and enrollee protections related to ILOSs, we believe it would be appropriate to use a risk-based approach for States' documentation and evaluation requirements. This proposed reporting requirement is authorized by sections 1902(a)(6) and 2107(b)(1) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. Therefore, we propose that the ILOS documentation States would have to submit to CMS, as well as an evaluation States would have to complete, would vary based on a State's projected ILOS cost percentage for each managed care program. We believe the projected ILOS cost percentage would be a reasonable proxy for identifying States that offer a higher amount of ILOSs, in comparison to overall managed care program costs, and likely could have a corresponding higher impact to Federal expenditures. As we considered the types of State activities and documentation that could vary under this proposed risk-based approach, we considered which ones would be critical for all States to undertake for implementation and continual oversight of the use of ILOSs, but would not require our review unless issues arose that warranted additional scrutiny. We propose that documentation requirements for States with a projected ILOS cost percentage that is less than or equal to 1.5 percent would undergo a streamlined review, while States with a higher projected ILOS cost percentage would have more robust documentation requirements. Additionally, we propose States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS. These parameters are explained further in sections I.B.4.d. and g. of this proposed rule.

As we considered a reasonable percentage for this risk-based approach, we evaluated flexibilities currently offered in part 438 to assess if similar thresholds would be reasonable for this purpose. These flexibilities included the opportunity available to States to adjust rates

without the requirement for a revised rate certification. Specifically, we are referring to the 1 percent flexibility for States that certify rate ranges in accordance with § 438.4(c)(2)(iii) and the 1.5 percent flexibility for States that certify capitation rates in accordance with § 438.7(c)(3). An additional flexibility currently available to States relates to incentive arrangements. In accordance with § 438.6(b)(2), total payment under States' managed care plan contracts with incentive arrangements are allowed to be no greater than 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. As we evaluated a reasonable and appropriate threshold to utilize for this risk-based approach, we explored utilizing similar flexibilities of 1 percent, 1.5 percent and 5 percent, and also considered 2.5 percent as a mid-point in this 5 percent range.

We do not believe 5 percent is a reasonable percentage for this risk-based approach as this is the proposed limit for the projected and final ILOS cost percentages described in this section. We believe a greater degree of State documentation, and CMS oversight, is necessary for States that offer ILOSs that represent a higher share of overall managed care program costs, and likely have a corresponding higher impact on Federal expenditures. In the 2020 final rule, we finalized § 438.4(c)(2)(iii) to permit States that certify rate ranges to make rate adjustments up to 1 percent without submitting a revised rate certification. Our rationale was that States using rate ranges were already afforded additional flexibility given the certification of rate ranges so it was not appropriate to utilize the same 1.5 percent flexibility that is offered to States that certify capitation rates (85 FR 72763). We do not believe a similar rationale is appropriate or relevant for this proposal, and thus, we do not believe 1 percent would be the most appropriate threshold. We are also concerned that utilizing 2.5 percent for a risk-based approach would result in inadequate Federal oversight to ensure program integrity, such as fiscal safeguards and enrollee protections related to ILOSs. We believe 1.5 percent, a de minimis amount, is appropriate to propose for utilization of a risk-based approach for States' documentation and evaluation requirements, and associated CMS review, as ILOS expenditures less than or equal to 1.5 percent

would likely be a relatively minor portion of overall managed care program expenditures. Therefore, we propose 1.5 percent for this risk-based approach in § 438.16(d)(2); States with a projected ILOS cost percentage that exceeds 1.5 percent would be required to adhere to additional requirements described in sections I.B.4.d. and g. of this proposed rule. For separate CHIP, we propose to adopt the new documentation requirements for States with a cost percentage that exceeds 1.5 percent at § 438.16(d)(2) by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(2).

c. Enrollee rights and protections (§§ 438.3(e), 457.1201(e), 457.1207)

Consistent with the ILOS definition proposed in § 438.2, ILOSs are immediate or longer term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize the covered services and settings under the State plan. They can be utilized to improve enrollees' health care outcomes, experience, and overall care; however, ILOSs are an option and not a requirement for managed care plans. While ILOSs are offered to Medicaid and CHIP enrollees at the option of the managed care plan, the provision of an ILOS is also dependent on the enrollees' willingness to use the ILOS instead of the State plan-covered service or setting. Medicaid managed care enrollees are entitled to receive covered services and settings under the State plan consistent with section 1902(a)(10) of the Act. As ILOSs can be offered as substitutes for covered State plan services and settings that Medicaid enrollees are otherwise entitled to, we believe that it is of the utmost importance that we identify the enrollee rights and managed care protections for individuals who are offered or opt to use an ILOS instead of receiving State plan-covered service or setting. To ensure clarity for States, managed care plans, and enrollees on the rights and protections afforded to enrollees who are eligible for, offered, or receive an ILOS, we propose to add new § 438.3(e)(2)(ii)(A) and (B) under § 438.3(e)(2)(ii) to specify our meaning of enrollee rights and protections that are not explicitly stated elsewhere in part 438. We believe it would be appropriate to add this clarity to § 438.3(e)(2)(ii) as these are not new rights or protections, but rather, existing rights and

protections that we believe should be more explicitly stated for all ILOSs, including short-term IMD stays.

We propose to specify, in § 438.3(e)(2)(ii)(A), that an enrollee who is offered or utilizes an ILOS would retain all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they would retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option. We believe this proposed addition would ensure clarity that the rights and protections guaranteed to Medicaid managed care enrollees under Federal regulations remain in full effect when an enrollee is eligible to be offered or elects to receive an ILOS. For example, enrollees retain the right to make informed decisions about their health care and to receive information on available treatment options and alternatives as required in § 438.100(b)(2)(iii). To ensure that enrollee rights and protections would be clearly and consistently provided to enrollees, we propose to revise § 438.10(g)(2)(ix) to explicitly require that the rights and protections in § 438.3(e)(2)(ii) be included in enrollee handbooks if ILOSs are added to a managed care plan's contract. For separate CHIP, enrollee rights and protections are unique from those offered to Medicaid enrollees, and are instead located under subparts K and L of part 457. To acknowledge these differences, we propose to amend § 457.1207, (which includes an existing cross-reference to § 438.10) to reference instead to the separate CHIP enrollee rights and protections under subparts K and L of part 457. Protections to ensure that managed care enrollees have the ability to participate in decisions regarding their health care, and have avenues to raise concerns including their right to appeals related to adverse benefit determinations and grievances are critical to ensure that ILOSs are utilized in a reasonable, appropriate, and effective manner.

We believe safeguards and protections for enrollees that elect to use an ILOS should be specified, particularly since ILOS costs can vary compared to costs for the State plan service or setting for which it is a substitute. Specifically, we want to make clear that the provision or offer of an ILOS may not be used coercively or with the intent to interfere with the provision or

availability of State plan-covered service and setting that an enrollee would otherwise be eligible to receive. Therefore, we propose to add § 438.3(e)(2)(ii)(B) to ensure that an ILOS would not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and a managed care plan may not deny an enrollee access to a service or setting covered under the State plan on the basis that an enrollee has been offered an ILOS as a substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past. While ILOSs can be effective substitutes for services and settings covered under the State plan, we want to ensure consistent and clear understanding for enrollees, States, and managed care plans on how ILOSs can be appropriately utilized to meet an enrollee's needs.

For separate CHIP, we propose to adopt the enrollee rights and protections at § 438.3(e)(2)(ii)(A) and (B) through an existing cross-reference at § 457.1201(e). However, separate CHIP enrollee rights and protections are unique from those offered to Medicaid enrollees and are instead located under subparts K and L of part 457. To acknowledge these differences, we propose to amend § 457.1201(e), which already includes a cross-reference to § 438.3(e) to State, "An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with § 438.3(e) of this chapter. . . except … that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part."

We believe that a strong foundation built on these enrollee rights and protections would also ensure that ILOSs may have a positive impact on enrollees' access to care, health outcomes, experience, and overall care. As such, we believe these enrollee rights and protections must be clearly documented in States' managed care plan contracts. Therefore, we propose this documentation requirement in § 438.16(d)(1)(v). For separate CHIP, we propose to adopt the requirement for enrollee rights and protections for ILOSs to be documented in managed care plan contracts by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(1)(v).

d. Medically appropriate and cost effective (§§ 438.16(d), 457.1201(e))

In § 438.3(e)(2)(i), managed care plans may cover an ILOS if the State determines the ILOS is medically appropriate and cost effective substitute for a covered State plan service or setting. This policy is consistent with authority in section 1902(a)(4) of the Act to establish methods for proper and efficient operations in Medicaid as well as the nature of capitation payments based on risk-based capitation rates recognized in section 1903(m)(2)(A) of the Act. We interpret medically appropriate and cost effective substitute to mean that an ILOS may serve as an immediate or longer term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize a covered service or setting under the State plan. We believe this is a reasonable interpretation in acknowledgement that health outcomes from any health care services and settings may also not be immediate. We offer the following examples to illustrate the difference between an ILOS that is an immediate versus longer term substitute for a State plan service or setting, or when the ILOS can be expected to reduce or prevent the future need to utilize a covered service or setting under the State plan.

For example, transportation to and services provided at a sobering center could be offered as a medically appropriate and cost effective immediate substitute for target populations for specific State plan services or settings, such as an emergency room visit or hospital inpatient stay. Alternatively, we can envision target populations for which an ILOS, such as housing transition navigation services, might serve as a longer term substitute for a covered State plan service or setting, or when the ILOS can be expected to reduce or prevent the need to utilize the covered service or setting under the State plan, such as populations with chronic health conditions and who are determined to be at risk of experiencing homelessness. The managed care plan might choose to offer medically tailored meals to individuals with a diabetes diagnosis and poorly managed A1C levels. While not an immediate substitute for a State plan-covered service such as emergency room visits or inpatient hospital stays, medically tailored meals

consistently provided to the individual over a period of time could contribute to improved management of the diabetes. In the long term, improved management might lead to fewer complications related to diabetes and consequentially, fewer emergency room visits and inpatient stays thereby demonstrating the ILOS was both medically appropriate and cost effective for the individual.

We believe it is important to ensure appropriate documentation to support a State's determination that an ILOS is a medically appropriate and cost effective substitute, either long or short term, for a State plan-covered service or setting. ILOS documentation requirements for States would permit CMS and the State to better monitor the use of ILOSs, safeguard enrollee rights, facilitate fiscal accountability, and promote transparency to ensure the efficient and appropriate use of Medicaid and CHIP resources. Therefore, we propose to expand the documentation requirements for ILOSs through the addition of requirements in § 438.16. Specifically, we propose at § 438.16(d)(1), elements that must be included in any managed care plan contract that includes ILOS(s) in order to obtain CMS approval consistent with § 438.3(a). In accordance with § 438.3(e)(2)(iii), States are already required to authorize and identify ILOSs in each managed care plan contract and such ILOSs are offered at the option of the managed care plan. Therefore, we believe it is consistent with a risk contract to require States to provide sufficient detail regarding any ILOSs covered under the contract and accounted for in the capitation rates per § 438.3(e)(2)(iv).

In our experience reviewing managed care plan contracts, States have not always provided sufficient detail in their managed care plan contracts for Federal review. For example, some contracts have included only general language that ILOSs are provided at the option of the managed care plan and have not clearly identified each ILOS that the State has authorized in sufficient detail. We believe clarity is needed to ensure accountability and transparency in managed care plan contracts. Therefore, we propose § 438.16(d)(1)(i) and (ii) to require that States would include within each managed care plan contract that includes ILOS(s), the name

and definition for each ILOS and clearly identify the State plan-covered service or setting for which each ILOS has been determined to be a medically appropriate and cost effective substitute by the State. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(1)(i) and (ii) by amending § 457.1201(e) to include the cross-reference. By requiring that this information be clearly identified in the contract, we believe that managed care plans would have sufficient detail on the ILOSs to be able to utilize ILOSs appropriately while enabling States and CMS to more effectively monitor each ILOS over time. We also believe including this level of detail in the contract would be an appropriate fiscal protection to ensure that capitation rates are developed in an actuarially sound manner in accordance with § 438.4 for Medicaid, and developed with actuarially sound principles in accordance with § 457.1203(a) for separate CHIP. Actuarially sound capitation rates, as defined in § 438.4(a) for Medicaid, and actuarially sound principles as defined at § 457.10 for CHIP, are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract. Additionally, for Medicaid, such capitation rates must be developed in accordance with the requirements in § 438.4(b), including the requirements that the actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the contract as required in § 438.4(b)(2).

The existing regulation § 438.3(e)(2)(i) indicates that a managed care plan may offer an ILOS if the State determines that the ILOS is a medically appropriate and cost-effective substitute for a covered service or setting under the State plan. As noted in section I.B.4.a of this proposed rule, we are proposing a definition of ILOS in § 438.2 to specify that ILOSs may be determined to be cost effective and medically appropriate as immediate or longer-term substitutes for State plan-covered services and settings, or when the ILOSs can be expected to reduce or prevent the future need to utilize State plan-covered services and settings. Current regulations do not require States or managed care plans to document any details related to the

determination of medical appropriateness and cost effectiveness, either broadly or for a specific enrollee who is offered an ILOS. For managed care plans to appropriately offer ILOSs to enrollees consistent with the State's determination of medical appropriateness and cost effectiveness, States would have to identify the target populations for each ILOS using clear clinical criteria. Prospective identification of the target population for an ILOS would also be necessary to ensure capitation rates are developed in an actuarially sound manner in accordance with § 438.4, including the requirements that the actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the contract as required in § 438.4(b)(2) and meet the applicable requirements of part 438, including ILOS requirements as required in § 438.4(b)(6). For these reasons, we propose a new requirement at § 438.16(d)(1)(iii) to require States to document within each managed care plan contract the clinically defined target population(s) for which each ILOS has been determined to be a medically appropriate and cost effective substitute. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(1)(iii) by amending § 457.1201(e) to include the cross-reference. We propose the phrase "clinically defined target populations" as we believe that States would have to identify a target population for each ILOS that would have to be based on clinical criteria. This would not preclude States from using additional criteria to further target certain clinically defined populations for ILOSs.

While States may establish target population(s) for which an ILOS is medically appropriate, we believe that the actual determination of medical appropriateness should be completed by a provider, for each enrollee, using their professional judgement, and assessing the enrollee's presenting medical condition, preferred course of treatment, and current or past medical treatment to determine if an ILOS is medically appropriate for that specific enrollee. Therefore, we propose, at § 438.16(d)(1)(iv), to require that the managed care plan contract document a process by which a licensed network or managed care plan staff provider would have to determine that an ILOS is medically appropriate for a specific enrollee. Under this proposal,

this determination and documentation could be done by either a licensed network provider or a managed care plan staff provider to ensure States and managed care plans have capacity to implement this requirement, consistent with State standards. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(1)(iv) by amending § 457.1201(e) to include the cross-reference. The provider would have to document the determination of medical appropriateness within the enrollee's records, which could include the enrollee's plan of care, medical record (paper or electronic), or another record that details the enrollee's care needs. This documentation would have to include how each ILOS would be expected to address those needs.

As discussed in section I.B.4.b. of this proposed rule, we propose a risk-based approach based on a State's projected ILOS cost percentage, for State documentation and evaluation requirements of ILOSs that would require standard streamlined documentation to CMS for States with a projected ILOS cost percentage less than or equal to 1.5 percent while States with a projected ILOS cost percentage that exceeds 1.5 percent would be required to submit additional documentation. To specify the proposed additional documentation requirements for a State with a projected ILOS cost percentage that exceeds 1.5 percent, we propose, at § 438.16(d)(2), the documentation requirements in paragraphs § 438.16(d)(2)(i) and (ii), and that this documentation would be submitted to CMS concurrent with the managed care plan contract that includes the ILOS(s), for review and approval by CMS under § 438.3(a). We believe concurrent submission is the most efficient, since each ILOS must be authorized and identified in States' contracts with a managed care plan as required in § 438.3(e)(2)(ii). In § 438.16(d)(2)(i), we propose that the State submit a description of the process and supporting evidence the State used to determine that each ILOS would be a medically appropriate service or setting for the clinically defined target population(s), consistent with proposed § 438.16(d)(1)(iii). As ILOSs are often substitutes for State plan-covered services and settings that have already been determined medically appropriate, we expect that States would have to use evidence-based guidelines, peer reviewed research, randomized control trials, preliminary evaluation results from pilots or demonstrations,

or other forms of sound evidence to support the State's determination of an ILOS' medical appropriateness. Lastly, in § 438.16(d)(2)(ii), we propose that the State provide a description of the process and supporting data that the State used to determine that each ILOS is a cost effective substitute for a State plan-covered service or setting for the defined target population(s), consistent with the proposed § 438.16(d)(1)(iii). CMS has the authority to deny approval of any ILOS that does not meet standards in regulatory requirements, and thereby does not advance the objectives of the Medicaid program, as part of our review of the associated Medicaid managed care plan contracts and capitation rates. For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(2) by amending § 457.1201(e) to include the cross-reference.

While we believe that a risk-based approach for States' ILOS documentation and evaluation requirements is a reasonable and appropriate balance of administrative burden and fiscal safeguards, we always reserve the right to ask for additional documentation from a State as part of our review and approval of the managed care plan contracts and rate certifications as required respectively in §§ 438.3(a) and 438.7(a), and we are not precluded from doing so by our proposal to add § 438.16(d)(2)(i) through (ii). Therefore, we propose to require at § 438.16(d)(3) that any State must provide additional documentation, whether part of the managed care plan contract, rate certification, or supplemental materials, if we determine that the requested information would be pertinent to the review and approval of a contract that includes ILOS(s). For separate CHIP, we propose to adopt the new documentation requirements at § 438.16(d)(3) by amending § 457.1201(e) to include the cross-reference, except that references to rate certifications do not apply.

e. Payment and rate development (§§ 438.3(c), 438.7(b), 457.1201(c))

In accordance with existing regulations at § 438.3(e)(2)(iv), States are required to ensure the utilization and actual cost of ILOSs are taken into account in developing the benefit component of the capitation rates that represents covered State plan services, unless a statute or

regulation explicitly requires otherwise. Additionally, through existing regulations at § 438.4(b)(6), States' actuaries are required to certify that Medicaid capitation rates have been developed in accordance with the ILOS requirements outlined in § 438.3(e). We relied on authority in section 1903(m)(2)(A)(iii) of the Act and regulations based on our authority under section 1902(a)(4) of the Act, to establish actuarially sound capitation rates. While ILOS utilization and actual costs, when allowed, are included in rate development, the existing regulations at § 438.3(c)(1)(ii) do not clearly acknowledge the inclusion of ILOSs in the final capitation rates and related capitation payments. Existing regulations at § 438.3(c)(1)(ii) require that the final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with the requirements of part 438 subpart K (Parity in Mental Health and Substance Use Disorder Benefits), and represent a payment amount that is adequate to allow the managed care plan to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements. As an ILOS is not a managed care plan requirement, but rather offered at the option of the managed care plan, it would not be included within the requirement in § 438.3(c)(2)(ii) related to contractual requirements. We propose to revise § 438.3(c)(1)(ii) to include "ILOS" to ensure clarity on this matter. This technical change would be included in separate CHIP regulations through an existing cross-reference at § 457.1201(c). We consider this a technical correction to § 438.3(c)(1)(ii) as §§ 438.3(e)(2)(iv) and 438.4(b)(6) clearly denote the inclusion of ILOSs in rate development and we believe this was inadvertently excluded from the final regulatory text in the 2016 final rule.

Additionally, we propose to revise § 438.7(b)(6) and the proposed § 438.7(c)(4) (see section I.B.2.l. of this proposed rule) to add "ILOS in § 438.3(e)(2)" to ensure any contract provision related to ILOSs must be documented in all rate certifications submitted to CMS for review and approval. We believe this is necessary to ensure compliance with proposed new regulatory requirements in § 438.16(c)(1)(i) and (c)(4)(i), described in section I.B.4.b. of this

proposed rule, to ensure that the projected ILOS cost percentage documented in the rate certification would not exceed the proposed 5 percent limit. This is a similar approach to the current requirements in § 438.7(b)(6) which require a revised rate certification for any change to a contract provisions related to payment in § 438.6, including incentive arrangements that have a similar 5 percent limit in accordance with § 438.6(b)(2). We intend to issue additional guidance in the Medicaid Managed Care Rate Development Guide, in accordance with § 438.7(e), on the Federal standards and documentation requirements for adequately addressing ILOSs in all rate certifications. For separate CHIP, we do not plan to adopt the proposed change at § 438.7(b)(6) since rate certifications are not applicable to separate CHIP.

As risk-based capitation rates are developed prospectively, States' actuaries will make initial assumptions regarding managed care plan and enrollee utilization of ILOSs and associated costs. Since ILOS are offered at the option of the managed care plan and Medicaid enrollee, States and their actuaries should closely monitor whether managed care plans elect to offer these ILOs and enrollees utilize these ILOSs. States' actuaries should assess if adjustments to the actuarially sound capitation rates are necessary in accordance with §§ 438.4, 438.7(a) and 438.7(c)(2). For example, a rate adjustment may be necessary if managed care plan actual uptake of ILOSs varies from what is intially assumed for rate development and results in an impact to actuarial soundness.

f. State monitoring (§§ 438.16(d) and (e), 438.66(e), 457.1201(c))

In the 2016 final rule, we clarified the term "monitoring" to include oversight responsibilities, and we required standard data elements that a State's monitoring system must collect to inform performance improvement efforts for its managed care program(s). We wish to continue to strengthen State and CMS oversight of each Medicaid managed care program with the addition of proposed text to explicitly address States' monitoring of ILOSs. We rely on the authority in section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid.

Currently, § 438.66 requires that States establish a system to monitor performance of managed care programs broadly, § 438.66(b) outlines the data elements that a State's system must collect, § 438.66(c) establishes expectations for State use of such data for performance improvement, and § 438.66(e) requires States to provide a report on and assessment of each managed care program. When ILOSs are included in a managed care plan's contract, they too must be included in the State's monitoring activities required in § 438.66(b) and (c). We believe States must ensure appropriate monitoring, evaluation, and oversight of ILOSs. We believe additional protections are necessary to ensure the delivery of ILOSs. In the 2015 notice of proposed rulemaking, we proposed expanded State monitoring requirements in § 438.66 and noted that our experience since the 2002 final rule has shown that strong State management and oversight of managed care is important throughout a program's evolution, but is particularly critical when States transition large numbers of beneficiaries from FFS to managed care or when new managed care plans are contracted (see 80 FR 31158). We subsequently finalized these requirements in the 2016 final rule. We believe that this logic is also applicable when a State expands the use of ILOSs as we have seen in recent years. Therefore, our proposals in this section further strengthen these existing Federal requirements related to States' monitoring activities for each managed care program.

As with all covered services and settings, States and their managed care plans must comply with all enrollee encounter data requirements in §§ 438.242 and 438.818. We rely on authority in section 1903(m)(2) of the Act to require sufficient encounter data and a level of detail specified by the Secretary. Complete, accurate, and validated encounter data would also support the evaluation and oversight of ILOS proposals described in sections I.B.4.g. and h. of this proposed rule, and ensure appropriate rate development, as described in section I.B.4.e. of this proposed rule. In § 438.242(c)(2), we require that contracts between a State and its managed care plans provide for the submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight,

and program integrity needs. Further, at § 438.242(d), States must review and validate that encounter data collected, maintained, and submitted to the State by the managed care plan is a complete and accurate representation of the services and settings provided to enrollees. Because ILOSs may not be easily identifiable in CPT® and Healthcare Common Procedure Coding System (HCPCS), we believe it is imperative that States identify specific codes and modifiers, if needed, for each ILOS and provide that information to its managed care plans to ensure consistent use. For example, the use of a modifier is useful when a State needs to separately identify an ILOS from a State plan-covered service or setting that may utilize the same HCPCS code. We propose in § 438.16(d)(1)(vi), to require that States include a contractual requirement that managed care plans utilize the specific codes established by the State to identify each ILOS in enrollee encounter data. States could require the use of specific HCPCS or CPT codes and modifiers, if needed, that identify each ILOS. To the extent possible, we encourage States to work towards the development of standard CPT® and HCPCS codes for ILOSs, and States may wish to collaborate with appropriate interested groups. For separate CHIP, while the provisions at § 438.66 are not applicable, we propose to adopt the new coding requirements at § 438.16(d)(1)(vi) by amending § 457.1201(c) to include the cross-reference.

We considered allowing States to include this level of data outside of the managed care plan contract, such as in a provider manual or similar documents; however, those documents are frequently not readily available to interested parties and some are not made publicly available. We believe requiring specific codes to be in the managed care plan contracts would ensure that we can easily identify ILOSs in T-MSIS data, support program integrity activities, and ensure that the information is publicly available as required at § 438.602(g)(1). For these reasons, we believe requiring the codes in the managed care plan contract would be the most appropriate and efficient option. We also believe this proposal would ensure that ILOSs are easily identifiable in the base data utilized for development of capitation rates in accordance with rate development standards described in § 438.5(c), and the associated development of the projected and final

ILOS cost percentage which are built off of capitation rates and capitation payments as proposed in section I.B.4.b. of this proposed rule.

States are required to submit an annual performance report to CMS for each Medicaid managed care program administered by the State in accordance with § 438.66(e)(1), known as the MCPAR. In § 438.66(e)(2), we specify the content of the MCPAR, including § 438.66(b)(11) that specifies accessibility and availability of covered services in the managed care plan contract. As ILOSs are substitutes for State plan-covered services and settings, we believe States should already be reporting on ILOSs in MCPAR, but to improve clarity for States, we propose to add an explicit reference. Therefore, we propose a minor revision to § 438.66(e)(2)(vi) to add the phrase "including any ILOS." To facilitate States' reporting of their monitoring activities and findings for ILOSs in MCPAR, we intend to update the MCPAR report template to enable States to easily and clearly include ILOS data throughout the report. We believe that it is important for States to monitor trends related to the availability and accessibility of ILOSs given the unique and innovative nature of some ILOSs, and we believe using MCPAR would be an efficient way for States to report their activities.

g. Retrospective evaluation (§§ 438.16(e) and 457.1201(e))

As part of Federal monitoring and oversight of Medicaid and CHIP programs, we regularly require States to submit evaluations to CMS that analyze cost or cost savings, enrollee health outcomes or enrollee experiences for a specific Medicaid or CHIP benefit, demonstration, or managed care program. For example, as set forth in an SMDL[140] published on December 22, 1998, States with a program authorized by a waiver of section 1915(b) of the Act must conduct two independent assessments of the quality of care, cost effectiveness and impact on the State's Medicaid program, and access to care to ensure compliance with § 431.55(b)(2)(i) through (iii). There are also quality requirements at §§ 438.340 and 457.1240(e) for States contracting with a managed care plan to develop and implement a written quality strategy for assessing and

140 *https://www.medicaid.gov/federal-policy-guidance/downloads/smd122298.pdf.*

improving the quality of health care and services furnished by the plan. We also believe that States should evaluate and demonstrate that ILOSs are cost effective, medically appropriate, and an appropriate and efficient use of Medicaid and CHIP resources and that such a requirement would be consistent with those existing requirements and the proposals outlined in sections I.B.4. of this proposed rule. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP respectively, and sections 1902(a)(6) and 2107(b)(1) of the Act which requires that States provide reports, in such form and containing such information, as the Secretary may from time to time require. To reduce State and Federal administrative burden, where possible, we again propose a risk-based approach to the State documentation requirement that would be proportional to a State's ILOS cost percentage. We propose, in § 438.16(e)(1) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to submit a retrospective evaluation to CMS of ILOSs, if the final ILOS cost percentage exceeds 1.5 percent, though we do strongly encourage all States that include ILOSs in their managed care plan contracts to conduct a retrospective evaluation of all ILOSs. As a State could authorize multiple ILOSs in one managed care program, we believe that this evaluation should evaluate each ILOS in order to clearly assess the impact and effectiveness of each ILOS.

With § 438.16(e)(1)(i) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose that an evaluation be completed separately for each managed care program that includes an ILOS. We considered allowing States to evaluate ILOSs across multiple managed care programs to reduce State administrative burden and alleviate potential concerns regarding sample size for the evaluation. We further considered permitting States to self-select the appropriate level at which to evaluate ILOSs including for each managed care program, across managed care programs, or by managed care plan contract. However, in our experience, a State with multiple managed care programs (for example, behavioral health, physical health, etc.) could have differing enrollee eligibility criteria, populations, covered

benefits, managed care plan types, delivery models, geographic regions, or rating periods among the separate managed care programs. Including more than one managed care program in an evaluation would likely impact evaluation rigor and could dilute or even alter evaluation results due to the variability among managed care programs. As States would be required to provide the ILOS cost percentage for each managed care program, we believe that it is necessary for the evaluation to also be conducted at the individual program level as it is one measure to aid in evaluating the overall impact of the ILOSs. For these reasons, we believe it would be critical for States to provide separate evaluations for each managed care program that includes ILOSs. We seek public comment on whether the evaluation should be completed for each managed care program, across multiple managed care programs, each managed care plan contract, or at a level selected by the State.

Since these proposed retrospective evaluations would utilize complete encounter data, we considered several options for the length of the evaluation period. Often, evaluation reports are required on an annual basis, such as MCPAR in § 438.66(e) or the Network Adequacy and Access Assurances report in § 438.207(d). We considered requiring an annual submission for the report required in § 438.16(e)(1), but believed that encounter data would be insufficient to result in meaningful analysis. We also considered a 3-year evaluation period, which may be sufficient for ILOSs that are immediate substitutes, but enrollees may need to receive longer term substitutes for a period of several years in order for a State to have robust data. We also considered a 10-year period, but we concluded that seemed to be an unreasonably long time to obtain information on the efficient and effective use of these unique services and settings. We concluded that a 5-year period would provide sufficient time to collect complete data. Therefore, we propose in § 438.16(e)(1)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that a State's retrospective evaluation would have to use the 5 most recent years of accurate and validated data for the ILOSs. We believe the 5-year period would allow managed care plans and enrollees to become comfortable with the available ILOSs

and opt to provide or receive them, thus generating the necessary data for the evaluation. Even for ILOSs that are longer term substitutes, we believe a 5-year period would be sufficient to permit robust data collection for cost effectiveness and medical appropriateness. We request comment on the appropriate length of the evaluation period.

By proposing that retrospective evaluations be completed using the five most recent years of accurate and validated data for the ILOS(s), we recognize that we need to also propose the scope of the evaluation. We considered permitting States to identify an appropriate 5-year evaluation period, but ultimately decided against this as it could create a perverse incentive to identify a favorable evaluation period for each ILOS in order to circumvent the termination process proposed in § 438.16(e)(2)(iii) and described in section I.B.4.h. of this proposed rule. We also considered if the evaluation period should begin with the first year that a State exceeds the 1.5 percent final ILOS cost percentage threshold, but decided against this option as we believe it is necessary for evaluation rigor to establish an early or, ideally pre-intervention, baseline from which to evaluate the impact of a new ILOS over time. We concluded that States' evaluations should be retroactive to the first complete rating period following the effective date of this provision in which the ILOS was included in the managed care plan contracts and capitation rates; we propose this in § 438.16(e)(1)(iv) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP. We believe that our proposed approach is aligned with identified best practices for evaluation. We would encourage States to consider developing a preliminary evaluation plan for each ILOS as part of the implementation process for a new ILOS and any time States significantly modify an existing ILOS. We request comment on the appropriate timing of an ILOS evaluation period.

To ensure some consistency and completeness in the retrospective evaluations, we believe there should be a minimum set of required topics to be included. First, in § 438.16(e)(1)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose to require that States must utilize data to at least evaluate cost,

utilization, access, grievances and appeals, and quality of care for each ILOS. Similar elements are required in evaluations for programs authorized by waivers approved under sections 1915(b) and 1915(c) of the Act and demonstrations under section 1115(a) of the Act. We believe these five proposed elements would permit CMS and States to accurately measure the impact and programmatic integrity of the use of ILOSs. We expand upon these elements in § 438.16(e)(1)(iii) wherein we propose the minimum elements that a State, if required to conduct an evaluation, would have to evaluate and include in an ILOS retrospective evaluation. We propose, in § 438.16(e)(1)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate the impact each ILOS had on utilization of State plan-covered services and settings, including any associated savings. As an intended substitute for a State plan-covered service or setting, that is cost effective and medically appropriate as required in § 438.3(e)(2)(i), we believe that it is important to understand the impact of each ILOS on these State plan-covered services and settings and any cost savings that result from reduced utilization of such specific services and settings. We believe that this evaluation element would also require the State to evaluate potentially adverse trends in State plan services and settings utilization, such as underutilization of adult preventive health care. Per § 438.3(e)(2)(i), the State must determine that an ILOS is a cost effective substitute; therefore, we believe that it would be appropriate for a State to evaluate any cost savings related to utilization of ILOSs in place of State plan-covered services and settings.

Similarly, we propose in § 438.16(e)(1)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States evaluate trends in managed care plan and enrollee use of each ILOS. We believe that it is necessary to understand actual utilization of each ILOS in order to evaluate enrollee access to ILOSs and related trends that occur over time. Trends in enrollee utilization of ILOSs could also be compared to data related to State plan services and settings utilization to determine if there is a correlation between utilization of certain ILOSs and decreased or increased utilization of certain State plan services

and settings. Trends in utilization of ILOSs may also help identify when enrollees choose not to utilize an ILOS to help States and managed care plans assess future changes in authorized ILOSs. We believe this is a key evaluation element necessary to determine if the ILOS was cost effective.

Critical to the authority for the allowable provision of ILOSs, is a State determination that an ILOS is a cost effective and medically appropriate substitute for a covered service or setting under the State plan as required in § 438.3(e)(2)(i). Therefore, we believe States should evaluate whether, after 5 years, its determinations are still accurate given actual enrollee utilization and experience. To achieve this, we propose § 438.16(e)(1)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which would require that States use encounter data to evaluate if each ILOS is a cost effective and medically appropriate substitute for the identified covered service or setting under the State plan or a cost effective measure to reduce or prevent the future need to utilize the identified covered service or setting under the State plan. We have included the following example to identify how a State could use encounter data to evaluate the medical appropriateness of an ILOS. A State may initially determine that the provision of air filters as an ILOS is a medically appropriate substitute service for individuals with an asthma diagnosis for emergency department visits, inpatient and outpatient services, and HCBS for activities of daily living (ADLs). After analyzing the actual encounter data, the State may discover that the provision of air filters to the target population did not result in decreased utilization of a State plan service such as emergency department, inpatient and outpatient services, nor HCBS for ADLs. In this instance, the evaluation results would demonstrate that the ILOS as currently defined was not cost effective for the target population of individuals as currently defined.

As ILOSs are services and settings provided to Medicaid and CHIP managed care enrollees in lieu of State plan-covered services and settings, we believe that it is important for States to evaluate the quality of care provided to enrollees who utilized ILOSs to ensure that the

ILOS(s) are held to the same quality standards as the State plan services and settings enrollees would otherwise receive. Quality of care is also a standard domain within evaluations of Medicaid and CHIP services, Medicaid and CHIP managed care plans, and Medicaid and CHIP programs as demonstrated by the ubiquitous use of the National Committee for Quality Assurance (NCQA) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and Healthcare Effectiveness Data and Information Set (HEDIS) measure set which includes standardized and validated quality of care measures for use by States and managed care plans operating within Medicaid and CHIP managed care environments. Accordingly, in § 438.16(e)(1)(iii)(D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose that States evaluate the impact of each ILOS on quality of care. We believe that States should use validated measure sets, when possible, to evaluate the quality of care of ILOSs, though we do not want to stifle State innovation in this area so we are not proposing to require it. We considered proposing to require that States procure an independent evaluator for ILOS evaluations. In consideration of the myriad of new proposed requirements within this proposed rule, we weighed the value of independent evaluation with increased State burden. We are concerned that it would be overly burdensome for States to procure independent evaluators for ILOS(s) due, in part, to the timing of the final ILOS cost percentage submission. In section I.B.4.b. of this proposed rule, we are proposing that the final ILOS cost percentage be submitted 2 years following completion of the applicable rating period, and we propose here that if the final ILOS cost percentage exceeds the 1.5 percent, States would be required to submit an evaluation. While States should conduct some evaluation planning efforts, it could be difficult and time consuming to procure an independent evaluator in a timely manner solely for the purpose of the ILOS evaluation since States would not know definitely whether an evaluation is required until 2 years following the rating period. We solicit comment on whether we should consider a requirement that States use an independent evaluator for ILOS evaluations.

We believe that States should, to the extent possible, leverage existing quality improvement and evaluation processes for the retrospective ILOS evaluation. Through §§ 438.364(a) and 457.1250(a), we require States to partner with an EQRO to produce an annual technical report that summarizes findings related to each MCO's, PIHP's, PAHP's, or PCCM entity's performance relative to quality, timeliness, and access to health care services furnished to Medicaid and CHIP enrollees. Through these existing EQR activities at § 438.364(b), and, if finalized, the newly proposed optional activity at § 438.64(c)(7), discussed in more detail in section I.B.5.c.3. of this proposed rule, we believe States could leverage the CMS-developed protocol or their EQRO to assist with evaluating the impact of ILOSs on quality of care. We believe this new optional activity could reduce burden associated with these new evaluation requirements for ILOSs.

The elements we have proposed in the evaluation should communicate a complete narrative about the State, managed care plans, and enrollees' experience with ILOSs. As key thresholds and limits on ILOSs, the projected and final ILOS cost percentages would be another element that CMS would consider as part of the overall mosaic to understand the impact that an ILOS might have on each managed care program. Although the final ILOS cost percentage is proposed to be submitted with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after each rating period that includes ILOS(s), we believe it is important to the completeness of the retrospective evaluation, that all final ILOS cost percentages available be included. Therefore, we propose in § 438.16(e)(1)(iii)(E) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that States provide the final ILOS cost percentage for each year in their retrospective evaluation, consistent with the report proposed in § 438.16(c)(5)(ii), (described in section I.B.4.b. of this proposed rule) with a declaration of compliance with the allowable 5 percent threshold proposed in § 438.16(c)(1)(i). We believe this necessary documentation of State compliance would be appropriate to be documented in the evaluation alongside the other data we have proposed to ensure a fulsome

evaluation that accurately demonstrates whether the ILOS(s) are an appropriate and efficient use of Medicaid and CHIP resources.

In section I.B.4.c. of this rule, we proposed to identify enrollee rights and protections for individuals who are offered or who receive an ILOS, and in section I.B.4.f. of this proposed rule we outlined requirements for States' monitoring of enrollee rights and protections. To determine if States have appropriately safeguarded and adequately monitored enrollee rights and protections, we propose in § 438.16(e)(1)(iii)(F) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require States to evaluate appeals, grievances, and State fair hearings data, reported separately for each ILOS, including volume, reason, resolution status, and trends. As ILOSs are substitutes for covered State plan services and settings, and are offered at the option of the managed care plan, we believe it would be important to evaluate appeals, grievances, and State fair hearing trends to ensure that enrollees' experience with ILOSs is not inconsistent or inequitable compared to the provision of State plan services and settings. We acknowledge that we already require for Medicaid, through § 438.66(e)(2)(v), that States include an assessment of the grievances, appeals, and State fair hearings annually in MCPAR. But the information we propose that States submit with the ILOS retrospective evaluation is different as it would be specific to each ILOS compared to the summary level information required by MCPAR. We believe collecting these data by ILOS will help evaluate the quality of care and enrollee experience related to the provision of each ILOS.

Finally, we believe an evaluation of the impact ILOSs have on health equity efforts is a critical component to measure enrollee experience, health outcomes, and whether ILOSs are an appropriate and efficient use of Medicaid and CHIP resources. As ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address SDOHs and HRSNs, we also believe it is critical to measure their impact on improving population health and reducing health disparities. We propose in § 438.16(e)(1)(iii)(G) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require

States to evaluate the impact of each ILOS on health equity efforts undertaken by the State to mitigate health disparities. To do this, managed care plans should submit enrollee encounter data, to the extent possible, that includes comprehensive data on sex (including sexual orientation and gender identity), race, ethnicity, disability status, rurality and language spoken. We remind managed care plans of their obligations in §§ 438.242(c)(3) and 457.1233(d) to submit all enrollee encounter data that States are required to report to CMS under § 438.818; currently, T-MSIS provides fields for sex, race, ethnicity, disability status, and language spoken.

To allow adequate time for claims run-out and the evaluation to be conducted, we propose in § 438.16(e)(1)(iv) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States submit a retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included the ILOS following the effective date of this provision, if finalized. This 2-year timeframe is similar to the timeframe utilized for independent assessments to evaluate programs authorized by waivers approved under section 1915(b) of the Act.

While we believe many ILOSs can be sufficiently validated as medically appropriate and cost effective substitutes within 5 years, we know that some may not. To fulfill our program monitoring obligations, we believe we must be able to require additional evaluations if the initial evaluation demonstrates deficiencies. We propose in § 438.16(e)(1)(v) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to explicitly assert our right to require States to provide additional 5-year retrospective evaluations. We believe that this could be a necessary flexibility when additional evaluation time might be needed, such as to demonstrate that an ILOS acting as a longer term substitute for a covered State plan service or setting is cost effective and medically appropriate. We also believe we may need to utilize this flexibility when a State substantially revises the ILOSs that are options within a managed care program.

For CHIP, our typical mechanism for retrospective managed care cost evaluation is through the CHIP Annual Report Template System (CARTS). We recognize that CARTS is completed annually by States and that our proposed timeframe for the retrospective evaluation is for a period of 5 years, but we considered whether it would be less burdensome to States to incorporate the CHIP ILOS retrospective evaluation into CARTS rather than as a stand-alone report. We seek public comment on whether or not the proposed retrospective evaluation should be incorporated into CARTS for CHIP ILOSs.

h. State and CMS oversight (§§ 438.16(e) and 457.1201(e))

If a State determines that an ILOS is no longer a medically appropriate or cost effective substitute or the State identifies another area of noncompliance in the provision of ILOSs, we believe CMS must be promptly notified. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. We propose, in § 438.16(e)(3) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to establish processes and timelines for State and CMS oversight of ILOSs. In § 438.16(e)(2)(i)(A) and (B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose to require that States notify CMS within 30 calendar days if the State determines that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance in this proposed section. Issues of noncompliance that would require State notification to CMS include, but are not limited to, contravening statutory requirements (for example, the provision of room and board), failure to safeguard the enrollee rights and protections enumerated under part 438, or the absence of the proposed provider documentation necessary to establish that an ILOS is medically appropriate for a specific enrollee. We believe that 30 days is a reasonable period of time for a State to identify and

confirm an area of noncompliance. We considered a 60-day notification period, but believe that States should notify CMS in a more expeditious manner so that CMS may assess and swiftly remediate issues of noncompliance that might cause harm to enrollees. We seek comment on the time period for State notification to CMS to ensure it is reasonable and appropriate.

We believe a termination process for ILOSs is critical to properly safeguard the health and safety of Medicaid and CHIP enrollees. Therefore, we propose a Federal oversight process at § 438.16(e)(2)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which would permit CMS to terminate the use of an ILOS, if we determine noncompliance or receive State notification of noncompliance as proposed in § 438.16(e)(2)(i). In § 438.16(e)(2)(iii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose a process for termination of an ILOS that would apply when a State terminates an ILOS, a managed care plan elects to no longer offer an ILOS to its enrollees, or CMS notifies the State that it must terminate an ILOS. In any of these events, we propose that the State would be required to submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision by the State to terminate an ILOS, a managed care plan notifying the State it will no longer offer an ILOS, or receipt of notice from CMS to terminate. In addition to 15 calendar days, we also considered 30, 60, and 90 calendar days, but ultimately decided on the former option. We recognize that 15 calendar days is a rapid submission timeline, but we firmly believe that such a transition plan would need to be implemented immediately following an ILOS termination to safeguard enrollee health and safety, and to maintain the integrity and efficient operation of the Medicaid program in accordance with sections 1902(a)(4) and 2101(a) of the Act. Given the submission timeline and that ILOSs are provided at the option of the managed care plan, we believe States should prepare an ILOS transition plan as part of the implementation process for any new ILOSs. The process for termination proposed at § 438.16(e)(2)(iii) is the same, regardless of whether the State, managed care plan or CMS

terminates the ILOS as the potential risks to enrollees are the same irrespective of which entity directs termination of the ILOS.

In § 438.16(e)(2)(iii)(A) through (D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose the elements States should include in the transition plan for the ILOS. We believe that a transition plan is necessary to protect the health and well-being of Medicaid and CHIP enrollees for whom the sudden termination of an ILOS, without an adequate transition plan, could have a significant negative impact. We rely on the authority in sections 1902(a)(4) and 2101(a) of the Act to establish methods for proper and effective operations in Medicaid and CHIP, and sections 1902(a)(6) and 2107(b)(1) of the Act which require that States provide reports, in such form and containing such information, as the Secretary may from time to time require. In § 438.16(e)(2)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, we propose to require that States establish a process to notify enrollees that the ILOS they are currently receiving will be terminated as expeditously as the enrollee's health condition requires. We also propose, in § 438.16(e)(2)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States create and make publicly available a transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to the care for any enrollees receiving an ILOS at the time of termination. From the period of notification onward, we would expect that a State and its managed care plans cease provision of the ILOS to any new enrollees. Together, we believe that these two actions would ensure adequate beneficiary protections, including adequate beneficiary notice and access to medically appropriate State plan-covered services and settings in a timely fashion.

In addition to enrollee focused activities, we propose that the transition plan also include administrative actions that States would take to remove a terminated ILOS from the applicable managed care plan contract(s) and capitation rates. ILOSs must be authorized and identified in

the managed care plan contract consistent with § 438.3(e)(2)(iii) and § 457.1201(e), and we believe it is equally important to ensure any terminated ILOS is removed from the managed care plan contract (and rate certification if necessary) to ensure clarity on contractual obligations and appropriate program integrity. We propose, in § 438.16(e)(2)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to direct States to remove the ILOS from the applicable managed care plan contracts and submit a modified contract to CMS for review and approval as required for Medicaid in § 438.3(a). Similarly, we permit States, through §§ 438.3(e)(2)(iv) and § 457.1201(e), to account for the utilization and actual cost of ILOSs in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly requires otherwise. As part of the transition plan, States would be required to provide an assurance that it would submit the necessary contract amendment, and outline a reasonable timeline for submitting the contract amendment to CMS for review and approval. In the event that an ILOS is terminated from the managed care plan contract, the State and its actuary, should evaluate if an adjustment(s) to the capitation rates is necessary to ensure Medicaid capitation rates continue to be actuarially sound, such as if the programmatic change would have a material impact to the rate development. As outlined in § 438.4 for Medicaid, actuarially sound capitation rates must be appropriate for the populations to be covered and the services to be furnished under the managed care plan contract, and the State's actuary must ensure that the capitation rates continue to be actuarially sound given any change to the contract. Therefore, we propose in § 438.16(e)(2)(iii)(D) to direct States to adjust the actuarially sound capitation rate(s), as needed, to remove utilization and cost of the ILOS from Medicaid capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2). As part of the transition plan, States would be required to provide an assurance that it would submit an adjustment to the capitation rates, as needed, and outline a reasonable timeline for submitting the revised rate certification to CMS for review and approval.

For separate CHIPs, States must develop capitation rates consistent with actuarially sound principles as required at § 457.1203(a). We also believe that in the event a CHIP ILOS is terminated, a State should evaluate if an adjustment to the capitation rate is needed to account for the removal of ILOS utilization and cost from the managed care plan contract. For this reason, we propose to adopt § 438.16(e)(2)(iii)(D) for separate CHIP through a new cross-reference at § 457.1201(e). However, we note that the requirements at § 438.7 are not applicable for 42 CFR part 457.

i. Applicability Dates (§§ 438.3(e), 438.7(g), 438.16(f), 457.1200(d))

We propose that States and managed care plans would be required to comply with the provisions outlined in §§ 438.2, 438.3(c)(1)(ii) and (e)(2)(i) through (iv), 438.10(g)(2)(ix), 438.66(e)(2)(vi) and applicable cross-references for separate CHIP at §§ 457.10, 457.1201(c) and (e), and 457.1207 no later than the effective date of the final rule. We believe this is appropriate as these proposals are technical corrections or clarifications of existing requirements. Additionally, we propose that States and managed care plans would have to comply with §§ 438.3(e)(2)(v), 438.16, 438.7(b)(6) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as we believe this is a reasonable timeframe for compliance. We propose to revise § 438.3(v) to add this proposed date, remove "July 1, 2017," and update "2015" and referenced citations; and add 438.7(g)(1) and 438.16(f). We propose to adopt the applicability date at § 438.16(f) for separate CHIP by adding § 457.1200(d).

5. Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review (§§ 438.330, 438.340, 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, 457.1250)

a. Quality assessment and performance improvement program (§ 438.330)

Regulations at § 438.330 establish the Quality Assessment and Performance Improvement (QAPI) programs that States must require of Medicaid managed care plans (that is,

MCOs, PIHPs, and PAHPs). Section 438.330(d) describes the performance improvement projects (PIPs) that States must require of Medicaid managed care plans as part of the QAPI program. Medicare Advantage (MA) plans are subject to similar (but not identical) requirements at § 422.152. Section 422.152 outlines the quality improvement program requirements for MA organizations, including the development and implementation of a Chronic Care Improvement Program (CCIP). Previously, CMS required MA organizations to develop and implement Quality Improvement Project (QIPs), which were an organization's initiatives focusing on specified clinical and nonclinical areas and were expected to have a favorable effect on health outcomes and enrollee satisfaction. However, CMS found the implementation of the QIP and CCIP requirements had become burdensome and complex, and removed the requirements for the QIP. With the removal of the QIP requirement with the 2019 Final Rule (83 FR 16440), we are proposing to update our regulations at § 438.330(d)(4) which still reference a QIP as a substitute for a PIP in managed care plans exclusively serving dually eligible individuals.

Through previous rulemaking, in the 2016 final rule (81 FR 27682), we implemented a policy, at § 438.330(d)(4), to allow States to permit Medicaid managed care plans exclusively serving dually eligible individuals to substitute an MA plan's quality improvement project (QIP) conducted under § 422.152(d) in the place of a Medicaid PIP, to prevent unnecessary duplication and increase flexibility for plans and States. Subsequently, in the final rule "Medicare Programs; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program," we removed the QIP from the requirements for MA organizations at § 422.152, because we determined that they did not add significant value and many were duplicative of existing activities, such as the Chronic Care Improvement Program (CCIP) (83 FR 16669). Due to an oversight at that time, we neglected to remove a reference to the QIP from § 438.330(d)(4) to conform with the changes at § 422.152. We are now proposing to replace the outdated reference at § 438.330(d)(4) to § 422.152(d) (which previously described the now-removed

QIP), with a reference to the CCIP requirements for MA organizations in § 422.152(c). This change would allow States to permit a Medicaid managed care plan exclusively serving dually eligible individuals to substitute an MA organization CCIP, conducted in accordance with the requirements at § 422.152(c), for one or more of the PIPs required under § 438.330(d). We believe the CCIP meets the same intent of the current regulation as an appropriate substitute for a PIP based on the quality improvement standards in a CCIP, including the identification of intervention goals and objectives, the collection and analysis of valid and reliable data, the assessment of performance and outcomes using quality indicators and measures, systematic and ongoing follow-up for increasing or sustaining improvement, and the reporting of results to CMS. We believe that permitting such a substitution would also maintain the intent of the current regulation to prevent unnecessary duplication and increase flexibility for plans and States, while allowing Medicaid managed care plans to maintain robust health improvement initiatives for dually enrolled individuals. Since the change to remove QIPs has been in place since 2019, we expect some States to already have CCIPs in place in lieu of QIPs, and therefore, are proposing that States must comply with this update in § 438.330(d)(4) no later than the rating period for contracts beginning after the effective date of the final rule in the applicability date provision at § 438.310(d)(1). We note this proposed change does not apply to separate CHIP because we did not apply § 438.330(d)(4) to separate CHIP in the 2016 final rule, and because § 457.310(b)(2) does not allow for concurrent health coverage in separate CHIP.

b. Managed Care State Quality Strategies (§§ 438.340, 457.1240)

Current regulations at § 438.340, which are included in separate CHIP regulations through an existing cross-reference at § 457.1240(e), set forth requirements for States to draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, or PAHP. The requirement also applies to a PCCM entity whose contract with the State provides financial incentives for improved quality outcomes, as described in § 438.310(c)(2). The quality strategy is intended to serve as a foundational tool

for States to set goals and objectives related to quality of care and access for their managed care programs. Current regulations at § 438.340(c) require States to make their quality strategy available for public comment when drafting or revising it, and require States to submit their initial quality strategy to CMS for feedback prior to adopting in final. These regulations also stipulate that States must review and update their quality strategy as needed, but no less than once every three years and submit the strategy to CMS whenever significant changes are made to the document or whenever significant changes occur within the State's Medicaid program. Building upon these requirements, we are proposing several changes to increase transparency and opportunity for meaningful ongoing public engagement around States' managed care quality strategies. We are proposing that States must comply with these updates in § 438.340 no later than 1 year from the effective date of the final rule, and are proposing to codify this applicability date at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP.

First, we are proposing to increase the opportunity that interested parties have to provide input into States' managed care quality strategy. Current regulations at § 438.340(c)(1) require that States make their quality strategy available for public comment when it is first adopted and when revisions are made. However, the current regulations do not require that the quality strategy be posted for public comment at the three-year renewal mark if significant changes have not been made. We are proposing to revise § 438.340(c)(1) to require that States make their quality strategy available for public comment at the 3-year renewal, regardless of whether or not the State intends to make significant changes, as well as whenever significant changes are made. The proposed change would promote transparency and give interested parties an opportunity to provide input on changes they think should be made to the quality strategy, even if the State itself is not proposing significant changes. Consistent with current policy, States will retain discretion under the proposed rule to define the public comment process. This proposed change would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

Second, we are proposing to revise § 438.340(c)(2)(ii) to clarify that the State Medicaid agency must post on its website the results of its 3-year review. The current regulations make clear at § 438.340(c)(2) that the review must include an evaluation, conducted within the previous 3 years, of the effectiveness of the quality strategy and that the results of the review must be made available on the State's website, but do not specifically state that the full evaluation must be posted on the website. Proposed revisions at § 438.340(c)(2)(ii) make clear that the evaluation, as part of the review, must be posted. We note that current § 438.340(c) allows for States to post the evaluation on the website as a standalone document or to include the evaluation in the State's updated and finalized quality strategy, which is required to be posted under § 438.340(d). The proposed change at § 438.340(c)(2)(ii) would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e). For additional information on the components and purpose of the managed care quality strategy, see the Quality Strategy Toolkit, available at *https://www.medicaid.gov/medicaid/downloads/managed-care-quality-strategy-toolkit.pdf*.

Third, we are proposing to clarify when States must submit a copy of their quality strategy to CMS. Current regulations at § 438.340(c)(3) require that States submit to CMS a copy of their initial quality strategy for feedback and a copy of the revised quality strategy whenever significant changes are made. The current regulations do not require States to submit to CMS subsequent versions of their quality strategy unless the State has made significant changes to the document or to their Medicaid program. We are proposing to modify § 438.340(c)(3)(ii) to require that States, prior to finalizing a revised or renewed quality strategy as final, submit a copy of the revised strategy to CMS at minimum every 3 years, following the review and evaluation of the strategy described at § 438.340(c)(2), in addition to when significant changes are made. These proposed changes would allow CMS the opportunity to provide feedback periodically to help States strengthen their managed care quality strategies before they are finalized, whether or not significant changes are made to a State's strategy or to

their Medicaid program. We propose to include this requirement into the provision at § 438.340(c)(3)(ii) for Medicaid by adding § 438.340(c)(3)(ii)(A) through (C), which would apply to separate CHIP through an existing cross-reference at § 457.1240(e). We are proposing at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States must comply with updates to § 438.340 no later than 1 year from the effective date of the final rule, which we believe would give States time to update internal processes accordingly.

Finally, we are proposing a technical correction to § 438.340(c)(3)(ii) to correct an internal citation related to State-defined significant changes. Currently, § 438.340(c)(3)(ii) references significant changes "as defined in the State's quality strategy per paragraph (b)(11) of this section[.]" However, § 438.340(b)(10) contains the information on a State's definition of a significant change. Therefore, we are proposing to replace "paragraph (b)(11)" with "paragraph (b)(10)" in § 438.340(c)(3)(ii). This proposed change would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

c. External Quality Review (§§ 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, 457.1250)

Current regulations at §§ 438.350, 438.354, 438.358, 438.360, 438.364, and 457.1250 provide requirements for the annual External Quality Review (EQR) on quality, timeliness, and access to the health care services furnished to Medicaid and CHIP beneficiaries enrolled in managed care. The regulations set forth the EQR-related activities that States or a qualified EQR organization (EQRO) must perform, and the information that must be produced from an EQR and included in an annual detailed EQR technical report. States must submit to CMS an annual EQR technical report, which must include, among other things, a description of data, including validated performance measurement data for certain mandatory EQR-related activities. The regulations also delineate the circumstances in which States may use the results from a Medicare or private accreditation review in lieu of conducting an EQR for a given managed care entity.

The EQR requirements in 438 Subpart E apply to each MCO, PIHP, and PAHP that has a contract with a State Medicaid or CHIP agency as well as certain PCCM entities whose contract with the State provides financial incentives for improved quality outcomes, as described in § 438.310(c)(2). We are proposing several changes to the EQR regulations that seek to accomplish two overarching goals: (1) eliminate unnecessary burdensome requirements; and (2) make EQR more meaningful for driving quality improvement.

(1) Removal of PCCM entities from scope of mandatory External Quality Review

In the final 2016 final rule, we added a definition of "primary care case management entity" in §§ 438.2 and 457.10 to recognize a new type of primary care case management system in Medicaid and CHIP. Previously, the regulations recognized, and continue to recognize, a primary care case manager (PCCM) as a physician or a physician group practice or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife that contracts with the State to furnish case management services to Medicaid beneficiaries. The 2016 final rule added the term "PCCM entity," which is defined in §§ 438.2 and 457.10 as an organization that provides one or more additional specified functions in addition to primary care case management services, for example, intensive case management, development of care plans, execution of contracts with and/or oversight responsibilities for other FFS providers, and review of provider claims, utilization and practice patterns, among others. We further recognized in the 2016 final rule that some PCCM entities have contracts with the State that provide financial incentives for improved quality outcomes. Per current § 438.310(c)(2), such PCCM entities are subject to a number of the requirements in 42 CFR part 438, subpart E (relating to Quality Measurement and Improvement and External Quality Review) to which PCCMs are not similarly subject.

Of particular relevance to this proposed rule, the regulations have long provided that States are not required to perform an annual EQR of the State's PCCMs. However, in the 2016 final rule, we provided at §§ 438.350 and 457.1250(a) that States are required to conduct an annual EQR of PCCM entities operating under a risk-bearing contract described in

§ 438.310(c)(2). We reasoned at the time that, while PCCMs traditionally are paid a per capita fee to provide case management services for Medicaid beneficiaries and otherwise are reimbursed for services rendered on a fee-for-service (FFS) basis, such PCCM entities function more like a managed care entity because their contracts include shared financial risk, and thus should be subject to the EQR requirements.

The 2016 final rule also provided for CMS review of States' contracts with their PCCM entities under § 438.3(r). Our reviews of these contracts have led us to reevaluate the policy to require an annual EQR of PCCM entities described in § 438.310(c)(2), as these contracts exhibit wide variability in the size, structure, and scope of case management and other services provided by risk-bearing PCCM entities. This variation calls into question the appropriateness of EQR as an oversight tool for many of the PCCM entities. For example, the scope of services for some of these PCCM entities may yield little to no data for EQR. In addition, some PCCM entities are a single provider or a small provider group, and we believe the cost and burden imposed by the EQR process may disincentivize them from entering into risk-bearing contracts with States aimed at improving quality and outcomes in the fee-for-service delivery system. We do not believe the EQR requirement should be a barrier for these types of PCCM entities to establish arrangements aimed at quality improvement when States have additional quality monitoring and oversight tools that may be sufficient (for example, QAPI program reviews described at § 438.330(e)).

Therefore, we propose to remove PCCM entities described in § 438.310(c)(2) from the managed care entities subject to EQR under § 438.350. Other requirements in 42 CFR part 438, subpart E that currently apply to risk-bearing PCCM entities described at § 438.310(c)(2) are not impacted by this proposed rule.[141] We note that States may perform additional oversight and

141 States are currently required to include their PCCM entities in CMS contract review under § 438.3(r), and for PCCM entities described at § 438.310(c)(2), States must include them in aspects of their quality assessment and performance improvement programs (QAPI) including an annual utilization and program reviews (§ 438.330(b)(2), (b)(3), (c), and (e)), and their quality strategy (§ 438.340), which includes a quality strategy effectiveness evaluation. States have the discretion under § 438.358(d) to use their EQRO to provide technical assistance to PCCM entities described at § 438.310(c)(2).

monitoring activities that are similar to external quality reviews for PCCM providers (and other providers not subject to EQR such as non-emergency medical transportation providers) at their discretion, and may choose to use an entity that is also an EQRO for these activities, however these activities would not be subject to 438 Subpart E regulations for EQR. Further, we believe that the removal of all PCCM entities from the mandatory scope of EQR will alleviate burden on States and PCCM entities while retaining appropriate tools for quality monitoring and oversight.

We propose conforming amendments to remove reference to PCCM entities described in § 438.310(c)(2) in §§ 438.310(b)(5), 438.358(a)(1), 438.364(a)(3) through (6), and 438.364(c)(2)(ii), and to remove the reference to § 438.350 from § 438.310(c)(2). We also propose removing the current provision at § 438.358(b)(2) that applies risk-bearing PCCM entities to the mandatory EQR activities, to conform with the proposed changes at § 438.350, and reserve this provision for future use. We maintain that EQROs must be independent from any PCCM entities they review at the State's discretion, as currently required under § 438.354(c), and propose a modification at § 438.354(c)(2)(iii) to clarify this. We note that these changes, if finalized, would be effective as of the effective date of the final rule. For separate CHIP, we likewise propose to exclude all PCCM entities from EQR requirements by removing the cross-reference to § 438.350 at § 457.1201(n)(2), by removing the reference to PCCM entities entirely from § 457.1250(a), and removing the cross-reference to § 457.1250(a) for quality requirements applicable to PCCM entities at § 457.1240(f).

(2) EQR review period

The current regulations provide that most EQR activities are performed using information derived from the preceding 12 months, but do not clearly indicate to which 12-month period the activity should pertain. Specifically, the current regulations at § 438.358(b)(1) (which apply to separate CHIP through § 457.1250(a)) require validation of information collected or calculated during "the preceding 12 months" for three of the mandatory EQR activities (validation of performance improvement projects, validation of performance measurement data, and validation

of network adequacy activities). The optional EQR activities described in § 438.358(c) also must be performed using information derived "during the preceding 12 months". In addition, we do not currently specify in the regulations when the EQR activity must take place relative to the finalization and posting of the annual report. The result is a lack of uniformity in the review periods included in States' annual EQR technical reports each year. In some cases, for example, States have reported on the results of EQR activities conducted three or more years ago, while other States have reported on the results of EQR activities conducted relatively close to the completion of the report. To support States' and CMS' ability to use the reports for quality improvement and oversight, we are proposing modifications to ensure consistency and align the data in the annual reports with the most recently available information used to conduct the EQR activities.

We propose to add a new paragraph (a)(3) in § 438.358 to define the 12-month review period for all but one the EQR-related activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c). The one exception is the activity described in § 438.350(b)(1)(iii), which requires a review within the previous 3 years. Under proposed § 438.358(a)(3), the 12-month review period for the applicable EQR activities begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity.

We understand that most performance measures run on a calendar year, while performance improvement projects and network adequacy assessments typically align with the contract year. Under the proposed rule, the 12-month review period for EQR activities does not have to be the same. For example, if an EQRO begins the performance measurement validation activity in July of 2022, and the State calculates performance measures on the calendar year, the review period for the performance measurement validation activity would be January 1 through December 31, 2021. Similarly, if the EQRO validates PIPs in November 2021 and the most

recent contract year ended in March 2021, the review period for the EQRO would be March 2020-March 2021.

We are also proposing to require at § 438.358(b)(1) and (c) that the EQR-related activities must be performed in the 12 months preceding the finalization and publication of the annual report. We believe these two proposed changes would result in more recent data being publicly posted in the annual EQR technical reports, and also would create more consistency among States regarding the time period represented by the data. Consistency in what data is reported could help make the EQR technical reports a more meaningful tool for monitoring quality between plans within and between States.

As noted, the proposed clarification of the 12-month review period for the applicable EQR-related activities described in § 438.350(b)(1) and (c) would be effectuated at proposed § 438.358(a)(3). We propose conforming changes to § 438.358(b)(1)(i), (ii) and (iv), and (c) to reference the EQR review period proposed at § 438.358(a)(3). We propose to modify the language at § 438.350(b)(1) and (c) to indicate that the EQR-related activities must be performed in the 12 months preceding the finalization of the annual reports. These proposed changes would apply equally to separate CHIP EQR requirements for MCOs, PIHPs, and PAHPS through an existing cross-reference to Medicaid's EQR-related activities in § 438.358 at § 457.1250(a). We are proposing that States must comply with these updates to § 438.358 no later than December 31, 2025, and are proposing to codify this applicability date at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. This applicability date aligns with the new annual due date for EQR technical reports as proposed at § 438.364(c)(2)(i), which we believe provides States sufficient time to make any contractual or operational updates following the final rule.

(3) Using an optional EQR activity to support current and proposed managed care evaluation requirements

We are proposing to add a new optional EQR activity to support States in their evaluations to learn more about quality outcomes and timeliness of and access to care in managed care plans and programs. Specifically, we believe the existing or proposed evaluation requirements included in this proposed rule for quality strategies at § 438.340(c)(2)(i), State Directed Payments (SDPs) at § 438.6(c)(2)(iv) and (v), and In Lieu of Services or Settings (ILOSs) at § 438.16(e)(1) may be implemented using this new EQR activity. We currently require at § 438.340(c)(2)(i) that States review their quality strategy at a minimum every 3 years, and that this review include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years. In this proposed rule, we are proposing new requirements related to the evaluation of SDPs at § 438.6(c)(2)(iv) and (v) and ILOSs at § 438.16(e)(1), described in more detail in sections I.B.2.j. and I.B.4.g. We discuss at length the challenges States have demonstrated regarding the SDP evaluation plans and results in section I.B.2.j. of this proposed rule, which indicates to us that States would likely benefit from additional technical assistance and support in conducting evaluations under the newly proposed SDP and ILOS requirements. Additionally, CMS' reviews of State quality strategy evaluations have revealed many challenges for States and a similar need for greater technical assistance. For this reason, we propose to add a new optional EQR activity at § 438.358(c)(7) to assist in evaluations of quality strategies, SDPs, and ILOSs, that pertain to outcomes, quality, or access to health care services. We are focusing the scope of the EQR optional activity to activities permissible under the statutory authority at Section 1932(c)(2) of the Act, which requires external review of the quality outcomes and timeliness of, and access to, the items and services for which the organization is responsible under the contract. We believe by adding this optional activity, States, their agent, or an EQRO could use the accompanying protocol that CMS would develop (in coordination with the National Governors Association in accordance with § 438.352) to assist with evaluation

activities related to quality strategies, SDPs, and ILOS, that are within the scope of EQR. We also believe EQROs may be well positioned to help with evaluations since their qualifications, as required under § 438.354(b), include research design and methodology, including statistical analysis, and quality assessment and improvement methods. We believe this optional activity would provide States critical technical assistance via a CMS-developed protocol that would enable more robust evaluations, which could lead to greater transparency and quality improvement in States' implementation of their quality strategy, SDPs and ILOSs. It could also reduce burden by allowing States to receive an enhanced match for activities carried out by an EQRO under this optional activity in accordance with section 1903(a)(3)(C)(ii) of the Act.

For separate CHIP, we did not adopt the proposed evaluation of SDPs at § 438.6(c)(2)(iv) and (v) (see sections I.B.2.a. and I.B.2.j. of this proposed rule). For this reason, we propose to amend separate CHIP EQR requirements at § 457.1250(a) to exclude references to § 438.6. However, we proposed to adopt the new ILOS retrospective evaluation requirements at § 438.16(e)(1) through our proposed cross-reference at § 457.1201(e) (see section I.B.4.g. of this proposed rule). Since section 2103(f)(3) of the Act requires external review of CHIP managed care plans, we also believe that CHIP EQROs are well positioned to assist with the proposed ILOSs evaluations and agree it would be beneficial to States to have this optional EQR activity. We propose to adopt the new EQR optional activity for separate CHIP through an existing cross-reference to § 438.358 at § 457.1250(a). If finalized, this optional activity would be available to States as of the effective date of the final rule.

(4) Non-duplication of mandatory EQR activities with Medicare or accreditation review

Current § 438.360 provides an option for States to exempt MCOs, PIHPs, or PAHPs from EQR-related activities that would duplicate activities conducted as a part of either a Medicare review of a Medicare Advantage (MA) plan or a private accreditation review. Section 438.360(a)(1) requires that, in order for a State to exercise this option with respect to private accreditation, the plan accreditation must be from a private accrediting organization recognized

by CMS "as applying standards at least as stringent as Medicare under the procedures in § 422.158 of this chapter[.]" Section 422.158 describes the procedures for private, national accreditation organizations (PAOs) to apply for approval of accreditation as a basis for deeming compliance with Medicare requirements, also referred to as "deeming authority." Sections 422.156 and 422.157 discuss conditions and applications of the deeming authority, under which a PAO may accredit MA plans for the purposes of deeming compliance with one or more specific areas of the MA program. The implementation of this current requirement at § 438.360(a)(1) has meant that PAOs must obtain deeming authority from CMS as a prerequisite for the States to use the PAO's plan accreditation review for the purposes of nonduplication of mandatory EQR activities. This means the PAO must obtain and periodically renew their MA deeming authority from CMS even if it is solely for the purpose of providing States the opportunity to use their reviews of a Medicaid managed care plans in lieu of conducting a similar EQR-related activity.

We believe the current regulation creates an unnecessary administrative burden on both CMS and PAOs and may restrict the availability of the EQR nonduplication option for States. We also do not believe that the current requirement is compelled under the statute. The statutory basis for the nonduplication provision, found at section 1932(c)(2)(B) of the Act, states, a State may provide that, in the case of a Medicaid managed care organization that is accredited by a private independent entity (*such as those described in section 1852(e)(4)*) or that has an external review conducted under section 1852(e)(3) of the Act, the external review activities conducted under subparagraph (A) with respect to the organization shall not be duplicative of review activities conducted as part of the accreditation process or the external review conducted under such section (*emphasis added*). Section 1852(e)(4) of the Act is the statutory basis for PAOs to obtain MA deeming authority from CMS. We do not read this provision as requiring every private independent entity to be described under section 1852(e)(4) of the Act in order for a State to exercise the nonduplication provision. Rather, we read section 1932(c)(2)(B) of the Act as

describing in general terms the types of organizations that would be eligible to participate in nonduplication, and providing organizations described in section 1852(e)(4) of the Act as an example.

Therefore, we propose at § 438.360(a)(1) to remove the requirement that PAOs must apply for MA deeming authority from CMS in order for States to rely on PAO accreditation reviews in lieu of EQR activities. We are proposing conforming changes to the title of § 438.362(b)(2) to remove language specific to Medicare Advantage deeming. Additionally, we are proposing to remove the requirements for PAOs related to MA deeming authority at § 438.362(b)(2)(i). This proposal would remove paragraph (b)(2)(i)(B) and modify paragraph (b)(2)(i) to include current § 438.362(b)(2)(i)(A). We believe this proposed change will reduce administrative burden among the private accreditation industry, as well as create more flexibility for States to leverage PAO reviews for nonduplication. We note that under § 438.360(a)(2) States will still be required to ensure the review standards used by any PAO are comparable to standards established through the EQR protocols under § 438.352, and pursuant to § 438.360(c), will need to explain the rationale for the State's determination that the activity is comparable in their quality strategy at § 438.340. If finalized, these changes would be effective as of the effective date of the final rule.

(5) External quality review results (§ 438.364)

(a) Data included in EQR technical reports

The current regulations at § 438.364, included in separate CHIP programs through an existing cross-reference at § 457.1250(a), describe what information must be included in the annual EQR technical reports as well as the public availability of the reports. While the information currently provided in the EQR technical reports is useful to CMS in our work with States to improve beneficiary access to and quality of care provided through a managed care delivery system, we believe these reports could and should provide additional information useful to both CMS and the public.

Current regulations at § 438.364(a)(2) describe the information the State must include in the annual EQR technical report for each EQR-related activity. Under § 438.364(a)(2)(iii), the EQR technical reports must include a description of data obtained, including validated performance measurement data for each PIP validation and performance measurement validation activity at § 438.358(b)(1)(i) and (ii), respectively. The current regulations, however, limit the data included in the reports to performance measurement data; the regulations do not require that other types of data that may be used to measure the outcomes associated with a PIP, such as percentages of enrollees that participated in the PIP or data on patient satisfaction based on services received from the plan, be included in the annual reports. The result is that reports often focus on whether the methods used to implement or evaluate the PIP were validated, but do not include the measurable data reflecting the outcomes of the PIP. Additionally, the regulations do not currently require the reports to include any data obtained from the mandatory network adequacy validation activity.

We believe validation alone is insufficient to provide CMS and interested parties with insight into plan performance on PIPs or States' effectiveness in driving quality improvement through PIPs. We also believe data on network adequacy validation is critical to understanding plan performance regarding timeliness and access to care. Therefore, we are proposing to revise § 438.364(a)(2)(iii) in two ways: (1) to require that the EQR technical reports include "any outcomes data and results from quantitative assessments" for the applicable EQR activities in addition to whether or not the data has been validated, and (2) to require this type of data from the mandatory network adequacy validation activity to also be included the EQR technical report. We believe this change will result in more meaningful EQR technical reports because they will include, in addition to validation information, the data demonstrating the outcome of PIPs and the results of quantitative assessments that determined plan compliance with network adequacy standards. This, in turn, will make the EQR technical reports a more effective tool to drive quality improvement and oversight in managed care. The proposed revisions to

§ 438.364(a)(2)(iii) for Medicaid would apply to separate CHIP through an existing cross-reference at § 457.1250(a). We propose at § 438.310(d)(4) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States must comply with these updates to the type of data in the EQR technical report no later 1 year from the issuance of the associated protocol, which we believe will provide the guidance and time for States and EQROs need to update their processes.

In addition to the proposed regulations in this section, we are considering adding guidance in the EQR protocols, described under § 483.352, for States to stratify performance measures collected and reported in the EQR technical reports under the performance measure validation activity. We believe stratification of performance measure data in EQR technical reports would support States' efforts to monitor disparities and address equity gaps. Stratifying performance measure data also aligns with proposed requirements for the mandatory reporting of Medicaid and CHIP Core Sets and proposed requirements in the MAC QRS proposed under new 42 CFR part 438 subpart G. We seek comment on how CMS could best support States in these efforts using future guidance we develop in the EQR protocols.

(b) Revising the date annual EQR technical reports must be finalized and posted

We currently require at § 438.364(c) that EQR technical reports be completed and available on the State's website required under § 438.10(c)(3) no later than April 30th of each year. However, we understand that most States with managed care programs use Healthcare Effectiveness Data and Information Set (HEDIS) measures. HEDIS measures represent the majority of measures included in the performance measure validation EQR activity. Data on these measures from the previous calendar year are audited and finalized in June annually. We therefore are proposing to revise § 438.364(c)(1) and (c)(2)(i) to change the April 30th date to December 31st. We believe this proposed change would align better with the HEDIS timeframes because the EQR performance measurement activity could then follow the HEDIS audit. We considered aligning the EQR technical report posting date with the end of the Federal fiscal year

on September 30th. However, we believe States and EQROs need more time to complete the EQR activities after receiving audited HEDIS data. We also believe December 31st is most appropriate because performance measurement data is most often calculated on a calendar year, so the December 31st date would result in data being at most 1 year old at the time the reports are posted on the State's website. We believe this change, coupled with those discussed in section I.B.5.c.2. of this proposed rule regarding changes to the EQR review period, would improve the utility of the technical reports for States, CMS and interested parties by making the data reported in them more current. The proposed changes at § 438.364(c)(1) and (c)(2)(i) for Medicaid would apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We seek comment on changing the posting date to December 31st annually. We also seek comment on whether additional time beyond December 31st is needed by States, and if so, how much time and why, or whether the posting date should remain at April 30th of each year, or a date between April 30th and December 31st and why. We are proposing at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP, that States come into compliance with this new due date by December 31, 2025, which we believe would provide enough time for contractual and operational updates.

(c) Notifying CMS when annual EQR technical reports are posted

Current regulations do not require States to notify CMS that their EQR technical report has been completed and posted on the State's website. We propose to revise § 438.364(c)(2)(i) to require that States notify CMS within 14 calendar days of posting their EQR technical reports on their website, for example, by providing CMS with a link to the report. Section 401 of the Children's Health Insurance Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111-3, enacted February 4, 2009) and section 2701 of the ACA require that CMS review and aggregate data from these reports in an annual report to the Secretary by September 30th. This proposed change would facilitate our review and aggregation of the required data and ensure that all States' data

are included in the annual report. We are proposing that the notice to CMS be provided "in a form and manner determined by CMS." However, we seek comment on whether we should require that this notice be provided via email or some other mode of communication. The proposed revisions at § 438.364(c)(2)(i) would apply to separate CHIP through an existing cross-reference at § 457.1250(a). We note that this requirement be effective as of the effective date of the final rule, which we do not believe will impose a great burden on States since most States already notify CMS when their EQR technical reports are posted by email.

(d) Revising website requirements for historical EQR technical reports

Currently, States are encouraged, but not required, to retain EQR technical reports from previous years on their websites. We are proposing to require States maintain at least the previous 5 years of EQR technical reports on their website. Retaining at least 5 years of past EQR technical reports would provide administrative efficiencies and additional transparency by allowing CMS to use historical data and information within the annual EQR technical reports for the purposes of reviewing States' managed care program and plan performance during contract renewals and waiver renewals. In addition, having archived reports would provide other interested parties insight into historical plan performance. In addition, section 1915(b) waivers can be approved for up to 5 years, and section 1115 demonstrations are often approved for 5 years, providing additional support for 5 years being an appropriate timeframe for this requirement.

We understand that almost half of States already retain at least 2 years' worth of EQR technical reports based on a review of State websites in 2022, and we seek comment on whether archiving 5 years of reports would pose a significant burden on States. We propose to add this provision to the requirements at § 438.364(c)(2) for Medicaid, which would apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We are proposing that States must comply with this update to § 438.364(c)(2)(iii) no later than December 31, 2025, and are proposing to codify this applicability date at § 438.310(d)(3)

for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. This applicability date aligns with the new proposed due date for the EQR technical reports, which we believe would provide the time needed to update websites accordingly.

(6) Technical Changes

We are proposing a technical change at § 438.352 to eliminate the apostrophe from National Governors Association to align with the correct name of the organization.

6. Medicaid Managed Care Quality Rating System (§§ 438.334 and 457.1240)

a. Background

In the 2016 final rule we established the authority to require States to operate a Medicaid managed care quality rating system (QRS) at § 438.334 and adopted the requirement for this provision, excluding provisions regarding consultation with the Medical Care Advisory Committee, to apply to separate CHIP at § 457.1240(d). We use the term "Medicaid and CHIP Managed Care Quality Rating System" ("MAC QRS") for this proposed rule in line with the terminology used in the 2020 final managed care rule (85 FR 72754). The MAC QRS requirements currently include public posting of quality ratings on the State's website, which is intended to provide beneficiaries and their caregivers with a web-based interface to compare Medicaid and CHIP managed care plans based on assigned performance indicators and ratings. As described in previous rulemaking, the policy objectives of the MAC QRS are threefold: (1) to hold States and plans accountable for the care provided to Medicaid and CHIP beneficiaries; (2) to empower beneficiaries with useful information about the plans available to them; and (3) to provide a tool for States to drive improvements in plan performance and the quality of care provided by their programs. Managed care is the dominant delivery system in the Medicaid program; of the 80.8 million individuals covered by Medicaid as of July 1, 2020, 67.8 million

(84 percent) were enrolled in a type of managed care.[142] Numerous States have implemented rating systems for Medicaid and CHIP managed care plans, but the MAC QRS represents the first time that States would be held to a minimum Federal standard for their rating systems and that Medicaid and CHIP beneficiaries in every State contracting with a managed care plan could access quality and other performance data at the plan level, supporting the ability of Medicaid and CHIP beneficiaries to select plans that meet their needs. The policies we are now proposing would establish the MAC QRS as a one-stop-shop where beneficiaries could access information about Medicaid and CHIP eligibility and managed care; compare plans based on quality and other factors key to beneficiary decision making, such as the plan's drug formulary and provider network; and ultimately select a plan that meets their needs. Many of the policies proposed for States' MAC QRS websites build upon existing data and information that States are already required to report publicly and to us. Thus, we believe that under the proposals in this rulemaking, States would be able to leverage many existing reporting systems and their current quality infrastructure to build their MAC QRS websites and provide a user-friendly experience for beneficiaries that informs their understanding of managed care plan performance and choice of plan.

Current requirements at § 438.334(b)(1) for Medicaid, which is adopted by cross-reference at § 457.1240(d) for separate CHIP, provide that CMS, in consultation with States and other interested parties, including beneficiaries, managed care plans, external quality review organizations (EQROs), tribal organizations, and beneficiary advocates (hereafter referred to as "interested parties"), will develop a MAC QRS framework that includes quality measures and a methodology for calculating quality ratings. The current regulations also provide States the option to either use the CMS-developed framework or establish an alternative QRS that produces substantially comparable information about plan performance, subject to our approval.

142 *https://www.medicaid.gov/medicaid/managed-care/downloads/2020-medicaid-managed-care-enrollment-report.pdf*.

Furthermore, the current regulations require that we develop a minimum set of mandatory quality measures that must be used, regardless of whether a State chooses to implement the CMS-developed QRS or an alternative QRS; this supports the goal of State-to-State comparisons of plan performance while reducing plan burden through standardization. The current regulations also require the MAC QRS framework to align, where appropriate, with other CMS managed care rating approaches (such as the Medicaid Scorecard initiative, the Medicare Advantage (MA) and Part D 5-star and the Qualified Health Plan (QHP) quality rating systems) as a way to reduce State and plan burden across quality reporting systems.

Since these regulations were issued, we have used a variety of forums to engage in robust consultation with interested parties to develop the framework of the MAC QRS to fulfill our obligation under § 438.334(b)(1) for Medicaid and under § 457.1240(d) for separate CHIP. These forums included beneficiary interviews, workgroup meetings, listening sessions, user testing of a MAC QRS prototype, and in-depth interviews with participants from State Medicaid programs, managed care plans, and EQROs. Through these extensive consultations, which took place between 2018 and 2022 and are summarized below, we learned about current State quality measure collection and reporting efforts and beneficiary needs and preferences related to the selection of a health plan. What we learned informed the MAC QRS framework proposed in this rulemaking. We summarize our consultation activities here:

- *2018 to 2022 Beneficiary and Caregiver Interviews:* Between 2018 and 2022, we conducted two rounds of individual interviews with a diverse selection of potential users of the MAC QRS. We conducted 96 interviews with people of differing age, race, ethnicity, geographic location, and Medicaid experience. The first round of 48 individual interviews focused on discovering beneficiary values and understanding the measures of health plan quality that matter to beneficiaries. Using a Human Centered Design approach, a MAC QRS website prototype was developed following an initial round of engagement with States and other interested parties as well as beneficiary and caregiver interviews, and then tested by the second group of 48 potential

users. This second group of individuals provided feedback on: website navigation and usability; the features that aided users' ability to identify health plans that align with their needs and preferences, such as being able to search for plans that cover specific providers and/or prescriptions; the ability to filter quality measures to show ratings stratified based on user-identified specifications such as age, race, and ethnicity; and information on health plan quality, including quality measures identified as desirable by participants. The two rounds of engagement culminated in a revised MAC QRS website prototype, linked to in section I.B.6.g. of this proposed rule, that incorporate content and features found most desirable by potential MAC QRS users.

- *2019 Measure Workgroup:* A workgroup consisting of 27 members from key groups, including State Medicaid and CHIP agencies, Medicaid and CHIP managed care plans, EQROs, and national organizations representing health care providers and beneficiaries, met between July and December 2019 to identify potential measures for the mandatory measure set and the feasibility of reporting certain measures.

- *2019 Interested Parties Listening Sessions:* Between August and November 2019, we held 15 listening sessions with 380 interested parties including Medicaid and CHIP Directors, Medicaid medical directors, managed care plan officials, and managed long-term services and supports (MLTSS) officials. Participants were requested to consider the presented measures and the feasibility of data collection and reporting. Website prototypes were presented to elicit feedback on feasibility, the comparison of measures by program and plan type, population stratification, and concerns related to measure presentation.

- *2019 and 2020 State, Health Plan and EQRO Interviews:* In 2019 and 2020, we conducted 20 interviews with 39 representatives from State Medicaid programs, managed care plans, and EQROs to obtain feedback regarding appropriate measures for inclusion in the MAC QRS, implementation of an alternative QRS, concerns about implementation of a MAC QRS,

and technical assistance needs. In addition, we obtained information on current approaches and methodologies used by States and plans to calculate quality measures.

- *2021 and 2022 Listening Sessions:* In 2021 and 2022, we held 11 listening sessions with over 280 participants, during which we shared a sample mandatory measure set containing over 25 measures. We requested feedback on feasibility of data collection and reporting; reliability of the measures; actionability for use in quality improvement by the managed care plan; gaps in representation of specific populations or conditions; and a feasible timeline for collecting, calculating, and displaying the sample mandatory measures.

Based on this consultation, we are now proposing a MAC QRS framework that includes mandatory measures, a rating methodology (either the CMS-developed methodology or an alternate methodology approved by CMS), and a mandatory website display format; the website display would be an additional third component of the MAC QRS framework. We are proposing that States must include the mandatory measures under the MAC QRS framework but that States may also include additional measures without implementing an alternative QRS. This would change the current regulations that include both mandatory and non-mandatory measures in the CMS-developed framework. We are also proposing the initial mandatory measure set that States must use regardless of whether they use the MAC QRS framework or a CMS-approved alternative QRS, as well as a subregulatory process under which CMS would engage regularly with interested parties in order to update the mandatory measure set over time.

Additionally, after consulting with prospective MAC QRS users, we now believe displaying quality ratings alone would not be useful in selecting a health plan without additional context about Medicaid and CHIP as well as other information about health plans. We are therefore proposing website display requirements as a new component of the overall framework, and propose that the MAC QRS website include information that draws from existing State data and information to ensure a State's MAC QRS is a meaningful and usable tool for beneficiaries. Finally, in light of the diverse starting points from which States will begin to implement their

MAC QRS, we are proposing to delay the deadline by which States must come into compliance with several of the requirements of the proposed MAC QRS framework to provide States with more time to implement the more complex requirements, including certain interactive display features. Importantly, States can use the optional EQR activity at § 438.358(c)(6) to assist with the quality rating of MCOs, PIHPs, and PAHPs. This could reduce burden by allowing States to receive an enhanced match for certain, limited activities carried out by an EQRO under this optional activity in accordance with section 1903(a)(3)(C)(ii) of the Act.

This proposal is made under our authority to implement and interpret in sections 1932(c)(1), 1932(a)(5)(C) and 2103(f)(3) of the Act, which provide that States that contract with MCOs for Medicaid managed care and CHIP, respectively, must develop and implement a quality assessment and improvement strategy that examines standards for access to care as well as other aspects of care and services directly related to the improvement of quality of care (including grievance procedures and information standards) and must provide comparative information on available plans related to health plan benefits and cost-sharing, service area, and available quality and performance indicators. As with most other requirements for managed care plans, we rely on section 1902(a)(4) of the Act to extend the same requirements to PIHPs and PAHPs that apply to MCOs in a Medicaid managed care program and on section 2103(f)(3) of the Act to extend the same requirements that apply to MCOs in CHIP to PIHPs and PAHPs. Throughout this section of the proposed rule, we note how the proposed Medicaid managed care regulations in part 438, subpart G (related to the MAC QRS) would apply equally to separate CHIP by a proposed cross-referenced added to § 457.1240(d).

The proposed set of minimum quality measures are intended to evaluate performance on quality of care, access to services, and outcomes. By measuring performance annually on specific quality measures (that is, mandatory measures adopted by us and any additional measures elected by the State), States will have information and data to monitor and evaluate performance of their managed care plans.

In exercising our authority under sections 1932(c)(1) and 2103(f)(3) of the Act, CMS may not implement standards for the implementation of a quality assessment or improvement strategies unless the Secretary implements such standards in consultation with the States. To fulfill this requirement, we have engaged in robust consultation with States, as described in section I.B.6.a. of this proposed rule, on the design of the MAC QRS, including the mandatory measure set, methodology, and display requirements. Going forward, we are proposing to continue to engage in consultation prior to making updates to the three components of the MAC QRS framework. In section I.B.6.e.3. of this proposed rule, we discuss our proposal for a subregulatory process through which we will continue to consult with States and interested parties to update the mandatory measure set; in section I.B.6.f. of this proposed rule, we discuss our proposal to continue to consult with States and interested parties to update the MAC QRS methodology, and in section I.B.6.g. of this proposed rule, we discuss our proposal to consult with States and interested parties to update our proposed website display requirements.

b. Provisions of the Proposed Rule (§§ 438.334, 438 subpart G, and 457.1240(d))

We are proposing to create a new subpart G in 42 CFR part 438 to implement the MAC QRS framework required under § 438.334 of the current regulations and establish the standards which States must meet for CMS to approve adoption of an alternative QRS and related requirements. Existing regulations at § 438.334 are redesignated to newly-created proposed sections in Subpart G with proposed revisions, discussed in detail below in this proposed rule. For separate CHIP, we propose to adopt the new provisions of subpart G in part 438 by cross-reference through an amendment at § 457.1240(d).

c. Definitions (§§ 438.334, 438.500, and 457.1240(d))

There are some technical and other terms relevant to our proposed regulations. Therefore, we propose the following definitions at § 438.500(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). Some proposed definitions are

discussed in more detail later in this proposed rule in connection with other proposed regulation text related to the definition.

- *Measurement period* means the period for which data are collected for a measure or the performance period that a measure covers.

- *Measurement year* means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.

- *Medicaid managed care quality rating system framework* (*QRS framewor*k) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.

- *Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system)* means the rating system described in subpart D of parts 422 and 423 of this chapter.

- *Qualified health plan rating system (QHP quality rating system)* means the health plan quality rating system developed in accordance with 45 CFR 156.1120.

- *Quality rating* means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.

- *Technical resource manual* means the guidance described in § 438.530.

- *Validation* means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

d. General Rule and Applicability (§§ 438.334(a), 438.505(a) and 457.1240(d))

Currently, § 438.334(a) lays out the general rule for the MAC QRS, including general requirements for States contracting with MCOs, PIHPs and/or PAHPs to furnish services to Medicaid beneficiaries. These requirements also apply to separate CHIP through a cross-

reference to § 438.334 at § 457.1240(d). Specifically, § 438.334(a) requires States to adopt a quality rating system using the CMS framework or an alternative quality rating system and to implement such quality rating system within 3 years of the date of the final rule published in the **Federal Register**. We are proposing at § 438.505(a)(2) for Medicaid, and for separate CHIP by cross-reference to Part 438, Subpart G at § 457.1240(d), to require States to implement their MAC QRS (or alternative QRS) by the end of the fourth calendar year following the effective date of the final rule (meaning the fourth calendar year following issuance of the final rule). This proposed change from the current 3-year implementation date under § 438.344(a) would provide States more time to make the operational and contractual changes needed to meet the requirements in this proposed rule and also give States flexibility to determine what time of year to publish their quality ratings. To illustrate the proposed timeline change, we provide the following example: if the final rule is effective on April 1, 2024, States would be required to implement their MAC QRS no later than December 31, 2028, and the data displayed in 2028 would be from the measurement year between January 1, 2026 and December 31, 2026. The timeline for future measurement and display years is discussed in detail in section I.B.6.e.7. of this proposed rule. The proposal at § 438.520(a)(6) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), would require implementation of some website display requirements, discussed in section I.B.6.g. of this proposed rule, after the proposed implementation date. We also discuss in section I.B.6.g. of this proposed rule, how several of the proposed display requirements build upon existing information and data States either already have or are currently required to report publicly or to CMS. We seek comment on whether these proposed policies, all together, would give States sufficient time to implement their MAC QRS or alternative QRS on a timeline that meets their operational needs.

We are also proposing for Medicaid, as a general rule, that States provide a support system for beneficiaries or users of a State's MAC QRS, leveraging existing State resources. In our user testing, described in greater detail in I.B.6.g. of this proposed rule, users responded

positively to the availability of live consumer assistance through telephone or online chat, which 83 percent of participants found useful as it helped them navigate the MAC QRS website and get the information they were looking for right away. Per § 438.71, States are currently required to develop and implement a beneficiary support system. The elements of the beneficiary support system are identified at § 438.71(b)(1) as including choice counseling for all beneficiaries in § 438.71 (b)(1)(i), assistance for enrollees in understanding managed care in § 438.71 (b)(1)(ii), and assistance related to the receipt of long-term services and supports at § 438.71 (b)(1)(iii). Currently, § 438.2 provides that choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions and includes answering questions and identifying factors to consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP. We believe that this existing support is an appropriate system for States to build upon to assist beneficiaries in using and understanding the information in the MAC QRS to select a managed care plan. In a new § 438.505(a)(3), we are therefore proposing for Medicaid that States would be required to use the beneficiary support system implemented under current § 438.71 to provide choice counseling to all beneficiaries, and assistance for enrollees on understanding how to use the managed care quality rating system to select a managed care plan, including the receipt of long-term services and supports. With the support system already in place, we believe States could leverage existing resources by developing new scripts and training existing staff. We discuss the importance of providing this assistance in section I.B.6.g. of this proposed rule where we provide an overview of the input we received from beneficiaries. However, since a beneficiary support system is not required for separate CHIP, we do not propose to adopt this provision for subpart L of part 457.

The current regulations at § 438.334(b)(1) for Medicaid, and applied by cross-reference at § 457.1240(d) for separate CHIP, require the MAC QRS framework to align, where appropriate, with the QHP quality rating system, the MA and Part D quality rating system and

other related CMS quality rating approaches as a way to reduce State burden across Federal quality reporting systems. We believe this requirement should continue to apply broadly to the MAC QRS framework and are therefore proposing to require this alignment, to the extent appropriate, as part of CMS' maintenance the MAC QRS framework. We propose to redesignate this requirement for alignment in § 438.334(b)(1) to its own provision at § 438.505(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). The importance of alignment of the MAC QRS with the MA and Part D and QHP quality rating systems was shared by States, managed care plans and other interested parties, affirming the requirement in our current regulations that, to the extent possible, the MAC QRS be aligned with the MA and Part D and QHP quality ratings systems, the Medicaid and CHIP Child Core Set, the Medicaid Adult Core Set, and other similar CMS initiatives such as the Medicaid and CHIP Scorecard and the CMS Universal Foundation.[143] We are also proposing, at § 438.505(c), that in maintaining the MAC QRS mandatory measure set and rating methodology, CMS will align with these other similar CMS programs and approaches when appropriate.

Finally, current regulations at § 438.334(a) for Medicaid managed care programs (applied to separate CHIP through a cross-reference in § 457.1240(d)) apply the requirements for the MAC QRS to each State contracting with an MCO, PIHP or PAHP to furnish services to Medicaid or CHIP beneficiaries. We are proposing to revise this to refer to "an applicable managed care plan as described in paragraph (b) of this section" in proposed § 438.505(a), and add an applicability provision at new § 438.505(b) stating that the provisions of newly-proposed subpart G apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The proposed provisions at § 438.505(a) and (b) are also proposed to apply to separate CHIP through a cross-reference at § 457.1240(d), but excluding all references to beneficiary support systems. We note that the current and proposed regulations in Subpart G do not apply to PCCM entities, consistent with current regulations at §§ 438.10(c)(2) and

143 *https://www.nejm.org/doi/full/10.1056/NEJMp2215539*.

457.1207; non-emergency medical transport PAHPs are also not included in the MAC QRS, in accordance with §§ 438.9 and 457.1206(b). In addition, our proposal for the MAC QRS framework excludes contracts between States and MA Dual Eligible Special Needs Plans (D-SNP) where the contract is only for the D-SNP to provide Medicaid coverage of Medicare cost sharing for the D-SNP enrollees; this is reflected in proposed § 438.505(b).

e. Establishing and Modifying a Mandatory Measure Set for MAC QRS (§§ 438.334(b), 438.510 and 457.1240(d))

The current regulations at § 438.334(b)(1) direct CMS, after consulting with States and other interested parties, to identify a mandatory set of QRS quality measures that align, where appropriate, with the MA and Part D and QHP quality rating systems and other related CMS quality rating approaches, and to provide an opportunity for public notice and comment on such mandatory measures. In this section we discuss the standards that guided CMS in identifying the initial mandatory measures and propose an initial mandatory measure set. We seek comment on our proposed initial mandatory measure set, which we will finalize in the preamble of the final rule. Under this proposal, we would not duplicate the list of the mandatory measures and specifications in regulation text in light of the regular updates and revisions contemplated by the rules we are proposing for ongoing maintenance of the MAC QRS. We also propose a subregulatory process to modify the mandatory measure set over time, including proposing to codify the standards that guided development of the proposed initial mandatory measure set.

(1) Standards for including measures in mandatory measure set (§§ 438.510(c), 457.1240(d))

Three distinct considerations guided the process of selecting individual measures to establish a concise proposed initial mandatory measure set. We are proposing at § 438.510(c)(1)-(3) to codify these three considerations as standards that we would apply in the future to determine when to add measures to the mandatory measure set, when to make substantive updates to an existing mandatory measure, and in some circumstances, when to remove a measure from the mandatory measure set. Specifically, a measure is only included in our

proposed initial mandatory measure set and would only be added in the future if (1) it meets five of the six measure inclusion criteria proposed in this section; (2) it would contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas (for example, preventive health, long term services and supports, etc.) within a concise set of mandatory measures; and (3) the burdens associated with including the measure do not outweigh the benefits to the overall quality rating system framework of including the new measure based on the measure inclusion criteria we are proposing. Under our proposal, and as discussed in section I.B.6.e.4. of this proposed rule, a measure would be added to the mandatory set if it meets each of these three standards. To determine whether a measure meets these standards, CMS would rely on the input received throughout the subregulatory process proposed in § 438.510(b) and discussed in section I.B.6.e.3. of this proposed rule and other relevant research and information. Similarly, a measure would be removed from the mandatory measure set if it no longer met these standards. This approach would ensure that each of the three proposed standards are met.

Using the MAC QRS goals described in section I.B.6.a. of this proposed rule as a guidepost during our discussion with States and other interested parties, we identified and refined six measure inclusion criteria: (1) is the measure meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan; (2) does the measure align with other CMS rating programs described in § 438.505(c) of this chapter; (3) does the measure assess health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity; (4) does the measure provide an opportunity for managed care plans to influence their performance on the measure; (5) is the measure based on data that are readily available, or available without undue burden on States and plans, such that it is feasible to report by most States and managed care plans; and (6) does the measure demonstrate scientific acceptability, meaning that the measure, as specified, produces consistent and credible results.

We used these six criteria to assess hundreds of measures suggested throughout our engagement with interested parties. We explain each proposed criterion here and describe how we assessed measures suggested during our engagement with interested parties against the criteria to select the proposed initial mandatory measure set of 18 measures, displayed in Table 1. In doing so, we also show how we would make future updates to the mandatory measure list using these criteria.

- *Usefulness to beneficiaries:* Whether the measure is meaningful and useful for beneficiaries or their caregivers when choosing a managed care plan. For the proposed mandatory set, we assessed whether a measure meets this criterion by seeking beneficiaries' feedback on which measures of health plan performance are most relevant to them. We then gave preference to measures that assess the quality of care or services most commonly identified by beneficiaries as relevant to selection of a health plan or their assessment of a health plan's quality. When adding, updating or removing measures, we intend to rely on the continued engagement with beneficiaries proposed in § 438.520(c) (discussed in section I.B.6.g.4. of this proposed rule) to apply a similar preference for changes that are either most meaningful and useful or most commonly described as meaningful and useful. Input from beneficiaries or beneficiary advocates with experience assisting beneficiaries will be particularly important in evaluating this criterion, but input from other interested parties will also be considered.

- *Alignment*: Whether the measure or measure concept is consistent with the principles of, or is represented in, one or more existing Federal, State, and/or Medicaid and CHIP quality reporting programs. For the measures listed in Table 1, we assessed whether a measure meets this criterion by identifying the extent to which States and other Federal programs (such as the Medicaid and CHIP Scorecard, the MA and Part D quality rating system, and the QHP quality rating system) currently collect or report the measure. We considered feedback on measures commonly used to assess health plan performance as well as the challenges and concerns with these measures. We gave preference to measures commonly collected or reported with few

reporting challenges. However, we also considered emerging measures that are not yet commonly collected or reported but align with a performance area or health outcomes measured by commonly used measures. As an example, an emerging measure such as the Person-Centered Contraception Counseling measure, which is not currently adopted at the plan level, could meet the alignment criterion if our workgroup identified that it overlaps with an existing, widely used measure in the area of contraception. We believe this approach more accurately reflects the continuing evolution of quality measurement and would allow the consideration of new, better measures, as they are developed. We note, however, that emerging measures would still be assessed based on the other criteria and standards described here and proposed at § 438.510(c)(1), (2), and (3), and it may take time for emerging measures to meet the final regulatory standards. Within the proposed measure set, 15 of the 18 measures are commonly reported by States[144], 16 of the 18 measures overlap with the 2023 and 2024 Core Set measures, 11 with the QHP quality ratings system, 13 with the 2021 Medicaid and CHIP Scorecard, and 5 with the MA and Part D quality rating system.

- *Relevance:* Whether the measure evaluates or measures the managed care plan's performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity. For the proposed measure set, we determined which of the areas each measure evaluates or measures. Preference was given to measures that evaluate or measure more than one area.

- *Actionability:* Whether there are opportunities for managed care plans to influence their performance on the measure. For the proposed measure set, we assessed whether a measure met this criterion by considering input on what actions managed care plans may take to improve or maintain measure performance and the extent to which the plans control, or are capable of influencing, what is being measured. We also considered whether the measure is currently specified at the plan level, meaning that measure specifications are available to calculate the

144 As reported by States for the 2020-2021 EQR reporting cycle.

measure at the plan (as opposed to provider or State) level. We gave preference to measures that are currently specified at the plan level and are more easily controlled or influenced by health plans.

- *Feasibility:* Whether the data needed to calculate the measure are readily available or could be captured without undue burden and could be implemented by most States and health plans. For the proposed measure set, we assessed whether a measure meets this criterion by considering the accessibility of the data required to calculate the measures and the proportion of plans or States that currently collect data for the measure. We gave preference to measures that require data that are easily accessible to plans (such as claims data) or are commonly collected.

- *Scientific Acceptability:* Whether the measure produces consistent (reliable) and credible (valid) results. We assessed whether a measure meets this criterion by reviewing evidence that use of the measure can draw reasonable conclusions about care in a given domain.[145]

Using feedback throughout our consultations related to the mandatory measure list, we assessed our list of suggested measures to identify the extent to which each measure met these inclusion criteria. During the same consultations, we received feedback (and our own evaluation showed) that while each of the six criteria were important to consider, it would be difficult for a measure to meet all six criteria. For instance, we found that requiring all six criteria could prevent the inclusion of either measures that are meaningful to beneficiaries but not commonly used by States, or measures aligned with State priorities for managed care quality and plan performance, but less useful to beneficiaries. We are therefore proposing in § 438.510(c)(1) that a measure must meet at least five of the six measure inclusion criteria to be considered against our other standards and included in the mandatory measure set in the future. We seek comment on the six criteria we are proposing to evaluate prospective measures for the mandatory measure

145 CMS Measures Blueprint: *https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/overview*.

set, and whether there are additional objective measure inclusion criteria that we should use to evaluate quality measures for inclusion as mandatory measures. Additionally, we seek comment on our proposal to require measures to meet five out of the six proposed criteria, and whether that threshold produces a sufficient number of measures to consider for the MAC QRS. Finally, we seek comment on the extent to which the measures in our proposed measure set meet the proposed measure inclusion criteria, including the reasons and/or supporting data for why the measure meets or does not meet the criteria. In our review of measures and development of the list of mandatory measures, we believe that each meets at least 5 if not all 6 of the criteria proposed at § 438.510(c)(1).

Through our work to develop the proposed mandatory measure set, we found that many measures meet at least five of the six measure inclusion criteria, and without additional guardrails in place we believe the set would quickly expand and become burdensome to States and plans. States and managed care plans generally recommended limiting the mandatory set to between 10 and 30 measures to ensure plans' ability to improve on selected measures and States' capacity to succeed in reporting, and to limit the impact of implementing a QRS on State and plan resources. Furthermore, our MAC QRS website prototype user testing showed that beneficiaries were evenly split between those with high informational needs who preferred detailed information from a lot of measures and those who valued clear, concise information on the big picture using fewer measures.

To maintain a concise measure set, we are proposing to codify two additional measure inclusion standards in § 438.510(c)(2) and (3). These two additional standards reflect the feedback we received on maintaining a "concise" mandatory measure list and provide a process by which to identify further distinctions among measures that meet our inclusion criteria and to consider the measure set as a whole as part of the selection process. First, in § 438.510(c)(2), we propose that a measure must contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas that are assessed within a concise

mandatory measure set. We have included as part of our standard proposed in § 438.510(c)(2) that the overall measure set should be "concise," given the feedback we received on limiting the number of measures in the mandatory measure set. we established and intend to maintain a goal of no more than 20 measures for the initial mandatory measure set. However, the proposed rule would retain flexibility for the number of measures to increase as the mandatory set is updated over time. we would consider each suggested measure in relation to other suggested measures and the overall mandatory measure set to identify those that are very similar or duplicative, keeping in mind the need for a mandatory measure set that is both representative and concise.

Second, we propose in § 438.510(c)(3) that a measure would be added to the mandatory measure set when the burdens of adding the measure do not outweigh the benefits based on the 6 criteria proposed at § 438.510(c)(1)(i) through (vi). we would compare similar measures, that is, those suggested for inclusion that measure performance within similar subpopulations of beneficiaries, health conditions, services, and performance areas as well as the extent to which a contemplated new measure meets the criteria listed in proposed paragraph (c)(1), to assess the benefits and burdens of including each measure in the mandatory measure set. Under our proposal, we would include a measure when all three of the standards proposed in § 438.510(c) are met. CMS would use the subregulatory process proposed in § 438.510(b) and discussed in section 1.B.6.e.3. of this proposed rule to determine which measures meet the proposed standards.

We seek comment on the standards proposed at § 438.510(c)(2) and (3) and how measures should be assessed using these standards. In particular, we seek comment on the appropriate balance of representation (of populations and performance areas) in the mandatory measure set and any additional considerations that may be missing from our proposed paragraph (c)(2). Further, we seek comment on whether there are additional considerations for the weighing of burdens and benefits of a measure under proposed § 438.510(c)(3).

(2) Mandatory Measure Set (§§ 438.510(a), (b), and 457.1240(d))

We propose in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that the quality rating system for managed care plans implemented by the State for Medicaid (and CHIP) managed care programs must include the measures in a mandatory measure set, which will be identified by CMS in the technical resource manual as proposed in § 438.530(a)(1). We note that in proposed § 438.520(b), discussed in section I.B.6.g.5. of this proposed rule, States can include other, additional measures outside the mandatory measure set. We received input through our consultations with interested parties, detailed in section I.B.6.a. of this proposed rule, on how to construct a mandatory measure set for the MAC QRS, including the number of measures, measure inclusion criteria, and performance areas and populations represented by the measures. After considering the priorities and other information gleaned through the several years of consultations described in section I.B.6.a. of this proposed rule, and applying the standards discussed in section I.B.6.e.1. of this proposed rule, we are proposing for public comment an initial set of 18 mandatory measures that represents the collective input we received during those consultations. This proposed initial set of mandatory measures can be found in Table 1. These proposed mandatory measures reflect a wide range of preventive and chronic care measures representative of Medicaid and CHIP beneficiaries.

TABLE 1: Proposed MAC QRS Mandatory Measure Set

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
2801	NCQA	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP-CH)	The percentage of members who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment. Ages: 1 to 17	Administrative**
0004	NCQA	Initiation and Engagement of Substance Use Disorder (SUD) Treatment	The percentage of new SUD episodes for members that result in the following: • Initiation of SUD Treatment. Percentage of new SUD episodes for members that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of SUD Treatment. The percentage of new SUD episodes for members that have evidence of treatment engagement within 34 days of the initiation visit. Ages: 13 – 17 | 18 to 64 | 65 and older	Administrative or EHR
0418* **	CMS	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF)	The percentage of members screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of the eligible encounter. Ages: 12 to 17 | 18 to 64 | 65 and older	Administrative or EHR
3489	NCQA	Follow-Up After Hospitalization for Mental Illness (FUH)	The percentage of emergency department (ED) visits for members with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. The following rates are reported: • The percentage of ED visits for mental illness for which the member received follow-up within 30 days of the ED visit (31 total days) • The percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days). Ages: 6 to 17 | 18 to 64	Administrative
1392	NCQA	Well-Child Visits in the First 30 Months of Life (W30)	The percentage of members who had the following number of well-child visits with a primary care practitioner (PCP) during the last 15 months. The following rates are reported: • Well-Child Visits in the First 15 Months. Children who turned age 15 months during the measurement year: Six or more well-child visits. • Well-Child Visits for Age 15 Months to 30 Months. Children who turned age 30 months during the measurement year: Two or more well-child visits.	Administrative

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			Ages: 0 to 15 months | 15 to 30 months	
1516	NCQA	Child and Adolescent Well-Care Visits (WCV)	The percentage of members who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement year. Ages: 3 to 21	Administrative
2372	NCQA	Breast Cancer Screening (BCS)	The percentage of women who had a mammogram to screen for breast cancer. Ages: 50 to 74	Administrative, EHR, or Electronic Clinical Data System (ECDS)♦
0032	NCQA	Cervical Cancer Screening (CCS)	The percentage of women who were screened for cervical cancer using either of the following criteria: • Women ages 21 to 64 who had cervical cytology performed within the last 3 years • Women ages 30 to 64 who had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years • Women ages 30 to 64 who had cervical cytology/high-risk human papillomavirus (hrHPV) co-testing within the last 5 years Ages: 21 to 64	Administrative, hybrid, or EHR
0034	NCQA	Colorectal Cancer Screening (COL)	The percentage of members who had appropriate screening for colorectal cancer. Ages: 50 to 75	Administrative, hybrid, or ECDS
2517	DQA	Oral Evaluation, Dental Services (OEV)	The percentage of members who received a comprehensive or periodic oral evaluation within the reporting year. Ages: 0 to 20	Administrative
2902	OPA	Contraceptive Care - Postpartum Women (CCP)	Among women who had a live birth, the percentage that: 1. Were provided a most effective or moderately effective method of contraception within 3 and 60 days of delivery. 2. Were provided a long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery. Ages: 15 to 20 | 21 to 44	Administrative
1517***	NCQA	Prenatal and Postpartum Care (PPC)	Percentage of deliveries of live births on or between October 8 of the year prior to the measurement year and October 7 of the measurement year that: 1. Received a prenatal care visit in the first trimester, on or before the enrollment start date or within 42 days of enrollment in Medicaid/CHIP (Timeliness of Prenatal Care Rate). 2. That had a postpartum visit on or between 7 and 84 days after delivery (Postpartum Care Rate). Ages: All Ages	Administrative or hybrid
0575/0059	NCQA	Hemoglobin A1c Control for Patients with Diabetes (HBD)	The percentage of members with diabetes (types 1 and 2) whose hemoglobin A1c (HbA1c) was at the following levels during the measurement year: • HbA1c control (<8.0%).	Administrative or hybrid

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• HbA1c poor control (>9.0%). Ages: 18 to 75	
1800	NCQA	Asthma Medication Ratio (AMR)	The percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. Ages: 5 to 18 | 19 to 64	Administrative
0018	NCQA	Controlling High Blood Pressure (CBP)	The percentage of members who had a diagnosis of hypertension and whose blood pressure (BP) was adequately controlled (< 140/90 mm Hg) during the measurement year. Ages: 18 to 85	Administrative, hybrid, or EHR
0006	AHRQ❖	CAHPS – How people rated their health plan	The percentage of members who rated their health plan a 9 or 10, where 0 is the worst health plan possible and 10 is the best health plan possible. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Getting care quickly	Composite of the following items: • The percentage of members who indicated that they always got care for illness, injury, or condition as soon as they needed, in the last six months. • The percentage of members who indicated they always got check-up or routine care as soon as they needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Getting needed care	Composite of the following items: • The percentage of members who indicated that it was always easy to get necessary care, tests, or treatment, in the last six months. • The percentage of members who indicated that they always got an appointment with a specialist as soon as needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – How well doctors communicate	Composite of the following items: • The percentage of members who indicated that their doctor always explained things in a way that was easy to understand. • The percentage of members who indicated that their doctor always listened carefully to enrollee. • The percentage of members who indicated that their doctor always showed respect for what enrollee had to say. • The percentage of members who indicated that their doctor always spent enough time with enrollee. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Health plan customer service	Composite of the following items:	Consumer Survey

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• The percentage of members who indicated that customer service always gave necessary information or help, in the last six months. • The percentage of members who indicated that customer service always was courteous and respectful, in the last six months. Ages: 1 to 17 | 18 and older	
Not endorsed	CMS	MLTSS-1 LTSS Comprehensive Assessment and Update	The percentage of Medicaid MLTSS plan participants who have documentation of a comprehensive assessment in a specified timeframe that includes documentation of core elements. Two performance rates and two exclusions rates are reported for this measure: • Assessment of Core Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) • Assessment of Supplemental Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements and at least 12 supplemental elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) Ages: 18 and older	Case Management Record Review
3547	CMS	MLTSS-7: LTSS Minimizing Institutional Length of Stay	The proportion of admissions to an institutional facility (for example, nursing facility, intermediate care facility for individuals with intellectual disabilities (ICF/IID)) for managed long-term services and support (MLTSS) plan enrollees that result in successful discharge to the community (community residence for 60 or more days) within 100 days of admission. This measure is reported as an observed rate and a risk-adjusted rate. Ages: 18 and older	Claims, Enrollment Data

* Refers to National Qualify Forum number. Measure endorsed by NQF can be found at NQF: Quality Positioning System ™ (qualityforum.org)
** Examples of administrative data collection methods are claims, encounters, vital records, and registries.
*** This measure is no longer endorsed by NQF.
♦ The HEDIS® Electronic Clinical Data System (ECDS) reporting standard defines data sources and types of structured data acceptable for use for a measure. The measures are provided as digital quality measures.
❖AHRQ is the measure steward for the survey instrument (NQF #0006) and NCQA is the developer of the survey administration protocol.

We considered including several other measures that are not included in the proposed initial mandatory set. These other measures were not included because they did not meet one or

more of the standards described in section I.B.6.e.1. of this proposed rule. These other measures and the reason we did not include them in Table 1, are described here:

- *Contraceptive measure:* States and other interested parties stated a desire for the MAC QRS to include a quality measure involving contraceptive services that would be relevant for all women, but many noted that there is not yet a measure they would recommend that meets this description. Beneficiaries did not specifically speak to the importance of a contraceptive measure, but consistently noted the desire to be involved in their care decisions and for providers to respect their health goals and needs when providing counseling on health care options. We considered various contraceptive measures in addition to CCP, the measure currently included in the proposed mandatory set. They include Contraceptive Care – All Women Ages 15 to 44 (CCW) and a new survey-based measure, Person-Centered Contraceptive Counseling (PCCC), that uses patient provided responses to assess the person-centeredness of contraceptive counseling. While we believe the PCCC measure aligns well with beneficiary preferences stated during beneficiary consultations, it failed to meet two of the six measure inclusion criteria. First, PCCC does not currently meet our requirement of feasibility as we did not find evidence that plans are currently collecting the data necessary to produce this measure and some interested parties stated concern about the perceived burden of reporting PCCC. Second, we believe the measure does not meet the scientific acceptability criterion as it is currently specified only at the provider level so it is unknown whether it produces consistent and credible results at the plan level. With respect to CCW and CCP, both measures meet at least five of the six inclusion criteria. Furthermore, both measures measure access to contraception that reduces unintended pregnancy in their respective populations and therefore each would contribute to balanced representation of beneficiaries by providing insight into the accessibility of contraceptive care among beneficiaries who may become pregnant. However, while both CCP and CCW would contribute to balanced representation within a concise mandatory measure set, we believe the benefits of including CCP are greater than those of CCW because CCP focuses on measuring

access to effective contraceptive care during the postpartum period, which can improve birth spacing and timing and improve the health outcomes of women and children.

- *Follow-up after Emergency Department Visit for Mental Illness (FUM) versus Follow-up After Hospitalization for Mental Illness (FUH):* There was support from States and other interested parties to include both of these measures, and including both would give a fuller picture of the percentage of emergency department and inpatient hospital discharges for which beneficiaries received follow-up services. These measures met all of our measure inclusion criteria and had similar benefits and burdens, but the two measures assessed important, but very similar services. We concluded that including both would not contribute to balanced representation within an overall mandatory set. Upon balancing benefits and burdens associated with each measure, we selected FUH because it was more commonly collected or reported at both the State and Federal level and more frequently used by States to assess plan performance. We provide a detailed analysis of our review of the FUH and FUM measures in section I.B.6.e.4. of this proposed rule.

- *Childhood Immunization Status (CIS):* We considered including the childhood immunization status measure, however, we included the well-child visit measure instead. Both measures met at least five of the six inclusion criteria and each could contribute to balanced representation within the overall mandatory set. However, when reviewing the burdens and benefits to the overall MAC QRS, we concluded the CIS measure would have little added benefit because our beneficiary testing showed that parents cared a lot about whether their children can get appointments (reflected in the well-child visit measure), but no beneficiary commented specifically on childhood immunizations.

- *Postpartum Depression Screening:* We considered this measure based on recommendations from the 2019 Measure Workgroup. However, we did not include this measure because it did not meet two of our six inclusion criteria. First, the measure is not aligned with any other CMS programs. Second, the measure did not meet our feasibility criterion because the

measure relies solely on a proprietary electronic clinical data systems (ECDS) reporting method. While this measure has been recommended for addition to the Core Set, CMS has deferred decisions related to the measure to assess how the proprietary nature of this information impacts the feasibility of reporting.

(3) Subregulatory process to update mandatory measure set (§§ 438.510(b) and 457.1240(d))

The current regulations at § 438.334(b)(2) establish that we may, after consulting with States and other interested parties and providing public notice and opportunity to comment, periodically update the Medicaid managed care QRS framework developed under current § 438.334(b)(1). We remain dedicated to the policy currently reflected in § 438.334(b)(1) and (b)(2) that requires engagement with interested parties for continuous improvement of the MAC QRS. In addition, continued engagement with States is consistent with our obligations under sections 1932(c)(1)(D) and 2103(f)(3) of the Act to consult with States in setting standards for measuring and monitoring managed care plan performance. However, we believe that requiring rulemaking to add new measures that may better meet beneficiaries' and States' needs or to remove measures whose utility has been surpassed by other measures would be overly restrictive and would undermine our ability to adapt the mandatory set to keep pace with changes in the quality field and user preferences. We also believe that a robust subregulatory process in which we interpret and apply substantive regulatory standards governing the measures to be included in the mandatory measure set can ensure that any changes reflect the extensive input from interested parties that is needed. We are therefore proposing to revise § 438.334(b)(2), redesignated at new proposed § 438.510(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we undergo a subregulatory process to engage with States and other interested parties, to obtain expert and public input and recommendations prior to modifying the mandatory measure set. Once the mandatory measure set is finalized through this rulemaking, we believe periodic, subregulatory updates and maintenance to add, remove, or update measures would ensure that the mandatory measure set

continues over time to adhere to our three proposed standards at § 438.510(c). To achieve these goals, we are proposing these modifications occur at least every other year (biennially).

With exceptions for removing measures for specific reasons proposed at § 438.510(d) and non-substantive updates to existing measures as proposed at § 438.510I(1), we are proposing in new § 438.510(b) that we will engage in a two-step subregulatory process to obtain input and recommendations from States and other interested parties prior to finalizing certain types of changes to the mandatory measure set in the future. This proposed engagement with States is similar to the public notice and comment process currently required by § 438.334(b) and consistent with our obligations under sections 1932(c)(1)(D) and 2103(f)(3) of the Act to consult with States in setting standards for measuring and monitoring managed care plan performance. Proposed § 438.510(b) would apply to separate CHIP by cross-reference through a proposed revision to § 457.1240(d).

As the first step in the process, we propose at § 438.510(b)(1) that CMS would engage with States and interested parties (such as State officials, measure experts, health plans, beneficiaries and beneficiary advocates or organizations, tribal organizations, health plan associations, health care providers, external quality review organizations and other organizations that assist States with MAC QRS ratings) to evaluate the current mandatory measure set and make recommendations to add, remove, or update existing measures. The purpose of this evaluation would be to ensure the mandatory measures continue to meet the standards proposed in § 438.510(c). We envision that this engagement could take several forms. For example, a workgroup could be convened to hold public meetings where the workgroup attendees would make recommendations to CMS to add and remove measures. Alternatively, a smaller series of meetings with interested parties could be held, or a request for information could be published to solicit recommendations from experts. In either case, we intend that recommendations would be based on the standards proposed in § 438.510(c) and discussed in section I.B.6.e.1. of this proposed rule.

At § 438.510(b)(2) we propose that the second step in the process would be for CMS to provide public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) that includes the mandatory measures identified for addition, removal or updating through the public engagement step. Following the public notice and opportunity for public comments, we propose at § 438.510(f) that we will publish the modifications to the mandatory measure set in the technical resource manual proposed at § 438.530 (this proposal is discussed in more detail in section I.B.6.e.7. of this proposed rule).

This subregulatory process shares similarities with the QHP quality rating system, which uses a call letter process to gather feedback on measure updates. It also aligns with how the Core Sets are updated annually. As part of the Core Set annual review and selection process, a workgroup made up of Medicaid and CHIP interested parties and measurement experts convenes annually, in a public meeting, and develops a set of recommendations for changes to the Core Sets. These recommendations are posted in a draft report for public comment, and the final report that is submitted to CMS includes both the workgroup recommendations and public comments. The annual updates to the Core Sets are based on the workgroup recommendations and comments, and using input from States and Federal partners, CMS decides whether to accept them prior to the updated Core Sets being finalized. Details on this process are available at *https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf*. While we generally are aligning the MAC QRS workgroup processes, as noted above, with the QHP quality rating and Core Set processes as appropriate, the MAC QRS is independent and will have its own processes.

If the proposed rule is finalized in 2024, the implementation deadline for each State's MAC QRS per proposed § 438.505(b) (which provides for such implementation to be no later than the fourth calendar year following publication of the final rule) would be December 31, 2028, and the first measurement year would be 2026. Since we are proposing to finalize our initial measure set in this rulemaking, any updates to the initial mandatory measure list made

pursuant to the subregulatory process proposed at § 438.510(b) would be effective no earlier than the year after the implementation of each State's MAC QRS. We believe it would be appropriate to initiate the proposed subregulatory process for the second display year (for example, 2029 if the rule is finalized in 2024) because the mandatory measure list would be 5 years old by then, and at least biennially thereafter (in line with proposed § 438.510(b)(2)). However, we seek comment on whether we should instead initiate the subregulatory process to update the mandatory measure list for the third display year (for example, 2030 if the rule is finalized in 2024). We also seek comment on the types of engagement that would be important under this proposed subregulatory process (for example, workgroups, smaller meetings, requests for information), the types of experts that CMS should include in the engagement, and the use of a call letter or similar guidance to obtain public input.

(4) Adding mandatory measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

Our proposal at § 438.510(c) states that CMS would add a measure to the mandatory measure set when all three standards proposed at § 438.510(c)(1)-(3) are met, based on available information, including input from the subregulatory process. Under our proposal, at least biennially, we would use the subregulatory process proposed in § 438.510(b) to gather input that would be used to determine if a measure meets the proposed standards to be added to the mandatory measure set. For example, CMS could request the workgroup's assessment of the list of measures suggested for addition (from the workgroup, CMS, or both), using our three proposed standards: the proposed criteria (per proposed § 438.510(c)(1)), input on how best to curate a balanced representation of measures from the suggested measures (per proposed § 438.510(c)(2)), and the benefits and burdens of adopting the measures (per proposed § 438.510(c)(3)). Using this input, CMS could identify a subset of measures from that list that best represents these standards. This subset of measures would then be considered eligible to add to the mandatory measure set and described in a call letter or similar written guidance, which would explain how standards in § 438.510(c) were applied using input from prior engagement activities

and CMS's research and preliminary evaluation. Through the call letter process, CMS would gather public comment including any additional evidence, explanations, and perspectives to determine whether the subset of measures meet the standards in proposed § 438.510(c). The measures that meet the proposed standards based on the totality of input and information compiled by CMS would be added to future iterations of the mandatory measure set. To further illustrate how we intend for the standards proposed in § 438.510(c) to be applied using the subregulatory process, we provide more specific detail in this section of our assessment of two measures considered for inclusion in the proposed mandatory measure set. We intend for the subregulatory process for adding measures to follow this same approach.

In previous discussions, States and other interested parties recommended both the Follow-Up After ED Visit for Mental Illness (FUM) and the Follow-Up After Hospitalization for Mental Illness (FUH) as potential measures to include in our preliminary measure set. As a first step, we used our own research and input from our consultations to assess the measures against the measure inclusion criteria, that we are now proposing as our first standard, and found that both measures meet each of our six proposed criteria (see Table 2).

TABLE 2: Example Inclusion Criteria Assessment

Criteria	FUM	FUH
Alignment	• Identified by 16 States as a measure collected from managed care plans in the '20-'21 EQR reporting cycle • Reported publicly as a measure of plan performance in 2 States • Core Set measure	• Identified by 19 States as a measure collected from managed care plans in the '20-'21 EQR reporting cycle • Reported publicly as a measure of plan performance in 4 States • Core Set and QHP QRS measure
Usefulness to Beneficiaries	• The importance of timely access to mental health services were consistently identified in our conversations with Medicaid beneficiaries	
Relevance	• Both measures address access to services	
Actionability	• States and plans identified various ways in which plans can address follow-up. The 30-day measure was generally thought to be more actionable than 7-day due to supply of mental health providers and the need for plan coordination in States that carve out behavioral health. •	• States and plans identified various ways in which plans can address follow-up. The 30-day measure was generally thought to be more actionable than 7-day due to supply of mental health providers and the need for plan coordination in States that carve out behavioral health. • Used by 3 States to assess plan performance as part of the State's quality strategy
Feasibility	• Relies on administrative data from claims that are owned or available to plans, but would require coordination between plans in States that offer behavioral through a separate managed care program.	
Scientific Acceptability	• Generally regarded as reliable and valid measure in our listening sessions • Endorsed by the National Quality Forum	

Second, we considered the two measures in light of our goals for balanced representation within a concise measure set. Given our goal to limit the initial mandatory measure set to fewer than 20 measures and the fact that both measures focus on assessing follow-up care for mental illness, we determined that including one of the two measures would best maintain balanced representation within the overall measure set and within the behavioral health performance area. We then weighed the benefits and burdens of including each measure using our assessment of

the extent to which each measure met our inclusion criteria. As represented in Table 2, we found that both measures had similar benefits and burdens, but the FUH measure had more benefits as it was more commonly collected or reported at both the State and Federal level and more frequently used by States to assess plan performance. We therefore chose to include the FUH measure in the proposed mandatory set.

(5) Removing existing mandatory measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

We are proposing at § 438.510(d)(1) that we may remove existing mandatory measures from the mandatory measure set if, after following the subregulatory process proposed at § 438.510(b), we determine that the measure no longer meets the standards for the mandatory measure set proposed at 438.510(c). We would use the same approach we described in section I.B.6.e.2. of this proposed rule and illustrated with our FUH/FUM example in section I.B.6.e.4. of this proposed rule to assess whether a measure continues to meet our measure inclusion criteria to remain in the mandatory measure set. We are also proposing at § 438.510(d)(2) through (4) to provide CMS the authority to remove mandatory measures outside of the subregulatory process proposed in § 438.510(b) in three circumstances: when the measure steward (other than CMS) retires or stops maintaining a measure (proposed at § 438.510(d)(2)), if CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes (proposed at § 438.510(d)(3)), or if CMS determines that a measure shows low statistical reliability under the standard identified in § 422.164(e) of this chapter (proposed at § 438.510(d)(4)).

These proposed criteria for removing measures outside the subregulatory process align with the current regulations governing the MA and Part D quality rating system[146]. When a measure steward such as NCQA or PQA retires a measure, they go through a process that

146 "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" (CMS-4201-F). Published in the **Federal Register** on April 12, 2023 (88 FR 22120). Available online at *https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program*.

includes extensive review by experts and solicit public comments from a variety of interested parties, including health plans, purchasers, consumers and other interested parties. The proposal to allow CMS to remove a measure if an external measure steward retires or stops maintaining a mandatory measure would allow us flexibility to ensure that measures included in the QRS mandatory measure set are maintained by the measure steward and consistent with the measure steward's underlying standards of clinical meaningfulness, reliability, and appropriateness for measures. Additionally, when there is a change in clinical guidelines such that measure specifications no longer align with or promote positive health outcomes, we believe it would be appropriate to remove the measure. Finally, we are proposing that CMS would have the authority to remove measures that show low statistical reliability (that is, how much variation between measure values that is due to real differences in quality versus random variation). We are using the same standard for statistical reliability as applied for the MA and Part D quality rating system under §§ 422.164(e) and 423.184(e). Any measures removed under these three circumstances proposed at § 438.510(d)(2) through (4) would be announced in the annual technical resource manual, proposed at § 438.530. We believe these criteria will allow us to swiftly remove measures that are no longer appropriate quality indicators of health plan performance. We seek comments on whether there are additional circumstances in which we should be able to remove a mandatory measure without engaging in the subregulatory process proposed at § 438.510(b).

(6) Updating mandatory measure technical specifications (§§ 438.510 and 457.1240(d))

In addition to adding and removing measures, we are also proposing rules at § 438.510(e) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), governing how we would handle updates to mandatory measures in the MAC QRS that are a result of changes made by a measure steward other than CMS to an existing mandatory measure's technical specifications. These are updates that measure stewards routinely make to quality measures, and can be non-substantive (such as changes that clarify instructions to identify services or procedures) or substantive in nature (for example, major changes to how the

measures are calculated). We are proposing different subregulatory processes by which these non-substantive and substantive updates to existing mandatory measures would be made. First, in proposed paragraph § 438.510(e)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that we would update the technical resource manual to revise descriptions of the existing mandatory measures that undergo non-substantive measure technical specification changes. In alignment with current practices in the MA and Part D quality rating system and the Core Sets, we are not proposing to use the subregulatory process proposed in § 438.510(b) for non-substantive changes because we believe they reflect routine measure maintenance by measures stewards that do not significantly affect the measure and would not need additional review by the workgroup and CMS. We are proposing in new paragraph § 438.510(e)(1)(i)-(iv) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to codify examples of the types of updates that are non-substantive under this proposal. This proposal is consistent with current practice and regulations for the MA and Part D quality rating system at §§ 422.164(d)(1) and 423.184(d)(1). We identify and describe the proposed non-substantive updates in detail below and seek comment on whether this list is exhaustive, whether it is an adequate list of examples of non-substantive changes, or whether we should consider adding other examples of non-substantive changes to the list. Examples of the types of changes we believe would be non-substantive for purposes of proposed § 438.510(e)(1) include, but are not limited to the following:

- If the change narrows the denominator or population covered by the measure with no other changes, the change would be non-substantive. For example, if an additional exclusion—such as excluding nursing home residents from the denominator—is added, the change would be considered non-substantive and would be incorporated through announcement in the annual technical resource manual.

● If the change does not meaningfully impact the numerator or denominator of the measure, the change would be non-substantive. For example, if additional codes are added that increase the numerator for a measure during or before the measurement period, such a change would not be considered substantive. This type of change has no impact on the current clinical practices of the plan or its providers.

● If revisions are made to the clinical codes without change in the target population or the intent of the measure and the target population, the change would be non-substantive. The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. Examples of clinical codes, include, but are not limited to:

+ ICD-10-CM code sets, which are updated annually,

+ Current Procedural Terminology (CPT) codes, which are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient, and

+ National Drug Code (NDC) which is updated bi-annually.

● If the measure specification change provides additional clarifications for reporting, without changing the intent of the measure, the change would be non-substantive. Examples include:

+ Adding additional tests that would meet the numerator requirements.

+ Clarifying documentation requirements (for example, medical record documentation).

+ Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.

+ Adding alternative data sources or expanding of modes of data collection to calculate a measure.

Second, we propose at § 438.510(e)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we may update an existing mandatory measure that has undergone a substantive measure specification update (that is, an

update not within the scope of non-substantive updates, which are illustrated in § 438.510(e)(1)(i) through (iv), only after completing the subregulatory process proposed in § 438.510(b). We believe that most substantive measure specification updates to existing measures could result in new or different measures, thereby necessitating consideration and evaluation against the criteria and standards in proposed paragraph (c) using the process in proposed § 438.510(b). We seek comment on our proposal to incorporate substantive measure specification updates to existing mandatory measures only after consultation with States, other interested parties, and the public, or whether we should consider a separate process for these types of updates.

(7) Finalization and display of mandatory measures and updates (§§ 438.510(f) and 457.1240(d))

In new paragraph § 438.510(f) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that CMS would communicate modifications to the mandatory measure set and the timeline States would be given to implement modifications to the mandatory measure set in the annual technical resource manual. We propose to use the technical resource manual described in proposed § 438.530 to communicate the final updates. We are proposing that States would be given at least 2 calendar years from the start of the measurement year immediately following the technical resource manual in which the mandatory measure addition or substantive update was finalized to display the measurement results and ratings using the new or updated measure(s). We believe giving States at least 2 years would allow for contract and systems updates when new measures are added or substantive updates are made to the mandatory measure set. For example, if the technical resource manual finalized updates in August 2026, and the next measurement year after August started in January 2027, States would have, at a minimum, until January 2029 before they would be required to display the ratings for the mandatory measure updates in their MAC QRS. A State may elect to display the ratings for a new mandatory measure sooner. As two years from the start of the

measurement year would always be in January, we seek comment on whether there is a need for States to have the flexibility to update their quality ratings by the end of the second calendar year, which, based on the example above, would give States the flexibility to update the rating between January and December of 2029.

We are proposing the same implementation timeline for substantive updates to existing mandatory measures, since we believe these should be treated in the same manner as new measures. We are proposing this timeline based on discussions with States and other interested parties about operational considerations for implementation of new and substantively updated measures and the posting of the associated ratings. We are not proposing a specific deadline for States to stop display of a measure that has been removed from the mandatory measure set because States have the option to continue to display measures removed from the mandatory set as additional measures as described in section I.B.6.g.5. of this proposed rule. We seek comment on this flexibility considering the criteria under which measures can be removed at proposed § 438.510(d). We seek comment on whether our timeframes are appropriate for updates to the mandatory measure set or whether we should consider allowing for more or less time, and why.

In conclusion, we seek comment on the proposed subregulatory process to add and remove measures, as described in sections I.B.6.e.3. of this proposed rule, specifically the types of engagement (workgroup, smaller meetings, requests for information) and the types of experts that would be included in the engagement, and the use of a call letter or similar guidance to obtain public input on the MAC QRS mandatory measure set before it is substantively updated. We note that we are proposing the subregulatory process to update the mandatory measure set take place *at least* biennially. However, CMS could engage in this process more frequently in certain circumstances, such as in the case of rapidly evolving public health concerns. We seek comment on whether we should consider implementing the process on an annual basis, or another frequency, and why. We note that we are proposing to release the technical resource manual annually regardless of whether we are making any modifications to the mandatory

measure set, to address any non-substantive changes to measure specifications or any removals that occur outside of the subregulatory process, as described in section I.B.6.i. of this proposed rule.

f. MAC QRS Methodology (§§ 438.334(d), 438.515, 457.1240(d))

Fundamental to any QRS is the methodology used to calculate the quality ratings for States' managed care plans. Under current regulations at § 438.334(b)(1) CMS must, after consulting with interested parties and providing public notice and opportunity to comment, develop a methodology that States must use in the MAC QRS adopted by the State to calculate its plans' quality ratings, unless we approve an alternative methodology as part of an alternative MAC QRS in accordance with proposed § 438.525. During the extensive engagement with States and other interested parties described in section I.B.6.a. of this proposed rule, we identified two main themes to consider in the development of a MAC QRS methodology: (1) States are concerned about the burden associated with data collection and quality rating calculation, and (2) beneficiaries desire transparent, representative quality ratings. In developing the MAC QRS methodology that we are proposing here, we sought to balance these two, often competing preferences, while ensuring that quality ratings remained comparable within and among States. We also considered the Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers,[147] (referred to as "CMS Interoperability and Patient Access final rule") published in May 2020. That rule placed several requirements on State Medicaid FFS programs as well as on Medicaid managed care plans for the implementation of application programming interfaces to facilitate sharing information between payers,

147*https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020- 05050.pdf* Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. CMS-9115-F. Published in the Federal Register on May 1, 2020 (85 FR 25510 through 25640)

enrollees, and providers. Based on these considerations, at § 438.515 we propose requirements for collecting and using data to calculate managed care quality ratings for mandatory measures (that is, the MAC QRS methodology which we propose that States must use), unless we have approved an alternative QRS. The same requirements are proposed for separate CHIP managed care plans through a proposed cross-reference at § 457.1240(d).

Under current regulations at § 438.334(d), each year States would be required to collect data from each managed care plan with which they contract and issue an annual quality rating for each managed care plan based on the data collected. We are proposing to replace that policy with more specific requirements in proposed new § 438.515(a) for States to collect and validate data used by the State to calculate and issue quality ratings for each mandatory measure on an annual basis. First, we propose, at proposed § 438.515(a)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d)), that States must collect the data necessary to calculate quality ratings for mandatory measures from their contracted managed care plans and, as applicable and available without undue burden, the State's Medicaid fee-for-service program and Medicare. Specifically, we propose that data be collected from managed care plans that meet a minimum enrollment threshold of 500 or more enrollees on July 1 of the measurement year. This enrollment threshold is the same as the enrollment threshold for the QHP quality rating system requirement at section 1311(c)(4) of the Patient Protection and Affordable Care Act.

We believe that requiring States to calculate quality ratings for plans with fewer than 500 enrollees would be overly burdensome, as these plans may have limited resources for collecting and reporting data, and are more likely than plans with higher enrollment to have small denominator sizes that would make it inappropriate to issue and display quality ratings for some measures due to privacy or validity concerns. Further, through an analysis of 2019 Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files (which are research-optimized files of T-MSIS data), we determined that neither the number of managed care plans nor the

percentage of beneficiaries reported in the MAC QRS would be significantly reduced by excluding plans with enrollment below 500. Thus, we believe the proposed enrollment threshold maximizes inclusion of plans and enrollees, while also minimizing the burden of data collection and reporting on smaller plans. States would have the flexibility to include plans with fewer than 500 enrollees at their discretion, and we would encourage States to do so when appropriate and feasible.

At § 438.515(a)(1)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States would also be required to collect available data from the State's Medicaid fee-for-service (FFS) program, Medicare (including Medicare Advantage plans), or both if all necessary data cannot be provided by the managed care plans for the measures and collection of these data does not impose an undue burden on the State. For example, if a State delivers behavioral health services through a managed care program and all other services through its FFS program, the State would need to collect both managed care and FFS data to calculate quality ratings for the managed care plans participating in its behavioral health managed care program for many of our proposed behavioral health mandatory measures. Similarly, if a managed care plan provides services to enrollees who are dually eligible for Medicare and Medicaid services, it would be necessary for the State to collect data about services provided by Medicare to such enrollees to calculate quality ratings for some measures included on the proposed mandatory set. While we are proposing that States must collect data from these other sources as needed to calculate mandatory measures if the data are available for collection without undue burden, we are not proposing that States would calculate or assign quality ratings to Medicaid FFS or Medicare plans.

We considered requiring States to collect data only from their contracted managed care plans and then only when a plan is able to provide all data necessary to calculate and issue a quality rating for a given performance measure, which is a common practice among measure stewards. However, we are concerned that there would be instances where there is no single plan

from which a State could collect all data necessary to calculate one or more of the measures on our mandatory measure list. For example, of the 18 measures on our proposed mandatory measure set, four require data from more than one setting, including three of our proposed behavioral health mandatory measures. These four measures include Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP), Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET), Follow-Up After Hospitalization for Mental Illness) (FUH), and Asthma Medication Ratio (AMR). To calculate the three behavioral health measures, it is necessary to collect behavioral health or substance use service data as well as either pharmacy or physical health data. When these services are covered by separate plans or delivery systems, such as where a State has chosen to split Medicaid coverage of these services between separate managed care programs or use a combination of managed care and FFS delivery systems, these mandatory measures would be at risk of going unreported. Similar issues are raised for dually eligible individuals who receive coverage through Medicare and Medicaid. We note that Medicaid is the single largest payer of mental health services in the U.S., and behavioral health and substance use measures would be at particular risk of going unreported, as services provided in these settings are commonly provided through a separate managed care plan. We believe that our proposal for States to collect and use data from multiple sources will mitigate the risk of underreporting of mandatory measures, particularly those measures assessing behavioral health and substance use services.

We believe our proposal is aligned with ongoing efforts to expand access to health plan data at both the State and Federal level. For example, State data collection required for measures in the Child Core Set and behavioral health measures in the Adult Core Set, which will become mandatory effective for calendar year 2024, requires States to report measures using data from both managed care and FFS programs as well as Medicare data for dually eligible beneficiaries. Many of these measures overlap with the mandatory measures proposed for the MAC QRS, which means States will already be obligated to collect Medicaid managed care and FFS data

and to obtain Medicare data needed to calculate certain performance measures. Thus, we believe that the benefits of proposed § 438.515(a)(1)(ii) outweigh the costs of any increased burden on States.

Furthermore, there is an ongoing effort at the Federal and State levels to increase data availability and interoperability, including State access to managed care plan data. At the time of this proposed rule, data available for collection include encounter data received from a State's own Medicaid managed care plans under § 438.242 and data from FFS providers through claims and other reporting. Given existing data availability, we believe that the collection of such data would rarely result in an undue State burden. States can also obtain Medicare Part A, B and D data free of charge through the CMS State Data Resource Center (SDRC). Although Part C data are not available publicly through the SDRC, States may use their contracts with MA Dual Eligible Special Needs Plans (D-SNPs), which are required under § 422.107, to obtain Medicare data about the dually eligible individuals enrolled in those plans. As a significant number of States already obtain Part C data in this way, we believe such data would be available without undue burden in many cases, particularly where a State has already opted to obtain some Medicare Part C data in this way.

We understand that making contractual or systems changes to allow a State to collect such data without causing an undue burden, such as a substantial financial or resource investment, may mean that a State implements these changes over time, and that this timeline may extend past the implementation date proposed in § 438.505(a)(2). We intend the proposed standard "without undue burden" to facilitate a gradual implementation of contract or system changes to collect the necessary data. We also would be available to provide technical assistance to help States acquire and use available data to calculate MAC QRS quality ratings. We seek comment on the proposed requirement that States collect available data from multiple sources on the mandatory measures. In addition, we request comment on the type of technical assistance that

would be most helpful in assisting States in obtaining and using data from the sources specified in the proposed regulation.

Once the necessary data are collected to calculate quality ratings for each mandatory measure, our proposal at § 438.515(a)(2) would require States to ensure that all collected data are validated. This aligns with similar requirements in 45 CFR 156.1120(a)(2), which requires QHP issuers to validate data for the QHP QRS, and 42 CFR 422.162(c)(2), which requires MA organizations to provide unbiased, accurate and complete quality data to CMS for the MA and Part D quality rating system. Currently, § 438.320 defines validation for purposes of subpart E of part 438 as the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis. We are proposing the same definition for purposes of new subpart G at § 438.500. States may use the current optional EQR activity at § 438.358(c)(6) and 457.1250(a) — for which enhanced match may be available for Medicaid EQR-related activities performed for MCOs per § 438.370(a) – to assist with the calculation and validation of data used to generate quality ratings for the MAC QRS. Use of this optional activity may help reduce burden on States.

We are proposing in § 438.515(a)(3) that States use the validated data to calculate performance rates for managed care plans. Under this proposal, States would calculate, for each mandatory measure, a measure performance rate for each managed care plan whose contract includes a service or action being assessed by the measure, as determined by the State. Under this proposal, the mandatory measures would be assigned to the plan(s) based on whether the plan's contract covers the service or action being assessed by the measure, as identified by the State. We believe this would be straightforward for measures assessing single services or actions, but, as we noted previously in this section of the proposed rule, some States choose to deliver Medicaid services through different managed care programs. In these States, data necessary to calculate a measure performance rate for a given measure may be collected from two managed care plans. However, a State may determine that only one of these services or actions for which

data must be collected is being assessed by the measure. In such a case, the State must identify, among those plans from which the State collected data, the plans whose contract includes the service of action identified by the States as being assessed by the measure, and calculate and assign quality ratings accordingly.

For example, the Follow-Up After Hospitalization (FUH) measure listed in Table 2 requires data on two services: hospitalization and mental health services. In a State that offers behavioral and physical health services through separate managed care programs, the State would need hospitalization data from plans participating in the physical health program and mental health service data from the plans participating in the behavioral health program to calculate FUH performance rates. Because data are collected from more than one plan, our proposal would require States to determine which service or action is being assessed by the measure. If a State determines that the service or action being assessed by the FUH measures is the provision of timely follow-up of mental health services to an enrollee following a hospitalization for mental illness, the State would then be required to identify all plans that are contracted to provide the follow-up mental health services assessed by the FUH measure and assign each of those plans a quality rating for the FUH measure.

Lastly, our current regulation at § 438.334(d) requires States to issue *an* annual quality rating (that is, a single rating) to each managed care plan using the Medicaid managed care quality rating system (emphasis added). However, based on feedback we received from beneficiaries, we are proposing to revise that current policy and to require States to issue to each managed care plan a quality rating for each mandatory measure for which the managed care plan is accountable. As proposed at § 438.515(a)(4) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), States would be required to issue quality ratings as measure performance rates (that is, the individual percentage rates calculated under § 438.515(a)(3)). For example, a managed care plan that furnishes behavioral health services would likely be issued a measure performance rate for each of the proposed behavioral

health mandatory measures, depending on the availability of data. We also considered requiring States to calculate and display a performance rating that reflects a national baseline for each mandatory measure, which would align with the practice of States that currently publish managed care quality measures using an individual, percentage rating. However, we chose not to propose this requirement in this rulemaking. We seek comment on our proposal to issue individual performance rates and seek additional input on our decision not to require additional percentage ratings to reflect a national baseline for each mandatory measure.

The proposal to require that States issue quality ratings for individual quality measures is supported by the user testing we conducted during our engagement with interested parties. Beneficiaries stated varying preferences for the level of information that they would like to have, with roughly half preferring more detailed information, 40 percent preferring big picture information, and 10 percent falling in the middle. Many beneficiaries stated interest in quality ratings for specific measures that related to their individual health care needs, especially those that aligned with their understanding of important health indicators identified by trusted health care professionals, such as blood A1c levels for people with diabetes, demonstrating the value of including individual measure quality ratings.

Our user testing suggests that displaying managed care plan quality ratings both at the individual measure and the domain level would be most desirable to beneficiaries. This approach would allow beneficiaries who prefer big picture information to concisely compare plans at the domain-level, while beneficiaries who desire more detailed information could drill down into the domains to understand a plan's performance on the individual quality measures from which the domain score is derived. These findings are discussed in additional detail in section I.B.6.g. of this proposed rule. However, we did not significantly test domain level quality ratings and believe that additional engagement with interested parties and beneficiary testing would be necessary before requiring States to calculate and issue domain-level ratings. Therefore, we propose at § 438.515(c) for Medicaid, and for separate CHIP by cross-reference through a

proposed amendment at § 457.1240(d), that CMS will engage with States, beneficiaries, and other interested parties before proposing to implement domain-level quality ratings for managed care plans. Examples of potential care domains include behavioral health, chronic conditions, infant and children, and preventive care.

We believe that including domain-level quality ratings in the MAC QRS, in addition to measure-level quality ratings, would align best with the informational preferences expressed by beneficiaries who participated in testing of a MAC QRS prototype. We intend to propose the care domains, methodology, and website display requirements in future rulemaking. In calculating domain-level quality ratings, we are considering requiring States to calculate and assign quality ratings for a managed care plan only in those domains that are relevant to the managed care plan. For instance, while most care domains are likely to be relevant to an MCO, a care domain that focuses on infants and children is unlikely to be relevant to a plan that provides long term services and supports to dually eligible individuals. We seek feedback on our proposal to include individual percent scores, intended approach to domain-level ratings, and potential MAC QRS care domains.

To ensure that services provided to all Medicaid beneficiaries are reflected in each managed care plan's quality ratings, we propose at § 438.515(b)(1) that States must ensure that the quality ratings issued under proposed § 438.515(a)(4) include data for all beneficiaries who receive coverage from the managed care plan for a service or action for which data are required to calculate the quality rating. This includes beneficiaries who are dually eligible for Medicare and Medicaid and receive services through the Medicaid managed care plan, subject to the availability of data about the services received by dually eligible individuals. While we recognize that including dually eligible beneficiaries in quality ratings may require additional effort to obtain and analyze Medicare utilization data, especially where dually eligible beneficiaries are not in programs that integrate Medicare and Medicaid, we believe it is important to ensure that these beneficiaries can assess the quality of care furnished by available Medicaid plans for

beneficiaries who also are enrolled in Medicare. Furthermore, including dually eligible individuals in MAC QRS quality ratings would align with the Adult and Child Core Sets, as some measures require both Medicaid and Medicare data (see Core Set NPRM, 87 FR at 51317). Under proposed § 438.515(b)(1), only dually eligible individuals who receive full Medicaid benefits would be included in the MAC QRS, because individuals whose Medicaid eligibility is limited to assistance with Medicare premiums and/or cost sharing receive covered services exclusively through Medicare. We intend to provide additional guidance on which beneficiaries must be included in the quality ratings for each MAC QRS mandatory measure in the technical resource manual alongside technical specifications from the mandatory measure's measure steward. For separate CHIP, § 457.310(b)(2) does not allow for concurrent coverage with other health insurance, so our proposed amendment to § 457.1240(d) excludes dually eligible individuals from the scope of the required CHIP managed care quality rating.

In § 438.515(b)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States would be required to calculate quality ratings at the plan level by program. While some States have one managed care program through which they offer all Medicaid services, most States cover Medicaid services through multiple programs that are defined by the population served by the program and the set of benefits covered by the program. For example, a State may have one program that covers behavioral health services while a second program covers physical health services. Other States may choose to provide similar services through different managed care programs that serve different populations. In these States, different programs cover different services to meet the needs of different subpopulations of Medicaid beneficiaries, such as pregnant individuals, children in foster care, or those with disabilities, chronic conditions, or HIV/AIDS. In States with multiple managed care programs, managed care plans may choose which programs they will participate in by contracting with the State. Generally, beneficiaries would then select from the

managed care plans participating in each program for which the beneficiary is determined eligible, subject to requirements on access to multiple managed care plans in § 438.52.

Under our proposals, States that offer multiple managed care programs would calculate plan level ratings for each managed care plan participating in a single managed care program using only the service data described in § 438.515(b)(1) of beneficiaries enrolled in that managed care plan under that managed care program. A managed care plan that participates in multiple managed care programs would receive a distinct rating for each of these programs. These ratings would be produced using data only from those beneficiaries enrolled in the managed care plan under the specific managed care program. That is, ratings would be calculated at the plan level but with the plan dividing up its enrolled population based on the specific managed care program(s) that the State has contracted with the plan for coverage. As eligible beneficiaries select from available managed care plans within a program, we believe that plan level quality ratings for each program in which the plan participates will best align with what beneficiaries may expect to receive from each managed care plan participating in that program. This approach is distinguishable from single plan level ratings for all of the programs in which the plan participates, which would be calculated using all data from the plan regardless of the managed care program. We believe such ratings would not provide useful information to potential enrollees because such plan level ratings would reflect the quality of services provided to all beneficiaries covered by the plan, regardless of the program through which the beneficiary receives services from the plan, and may not reflect the performance that a beneficiary could expect based on the beneficiary's enrollment options. The proposed plan level ratings for each managed care program would produce quality ratings that are most representative of the care beneficiaries can expect to experience because each rating would be calculated only from data for beneficiaries enrolled in the same managed care plan under the same program. If a measure cannot be reported for a plan due to low denominator sizes, the plan would be issued an appropriate "missing data" message for that measure as the quality rating. We seek comment on

how this proposed policy would interact with our proposed minimum enrollment threshold, such as an analysis that assesses the extent to which a State's smaller plans may report missing data messages.

We considered the level at which ratings are assigned in the MA and Part D and QHP quality ratings systems as part of developing our proposal for the MAC QRS. In the MA and Part D quality rating system, quality ratings for most measures are assigned at the contract level, which consolidates data from all plan benefit packages offered under the contract to calculate a quality rating. Under a contract-level reporting unit, quality ratings would be calculated based on data from all enrollees served under a given contract between a State and a managed care plan. However, we do not believe that contract-level ratings would be as useful to Medicaid beneficiaries and would make it difficult for States to assess the quality of care provided to beneficiaries in separate programs that are often designed to improve the quality of care for a particular subpopulation of beneficiaries with unique care considerations. In the QHP quality rating system, quality ratings are assigned at the product level (for example, Exclusive Provider Organization Plan (EPO), Health Maintenance Organization (HMO), Point of Service (POS), and Preferred Provider Organization (PPO)). These products typically provide coverage of a similar set of comprehensive health care services, but vary in terms of how enrollees are able to access these services and at what cost. If an issuer of health care offered multiple products, each separate product would receive its own ratings. In Medicaid, product level ratings could correlate with ratings assigned at the PIHP, PAHP, or MCO level.

Under our proposal at § 438.515(b)(2), managed care plans that participate in multiple managed care programs would receive separate quality ratings under each program. These separate quality ratings would be calculated from data for only those beneficiaries enrolled in the managed care plan under a given program. We believe that this approach best balances the need for representative ratings with the level of effort States must employ to calculate quality ratings for the MAC QRS, while also accommodating the current way that States structure their overall

Medicaid and CHIP program and the need for comparable quality ratings both within and among States. While our proposed reporting unit would require the calculation of more quality ratings than those used by the MA and Part D or QHP quality rating systems, we believe that this additional work will also help States monitor the quality of the managed care programs that they have developed to ensure provision of high-quality, cost-efficient care to their beneficiaries. We seek comment on our proposal to use a program-level reporting unit for the MAC QRS as well as other recommendations for reporting units that would result in quality ratings that are both representative and less burdensome on States.

Finally, it is important to note that States could receive an enhanced match for assistance with quality ratings of MCOs performed by an EQRO, including the calculation and validation of MCO data, under the external quality review optional activity at § 438.358(c)(6), in accordance with § 438.370 and section 1903(a)(3)(C)(ii) of the Act.

g. MAC QRS Website Display (§§ 438.334(e), 438.520, 457.1240(d))

Current regulations at § 438.334(e), which would be redesignated at § 438.520(a) of this proposed rule, require States to prominently display the quality rating issued for each MCO, PIHP, or PAHP on the website required under § 438.10(c)(3) in a manner that complies with the standards in § 438.10(d). Our policies proposed at § 438.520 would establish new requirements for the website display, which were informed by extensive consultation with Medicaid beneficiaries and their caregivers and iterative testing of a MAC QRS website prototype. The consultation and testing revealed that the presentation of quality ratings greatly influences the usability and utility of the MAC QRS as a tool to assist beneficiaries in selecting a plan. Providing information to beneficiaries in a useable way is necessary for compliance with section 1932(a)(5) of the Act regarding provision of information, including comparative information on plan quality, to beneficiaries when a State mandates enrollment in an MCO. The same standards apply under section 2103(f)(3) of the Act to CHIP. To promote the efficient and economical operation of the Medicaid State Plan and CHIP, we apply the same requirements for all managed

care programs through our regulations. Our proposed requirements for Medicaid managed care programs in § 438.520 would also be applicable to separate CHIP under this proposal, through a cross-reference in the CHIP regulation at § 457.1240(d).

In our initial round of testing, participants struggled to understand how to use the MAC QRS prototype, and often dismissed or skipped over the quality ratings, noting that they did not understand the ratings or how they translated to member care. Subsequent revisions of our MAC QRS prototype focused on identifying how best to present quality ratings to prospective users in a way that supported beneficiaries' ability to understand and incorporate quality ratings and use them to inform their selection of a health plan. Based on our testing, it was clear that to truly empower beneficiaries as informed health care consumers, quality ratings are best presented as one part of a comprehensive website that efficiently guides the user through the considerations for identifying a quality health plan. We also learned that to be more useful, the website should address factors commonly considered by individuals in selecting a health plan, which include information not traditionally factored into health plan quality ratings, such as what providers are in the network and drug coverage. Using this feedback, we designed, tested, and refined the MAC QRS display components proposed in this rulemaking to align with the stated preferences of our user-testing participants.

The display components identified as most critical are included in proposed § 438.520; these components fall into three categories: (1) information to help navigate and understand the content of the MAC QRS website; (2) information to allow users to identify available managed care plans and features to tailor display information; and (3) features that allow beneficiaries to compare managed care plans on standardized information, including plan performance, cost and coverage of services and pharmaceuticals, and provider network. Based on the feedback we received during prototype testing, we believe that these components are critically important to ensure quality rating information can be readily understood by beneficiaries and used in decision-making. We are therefore proposing at § 438.520 that States display a MAC QRS

website that includes: (1) clear information that is understandable and usable for navigating a MAC QRS website; (2) interactive features that allows users to tailor specific information, such as formulary, provider directory, and quality ratings based on their entered data; (3) standardized information so that users can compare managed care programs and plans, based on our identified information; (4) information that promotes beneficiary understanding of and trust in the displayed quality ratings, such as data collection timeframes and validation confirmation; and (5) access to Medicaid and CHIP enrollment and eligibility information, either directly on the website or through external resources.

Importantly, we understand from our engagement with States and interested parties that some display requirements we believe align with the goals discussed in section I.B.6.a. of this proposed rule may require more technology-intensive implementation, such as the interactive features that allow users to tailor displayed information. We are therefore proposing to implement the proposed website display requirements in two phases. The first phase would be implemented by the end of the fourth year following the release of the final rule, as proposed at § 438.505(a)(2). In this phase, States would develop the MAC QRS website, display quality ratings, and would ensure that users can access information on plan providers, drug coverage, and view quality ratings by sex, race, ethnicity and dual eligibility status from the MAC QRS website. For instance, in lieu of an interactive search tool, the State may simply hyperlink to each managed care plan's existing provider directory and formulary to meet our proposed requirements. This first phase would accomplish the goal of having a one-stop-shop for beneficiaries to access the information we believe is key to their decision-making, but would not require States to develop the interactive tools identified in our research as more beneficial and usable by prospective users. In the second phase, States would be required to modify the website to provide a more interactive user experience with more information readily available to users on the MAC QRS website. This would entail including or moving some of the information required in other parts of 42 CFR part 438 to the MAC QRS website. For example, users could tailor the

display of information to their needs and search for plans that cover their providers and medications without leaving the MAC QRS website. We discuss our proposal for phasing-in more interactive features of the website display in more detail later in this section. We seek comment on which requirements should be phased in as well as how much time would be needed.

Given the visual nature of the website display, we are providing two sample MAC QRS prototypes; a simple website (Prototype A) that represents the information we are considering to require by the proposed implementation date in § 438.505(a)(2) and another MAC QRS prototype (Prototype B) that represents an interactive website that includes both the display features from the first implementation phase and the more technology-intensive features we are considering phasing in. These prototypes can be found at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html* and are meant to show our overall vision for the progression of the website display. In addition to the two prototypes, we intend to release a MAC QRS design guide following the final rule, which will provide a comprehensive overview of the results of our user testing that States may reference in the design of their MAC QRS website display. These materials would also provide CMS's interpretation of the requirements of the final rule as well as guidance on potential best practices in complying with the rule. We intend the design guide to include several components, including but not limited to: desirable features and content that States can implement at their discretion, plain language descriptions of mandatory measures, and display templates that States would have the option to use in the design of their MAC QRS. In the following paragraphs we discuss the proposed website display requirements and the feedback that led to their inclusion in the proposed website display.

(1) Navigational and orienting information (§§ 438.334(e), 438.520(a)(1) and (5), 457.1240(d))

Throughout our engagement, beneficiaries consistently stated the expectation that State Medicaid website and online plan selection processes would be difficult to navigate, and many

users shared that they had previously felt confused and overwhelmed during the process of selecting a managed care plan. When reviewing the initial MAC QRS prototype, some beneficiaries reported struggling to understand the purpose of the prototype and how and when the information could be useful. In light of this feedback, we tested a number of features to support users in understanding and navigating potential websites and found that beneficiaries responded positively to live assistance services (such as chat and telephone), and pop-ups and other mechanisms of displaying information to explain content as participants navigated the prototype.

We found that providing upfront clear information about what the MAC QRS is (a State-run, unbiased source of information on managed care plans and their performance) and is not (a sales funnel for a particular managed care plan) and what it can do (help compare available managed care plans and their quality and performance) and what it cannot do (determine eligibility for Medicaid and CHIP or enroll beneficiaries in a health plan) allowed participants to quickly determine the purpose of the MAC QRS and whether the information available would be a useful tool for them when selecting a managed care plan. We also found that some beneficiaries initially needed additional background on relevant programs such as Medicaid, CHIP, and Medicare to understand if they were eligible for, or enrolled in, a plan or program with ratings or information available through the MAC QRS. Once the purpose of the MAC QRS was established, beneficiaries positively responded to features that clearly conveyed how to use the information available in the MAC QRS to select a managed care plan in a simple, easy to understand manner, such as providing the steps to identifying, comparing, and selecting a managed care plan. In our testing prototype, users were wary about entering personal information to help identify and tailor the display of available managed care plans, such as zip code, age, sex, and health conditions–information that can be helpful in navigating a website designed to help individuals select a plan. However, when a clear explanation of how their information would be used, users became more comfortable providing personal information.

Based on these findings from user testing, we are proposing certain navigational requirements for the MAC QRS website display requirements in proposed § 438.520(a)(1). Specifically, we propose in § 438.520(a)(1)(i) that States must provide users with information necessary to understand and navigate the MAC QRS display, including a requirement to provide users with information on the MAC QRS purpose, relevant information on dual eligibility and enrollment through Medicare, Medicaid, and CHIP, and an overview of how the MAC QRS website can be used to select a managed care plan. We propose in § 438.520(a)(1)(ii) that States must provide information on how to access the beneficiary support system required under existing § 438.71 to answer questions related to the MAC QRS (proposed at § 438.505(a)(3) and described in section I.B.6.d. of this proposed rule). Since beneficiary support systems are not required for separate CHIP, our proposed amendment to § 457.1240(d) excludes references to this requirement. We seek comment on whether beneficiary supports similar to those proposed for Medicaid should be required for States for separate CHIP in connection with the MAC QRS information or on a broader basis through future rulemaking. Under proposed § 438.520(a)(1)(iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), States would be required to inform users of how any information they provide would be used. Finally, under proposed § 438.520(a)(5), States would be required to provide users with information or hyperlinks that direct users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan. This requirement ensures that users can easily navigate to the next steps in the plan selection process after reviewing the MAC QRS website.

We believe that States can implement these features by relying on existing public information or expanding current requirements. For instance, States are required to have the beneficiary support system at § 438.71 in place and can train existing staff on the MAC QRS. Through an environmental scan of State Medicaid websites, we found that all States currently have information describing their Medicaid and CHIP programs as well as programs available to

those dually eligible for Medicare and Medicaid. In both phases of the website display implementation, States may use these existing resources to comply with the requirements of proposed § 438.520(a)(1)(i) and (ii) either by hyperlinking to these resources from the MAC QRS website or incorporating existing information into the MAC QRS website display. Finally, as part of the MAC QRS design guide, we intend to provide plain language descriptions to illustrate what we would interpret the final rule to require; States may use such examples on their websites to provide an overview of how to use the MAC QRS to select a quality managed care plan.

(2) Tailoring of MAC QRS display content (§§ 438.334(e), 438.520(a)(2) and (a)(6), and 457.1240(d))

We also found that testing participants responded positively to features that allowed them to reduce the number of plans displayed to only those that met specific criteria, such as geographic location and eligibility requirements (for example, beneficiary age), so long as their privacy concerns were addressed by providing information on how and why such data would be used. Beneficiaries felt most comfortable providing their age and geographic location to identify health plans and we believe that these data points are likely sufficient to reduce the number of plans available to beneficiaries for comparison while also minimizing burden on States. Furthermore, dually eligible participants responded positively to the ability to easily identify those plans for which they were eligible. Therefore, we are proposing at § 438.520(a)(2)(i) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that each State's website must allow users to view available plans for which the user may be eligible based on users' age, geographic location, and dual eligibility status, as well as other demographic data identified by us in display guidance. Under the proposed rule, States would retain the flexibility to allow users to use additional information or eligibility criteria to further narrow down available managed care plans, such as searching by health condition like pregnancy or diabetes. In both phases of the website display implementation, States may meet

this requirement by linking to a PDF that clearly indicates plans available to a beneficiary based on the identified factors (see Prototype A at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html*). However, States may instead choose to implement an interactive display that allows the beneficiaries to input information upfront, and then tailors which managed care plans' information is displayed based on this information (see Prototype B at *https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/quality-rating-system/index.html*). In our environmental scan of State Medicaid websites, we identified many States that provide such a feature to help beneficiaries identify plans available to them. We believe this requirement supports the MAC QRS website being a one-stop-shop where beneficiaries can select a plan based on their eligibility information. We have made the judgment that requiring the development and use of the MAC QRS website in this manner is necessary for the proper and efficient operation of State Medicaid plans, and accordingly are proposing this requirement under our authority in section 1902(a)(4) of the Act, because this would support the beneficiary enrollment (and disenrollment) protections established in section 1932(a)(4)(A) of the Act . Based on our testing, the additional context is necessary and appropriate for beneficiaries to effectively use the information on plan quality ratings when choosing a managed care plan. Further, providing this flexibility for beneficiaries to choose how certain comparative information is presented is consistent with the requirement in section 1932(a)(5)(C) of the Act (which we have extended to information about PIHPs and PAHPs as well as MCOs using our authority in section 1902(a)(4) of the Act) for States to provide comparative information to beneficiaries about Medicaid managed care plans.

Participants in our user testing also prioritized confirming whether their current provider or prescriptions would be covered under a plan prior to navigating to other details about the plan. We therefore are proposing at § 438.520(a)(2)(ii) and (iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display provider directory and drug coverage information for each managed care plan in phase one of the

website display requirements. This information is already required to be available from managed care plans under existing § 438.10(h)(1) and (2) and § 438.10(i), which set forth the general requirements for provider directory and formulary information that plans must make available to beneficiaries. In the first phase, States could satisfy the proposed requirements by providing hyperlinks to existing plan formularies and provider directories required under § 438.10(h) and (i) (See Prototype A); this capability would be required by the general implementation date proposed under § 438.505(a)(2).

As previously mentioned, user-testing participants preferred an integrated search feature that allowed them to identify available plans that offered coverage of specific prescription drugs and providers, rather than being directed via hyperlink to each managed care plan's website, which would require them to conduct multiple searches to identify the plans that cover their prescriptions and providers. When consulted, States generally were supportive of the display requirements we are proposing in § 438.520(a)(2), but noted that a searchable formulary or directory would be difficult to design and implement by the implementation date proposed in § 438.505(a)(2). Under § 431.60(a) of the May 2020 CMS Interoperability and Patient Access final rule[148], States must implement an application programming interface (API) that permits third-party retrieval of certain data specified by CMS, including information about covered outpatient drugs and preferred drug list information (§ 431.60(b)(4)) and provider directory information (§ 431.70(b)). These requirements are applied in Medicaid managed care to MCOs, PIHP, and PAHPs under § 438.242(b)(5) and (6). We therefore believe that burden on managed care plans and States to provide the interactive search tools proposed in § 438.520(a)(2) would be minimized given that the data necessary to offer such tools is the same data that plans must make available through an API as specified in § 438.242(b)(5) and (6) and States could compile and

148 Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. CMS-9115-F. (85 FR 25510). Published in the **Federal Register** on May 1, 2020. (available online at *https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf).*

leverage this existing data to offer the search functionality we are proposing. However, we agree that States will need additional time to implement dynamic, interactive website display features. Therefore, we are proposing, at § 438.520(a)(6)(i) and (ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that States would be given at least two additional years after a State's initial implementation of their MAC QRS (that is, two additional years after the date proposed at § 438.505(a)(2) for initial implementation) to display provider directory and drug coverage information for each managed care plan through an integrated, interactive search feature that allows users to identify plans that cover certain providers and prescriptions (see Prototype B). We seek comment on this phased-in approach and a reasonable timeline for the second phase. In addition, we seek comment on the display requirements and technical assistance needs.

In § 438.520(a)(6)(iii) and (iv), we propose a second phase of implementation for the stratification of quality ratings, in which States would implement an interactive display that allows beneficiaries to view and filter quality ratings for specific mandatory measures identified by CMS by the factors which would already be required in phase one under proposed § 438.520(a)(2)(v) plus additional factors identified by CMS including, but not limited to, age, rural/urban status, disability, and language spoken by the enrollees who have received services (see Prototype B). This proposal would address feedback we received in testing the MAC QRS prototype websites with beneficiaries. We tested dynamic filters that allowed participants to view quality ratings representing services provided only to plan beneficiaries that aligned with participant-selected factors such as race, sex, and age. This feature increased participant positivity and trust in the quality ratings displayed, especially among those who raised concerns about the uniformity of experience among beneficiaries. Similar to our proposal to phase-in interactive plan provider directory and formulary tools, we are proposing to phase in the interactive display of quality ratings stratified by various demographic factors. In § 438.520(a)(2)(v) for Medicaid, and for separate CHIP by cross-reference through a proposed

amendment at § 457.1240(d), we therefore are proposing a first phase of implementation for this information that would require States to display quality ratings for mandatory measures stratified by factors including dual eligibility status, race and ethnicity, and sex. To reduce burden on States, we would permit States to report, if finalized, the same measurement and stratification methodologies and classifications as those proposed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule and the Access proposed rule. Measuring and making available performance reports on a stratified basis will assist in identifying health disparities. Driving improvements in quality is a cornerstone of the CMS approach to advancing health equity and also align with the CMS Strategic Priorities. In the first phase of implementation, a State's website would need to provide access to quality ratings that reflect the quality of care furnished to all of a plan's enrollees, as well as quality ratings that reflect the quality of care furnished to these subpopulations of a plan's enrollees (see Prototype A). This requirement is consistent with current efforts among measure stewards and other Federal reporting programs, such as the Child and Adult Core Sets, to stratify data to ensure that disparities in health outcomes are identified and addressed, not hidden (See Core Set proposed rule, 87 FR 51313). We are selecting these as our initial stratification factors as we believe this information is most likely to be collected as compared to our other proposed stratification factors. Furthermore, many testing participants shared their concern that health outcomes and customer experience may vary when stratified by race, ethnicity, or sex. We also believe that those who are dually eligible to receive Medicare and full Medicaid benefits would find it particularly useful to see quality ratings that focus specifically on the experience of such dually eligible beneficiaries. We believe that such ratings would allow beneficiaries who are dually eligible for Medicare and Medicaid to best identify a high-quality health plan, given the unique access considerations among this population. States would be required to display this information by the general MAC QRS implementation date proposed under § 438.505(a)(2). We seek comment on the feasibility of the proposed factors for stratifying quality ratings by the initial implementation date, and also whether certain mandatory

measures may be more feasible to stratify by these factors than others. We are proposing that this interactive tool would be available no earlier than two years after the general MAC QRS implementation date. We request comment on this proposal including the timeline for implementation, technical assistance that may be necessary for States to implement the proposed feature, and the proposed factors by which such quality ratings would be stratified.

(3) Plan Comparison Information (§§ 438.334(e), 438.520(a)(3), and 457.1240(d))

Our prototype testing showed us participants were often frustrated and confused by the need to navigate multiple websites to obtain health plan information, such as out of pocket expenses, plan coverage of benefits, providers, and pharmaceuticals; and health plan metrics such as average time spent waiting for care, weekend and evening hours, and appointment wait times. When compiled into a standardized display along with quality ratings in our website prototype, participants responded positively and found the ability to compare plans on out-of-pocket expenses and covered benefits to be particularly useful. After identifying available plans that aligned with their needs and preferences on these two variables, some participants reflected that they would use quality ratings as an additional way to narrow down and filter their options. When presented alongside quality ratings, this information allowed beneficiaries to better compare plans. Based on this testing, we are proposing in § 438.520(a)(3) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display, for each managed care plan, standardized information identified by CMS that allows users to compare available managed care plans and programs, including the name, website, and customer service telephone hot line of each managed care plan; premium and cost sharing information; a summary of covered benefits; certain metrics of managed care plan access and performance; and whether the managed care plan offers an integrated Medicare-Medicaid plan. Under proposed § 438.520(a)(3)(iii) and (iv), States would be required to identify comparative information about plans, specifically differences in premiums, cost-sharing, and benefits among managed care plans, to help users quickly identify where managed care plans do

and do not differ. We believe that this information should be readily available to States and providing comparative information of this type is consistent with the information disclosure requirements in section 1932(a)(5) of the Act. These requirements are illustrated in Prototype A and B.

Under proposed § 438.520(a)(3)(v), States would also be required to provide on the QRS website certain metrics of managed care plan performance that States must make available to the public under Part 438, subparts B and D regulations, including certain data most recently reported to CMS on each managed care program under § 438.66(e) (Medicaid only) and the results of secret shopper survey proposed at § 438.68(f) in this proposed rule. Proposed paragraph (a)(3)(v) authorizes CMS to specify the metrics that are required to be displayed this way. States already report information related to grievances, appeals, availability and accessibility of covered services under § 438.66(e) and we believe that displaying some of this information would be responsive to input we received from our testing participants and improve transparency for beneficiaries without imposing significant burden on States since the information is already reported to us. States could choose to integrate these metrics into the display of MAC QRS measures on the MAC QRS website or, as illustrated in Prototypes A and B, may choose to hyperlink to an existing page with the identified information from the MAC QRS webpage. These proposed requirements also support our goal for the MAC QRS to be a one-stop-shop where beneficiaries can access a wide variety of information on plan quality and performance in a user-friendly format to help inform their decision making. We seek comment on the inclusion of these metrics, and whether we should consider phasing in certain metrics first before others.

Lastly, at § 438.530(a)(3)(vi), we are proposing to require States to indicate when a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D-SNP and to provide a link to the integrated plan's rating under the MA and Part D quality rating system. The definitions of fully integrated dual eligible special needs

plan and highly integrated dual eligible special needs plan are at § 422.2. We believe this is the simplest and most efficient way to help dually eligible users understand how to use the two quality ratings together. Both Prototype A and B illustrate this requirement through a hyperlink to the integrated plan's MA and Part D quality rating. We seek comment on these requirements, including on our proposal to require States to provide standardized information that users may rely on to compare managed care plans and request feedback on the feasibility of providing this information by the date initial implementation date.

(4) Information on Quality Ratings (§§ 438.334(e), 438.520(a)(4) and (c), and 457.1240(d))

Our user testing found that participants were initially skeptical of data provided in the MAC QRS, stating confusion regarding the source of the data used and mistrust in the ratings generated because they were uncertain how they were derived. Additionally, some participants stated that they did not trust information from the health plans. In an effort to improve user trust through data transparency, we tested providing clear and comprehensive information on displayed quality ratings and identified three types of information that together resulted in increased participant trust of the quality ratings. These include descriptions of the quality ratings in plain language, how recent the data displayed are, and how the data were confirmed to be accurate. Based on this user feedback, in § 438.520(a)(4)(i) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States would provide plain language descriptions of the importance and impact of each quality measure. We found that a simple explanation of what a quality measure is assessing, as well as how the measure relates to a beneficiary's health and well-being, were most helpful to users in understanding displayed quality ratings. A simple explanation would satisfy the proposed requirement. Both Prototype A and B include example explanations for our proposed mandatory measures, and we intend to include a sample explanation of the quality ratings for each final mandatory measure in the design guide discussed in section I.B.6.g. of this proposed rule, which States may choose to use.

Users responded positively to information that showed when data were collected and whether data were validated. They appreciated knowing that an external, neutral organization calculated the measures, noting that they would not trust the measures if they were calculated solely by the managed care plan. In § 438.520(a)(4)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States be required to indicate the measurement period during which data were produced to calculate the displayed quality ratings. In § 438.520(a)(4)(iii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we propose that States must provide on the MAC QRS website when, how, and by whom quality ratings have been validated. This information would be provided in plain language and convey the role of parties (other than the rated plans) in validating data used to calculate the quality ratings, which will promote transparency and trustworthiness in the data. We note that States may use the External Quality Review optional activity described at § 438.358(c)(6) for EQRO assistance with quality ratings and link to the validated data included in the EQR technical reports. We seek comment on the display requirement proposed in § 438.520(a)(4) and request feedback on the feasibility of implementing these requirements by the initial implementation date proposed at§ 438.505(a)(2).

Finally**,** we believe that user preferences for how information should be displayed may change over time as the available data and the technology that enables website display of available data evolves. To ensure that the MAC QRS website continues to be a useful tool, we intend to periodically engage in additional consultations with MAC QRS users as part of a continuous improvement approach. We are proposing in § 438.520(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS periodically consult with interested parties, including MAC QRS users such as Medicaid and CHIP beneficiaries and their caregivers, to maintain and update the website display requirements for the information required in proposed § 438.520(a). These consultations may result in

proposed changes through rulemaking that add to or refine existing requirements or remove existing requirements that beneficiaries no longer find useful.

(5) Display of additional measures not on the mandatory measure set (§§ 438.334(e), 438.520(b), and 457.1240(d))

Under our proposal at § 438.510(a), States would have the option to display additional measures that are not included in the mandatory measure set if the two requirements set forth in proposed § 438.520(b)(1) and (2) are met. The same standards would apply to separate CHIP as proposed in § 457.1240(d) by cross-referencing part 438, subpart G.

First, we are proposing, in § 438.520(b)(1) to require States to obtain input from prospective MAC QRS users, including beneficiaries, their caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy. In this proposed rule, we have extensively noted the importance of the prospective user testing we engaged in and the extent to which this feedback directed our design of the MAC QRS framework and selection of the preliminary mandatory measure set. Just as beneficiary participation was, and will continue to be, critical in our design of the MAC QRS, we believe beneficiary participation is critical in the identification of any additional measures included in a State's MAC QRS. States could meet this requirement by ensuring that beneficiary members of the MCAC are present when obtaining input from the State's MCAC, or may engage in direct beneficiary interviews, focus groups, or prototype testing.

Second, we are also proposing at § 438.520(b)(2) that States must document the input received from prospective MAC QRS users on such additional measures, the modifications made to the proposed additional measures in response to the input, and rationale for not accepting input. We are also proposing this documentation to be reported as part of the MAC QRS annual report proposed under § 438.535(a)(3). For States that currently publish a QRS-like website, measures that are not in the mandatory measure set would be considered additional measures and

would be subject to this process prior to display. If a State obtained user input for the additional measure prior to displaying the measure on its current website, the State may use this input to meet this requirement.

h. Alternative Quality Rating System (§§ 438.334(c), 438.525, and 457.1240(d))

Current regulations at § 438.334(c) allow States, with CMS approval, to implement an alternative managed care quality system (alternative QRS) that uses different quality measures or applies a different methodology if the conditions set forth in § 438.334(c)(1)(i) through (iii) are met, including that the measure or methodology must be substantially comparable to the measures and methodology established by CMS under the MAC QRS framework. Based on feedback we received during our engagement with States and other interested parties, we are proposing to redesignate § 438.334(c) at § 438.525 for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), and to modify the current policy by narrowing the changes (compared to the MAC QRS framework described in proposed § 438.515) that would require our approval. We are also proposing to apply the same requirements for both Medicaid managed care programs and separate CHIP by revising § 457.1240(d) to require States to comply with § 438.525.

First, we are proposing to remove the language in current § 438.334(c)(1) that includes the use of "different performance measures" being subject to our review and approval as part of an alternative QRS. Current regulations at § 438.334(c)(1) require States to submit for our review and approval an alternative QRS request to include measures different than those included in the mandatory measure set identified by CMS. We believe requiring States to obtain our approval to include measures not required by us creates unnecessary administrative burden for both States and CMS. Under the proposed regulation, instead of requiring approval of different measures, we are proposing that States would have the flexibility to add measures that are not mandatory measures without prior approval from CMS.

We highlight here that the measure specifications established by measure stewards for mandatory measures are not considered part of the methodology described in proposed § 438.515 and are therefore not subject to § 438.525. Modifications to these specifications that are approved by the measure steward do not require a State to undergo any part of the alternative QRS process described in this section for the State to use those measure steward approved modifications to produce a rating for a mandatory measure. However, we would consider quality ratings for mandatory measures identified by CMS under § 438.510(a) that are calculated using specifications not approved by a measure steward to be a different measure. We believe that this policy provides flexibility to States while ensuring that the results on the mandatory measures remain comparable among States.

Second, we are proposing to further define the criteria and process for determining if an alternative QRS system is substantially comparable to the MAC QRS methodology described in proposed § 438.515. The current regulations at § 438.334(c)(4) provide that we will issue guidance on the criteria and process for determining if an alternative QRS meets the substantial comparability standard in current § 438.334(c)(1)(ii), redesignated at § 438.525(a)(2). We are proposing to eliminate § 438.334(c)(4) and redesignate as proposed § 438.525(c)(2)(i) through (iii) and specify in proposed § 438.525(c)(2)(iv) that States are responsible for submitting documents and evidence that demonstrates compliance with the substantial comparability standards. We believe that eliminating § 438.334(c)(4) is appropriate as this rulemaking provides an opportunity for States and other interested parties to submit comments on how CMS should evaluate alternative quality rating systems for substantial comparability.

In the future, we intend to issue instructions on the procedures and the dates by which States must submit an alternative QRS request to meet the implementation date specified in proposed § 438.505(a)(2). For requests or modifications made after implementation of the MAC QRS, we are considering accepting rolling requests instead of specifying certain dates or times of year when we will accept alternative QRS requests or modifications. We believe this may be

necessary given that States may have different contract cycles with managed care plans. We solicit comment on these different approaches.

Current § 438.334(c)(2) describes the information that States would submit to CMS as part of their request to implement an alternative QRS. We are proposing to redesignate § 438.334(c)(2), with revisions, at § 438.525(c)(2)(iv) to allow States to provide additional supporting documents and evidence that they believe demonstrates that a proposed alternative QRS would yield information regarding managed care plan performance that is substantially comparable to that yielded by the MAC QRS methodology described in § 438.515. Examples of such additional supporting documents could include a summary of the results of a quantitative or qualitative analysis of why the proposed alternative methodology is substantially comparable or calculations of mandatory measures with the alternative methodology and with the methodology required under § 438.515.

We seek comment on these proposals, in particular, the described process and documentation for assessing whether a proposed alternative QRS framework is substantially comparable, by when States would need alternative QRS guidance, and by when States would need to receive approval of an alternative QRS request to implement the alternative by the implementation date specified in proposed § 438.505(a)(2).

i. Annual Technical Resource Manual (§§ 438.334, 438.530, and 457.1240(d))

We propose at § 438.530(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS will develop and update annually a Medicaid managed care quality rating system technical resource manual no later than August 1, 2025, and update it annually thereafter. Providing clear and detailed information for reporting on MAC QRS measures not only supports States in implementing their MAC QRS but is also essential for consistent reporting and comparable quality ratings across States and managed care plans. This manual would include information needed by States and managed care plans to calculate and issue quality ratings for all mandatory measures that States would be required to

report under this proposed rule. This includes the mandatory measure set, the measure steward technical specifications for those measures, and information on applying our proposed methodology requirements to the calculation of quality ratings for mandatory measures. Under our proposal, we would publish an initial technical resource manual following the final rule, and would update the manual annually thereafter to maintain its relevance. We considered releasing the technical resource manual less frequently than annually, but we do not believe this manual could be properly maintained unless it is updated annually due to the inclusion of updates to the technical specifications for the mandatory measures.

Proposed § 438.530(a) identifies the components of the technical resource manual to be issued by CMS. As described in § 438.530(a)(1), we propose to use the technical resource manual to identify the mandatory measures as well as any measures newly added or removed from the previous year's mandatory measure set. We intend for the first technical resource manual to include details on the initial MAC QRS mandatory measure set that will be finalized after consideration of the public comments received in response to this proposed rule.

These content requirements for the technical resource manual proposed at new § 438.530(a)(1) through (3) include the following:

- The mandatory measure set so States know what they are required to report.
- The specific MAC QRS measures newly added to or removed from the prior year's mandatory set as well as a summary of the engagement and public comments received during the engagement process in § 438.510(b) used for the most recent modifications to the mandatory measure set. To provide a complete picture of any changes being made to the MAC QRS measures, we propose this summary to include a discussion of the feedback and recommendations received, the final modifications and timeline for implementation, and the rationale for recommendations or feedback not accepted.
- The subset of mandatory measures that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by CMS in the

annual technical resource manual as required under § 438.520(a)(2)(v) and (a)(6)(iii). We discuss the rationale for inclusion of stratifiers in section I.B.6.g.2. of this proposed rule.

- How to use the methodology described in § 438.515 to calculate quality ratings for managed care plans. We seek comment on which topics States and health plans would like technical assistance or additional guidance to ensure successful implementation of the rating system.

- Technical specifications for mandatory measures produced by measures stewards as part of the proposed annual technical resource manual. We believe this information would assist States and health plans in the calculation of quality ratings for mandatory measures and aligns with the practices of the Adult and Child Core Set and the MA and Part D and QHP quality rating systems.

Lastly, at § 438.530(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we are proposing the general rule that CMS take into account stratification guidance issued by the measure steward and other CMS reporting programs when identifying which measures, and by which factors, States must stratify mandatory measures. Under this proposal, we plan to implement a phased-in approach for specifying the mandatory measures for which data must be stratified and the factors by which such data must be stratified. We intend to align with the stratification schedule which is proposed in § 437.10(d) of the Mandatory Medicaid and CHIP Core Set Reporting Proposed Rule (see 87 FR 51327). We believe this alignment with the Core Set stratification would minimize State and health plan burden to report stratified measures. For any MAC QRS measures that are not Core Set measures, we would consider, and align where appropriate, with the stratification policies for the associated measure steward or other CMS reporting programs. Additional information regarding MAC QRS stratification requirements are proposed in section I.B.6.g.2. of this proposed rule.

Based on feedback we received through listening sessions with interested parties, we are considering releasing an updated technical resource manual at least five months prior to the

measurement period for which the technical resource manual will apply. This is in alignment with the proposed date for the first technical resource manual of August 1, 2025 for a 2026 measurement year, and would ensure that States have enough time to implement any necessary changes before the measurement period and, if necessary, submit and receive approval for an alternative QRS request. In our listening sessions, interested parties noted that this timeline would align with those used by other measure stewards (for example, NCQA for HEDIS measures) and would ensure that States and managed care plans are able to identify and make necessary contractual, systems, and data collection changes to facilitate additional data collection required for the upcoming measurement period. We seek comment on whether this timing is appropriate for States to implement any changes included in the reporting and technical guidance for the initial measurement year as well as subsequent measurement years.

j. Reporting (§§ 438.334, 438.535, and 457.1240(d))

We are proposing requirements at § 438.535 for States to submit to CMS, upon request, information on their MAC QRS to support our oversight of Medicaid and CHIP and compliance with MAC QRS requirements, to ensure beneficiaries can meaningfully compare ratings between plans, and to help us monitor trends in additional measures and use of permissible modifications to measure specifications used among States, which could inform future additions to the mandatory measures and modifications of our methodology. We are proposing any request for reporting by States would be no more frequently than annually. We are proposing the report would include the following components:

- A list of all measures included in the State's MAC QRS, including a list of the mandatory measures reported and any additional measures a State has chosen to display in their MAC QRS to inform updates to the measures list;
- An attestation that displayed quality ratings for all mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used

to calculate any additional measures when it deviates from the methodology proposed in § 438.515;

- If a State chooses to display additional quality measures, a description of and the required documentation for the process required under § 438.520(b);
- The date on which the State publishes or updates their quality ratings for the State's managed care plans;
- The link to the State's MAC QRS website to enable CMS to ensure the MAC QRS ratings are current; and
- The use of any technical specification adjustments to MAC QRS mandatory measures, which are outside the measure steward's allowable adjustment for the mandatory measure, but that the measure steward has approved for use by the State. As discussed in section I.B.6.f. of this proposed rule, we do not consider measure steward technical specifications to be part of the MAC QRS rating methodology, but they are part of the measures. Therefore, we do not require States to submit such adjustments to us for approval as an alternative QRS and believe State reporting is more appropriate to better understand if such adjustments impact plan-to-plan comparability or comparability within and among States.
- A summary of each alternative QRS approved by CMS, including the effective dates (the time period during which the alternative QRS was, has been, or will be applied by the State) for each approved alternative QRS.

We propose these reporting requirements at new § 438.535(a)(1) through (7) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). We propose in § 438.535(a) the report will be "in a form and manner determined by CMS" because we intend to establish an online portal that States could access to easily submit this information to us. At § 438.535(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d) we propose that States would be given a

minimum of 90 days' notice to provide such a report. We seek comment on whether States prefer one annual reporting date or a date that is relative to their MAC QRS updates.

k. Technical Changes (§§ 438.334, 438 Subpart G, 438.358, and 457.1240(d))

We are proposing several technical changes to conform our regulations with other parts of our proposed rule, which include:

- Redesignating the regulations under current § 438.334(a) to 42 CFR part 438, subpart G, § 438.505;
- In current § 438.358(c)(6), changing the reference for this EQR optional activity from § 438.334 to part 438, subpart G to align with the proposed redesignating of § 438.334;
- In current § 438.334(a)(1), redesignated to § 438.505(a)(1)(i), changing the "Medicaid managed care quality rating system developed by CMS in accordance with paragraph (b) of this section" to "QRS framework" to align with the proposed definition of QRS framework in new § 438.500;
- In current § 438.334(a)(2), redesignated to § 438.505(a)(2)(ii), changing "in accordance with paragraph (c) of this section" to "in accordance with § 438.525 of this subpart" to align with the proposed alternative QRS requirements in new § 438.525;
- Modifying current § 438.334(a)(3), redesignated to § 438.505(a)(2), to use the term "the final rule" instead of "a final notice" to refer to the proposed rules herein, if finalized;
- Modifying current § 438.334(c)(1), redesignated to § 438.525(a), by replacing "different methodology" with "alternative methodology" to better align with the proposed terminology used in the new proposed § 438.525);
- In current § 438.334(b)(1), redesignated to § 438.505(c), replacing "related CMS quality rating approaches" with "similar CMS quality measurement and rating initiatives" to better describe how we are aligning the QRS framework;

- Redesignating current § 438.334(c)(3)(i) to § 438.525(c)(2)(i) and modifying by removing "alternative quality rating system framework, including the quality measures" to align with our proposal under new § 438.525;

Unless otherwise noted, these technical changes are equally proposed for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d).

II. 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 preamble, "collection of information" is defined under 5 CFR 1320.3 of the PRA's implementing regulations. To fairly evaluate whether a collection of information 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). Table 3 presents BLS' mean hourly wage, our

estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 3: National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
All Occupations	00-0000	28.01	n/a	n/a
Accountant	13-2011	40.37	40.37	80.74
Actuary	15-2011	60.24	60.24	120.48
Business Operations Specialist, All Other	13-1199	38.64	38.64	77.28
Computer Programmer	15-1251	54.68	54.68	109.36
Customer Service Rep	43-4051	18.79	18.79	37.58
Database Administrator	15-1242	49.25	49.25	98.50
General and Operations Manager	11-1021	55.41	55.41	110.82
Medical Records Specialist	29-2072	23.23	23.23	46.46
Office Clerk, General	43-9061	18.98	18.98	37.96
Statistician	15-2041	47.81	47.81	96.62
Registered Nurse	29-1141	39.78	39.78	79.56
Web Developer	15-1245	39.09	39.09	78.18

States and the Private Sector: As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Beneficiaries: To derive average costs for beneficiaries we believe that the burden will be addressed under All Occupations (BLS occupation code 00-0000) at $28.01/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

B. Proposed Information Collection Requirements (ICRs)

To estimate the burden for the requirements in part 438, we utilized State submitted data by States for enrollment in managed care plans for CY 2020. The enrollment data reflected 58,521,930 enrollees in MCOs, 37,692,501 enrollees in PIHPs or PAHPs, and 6,089,423 enrollees in PCCMs, for a total of 67,836,622 Medicaid managed care enrollees. This includes

duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. These data also showed 43 States that contract with 467 MCOs, 11 States that contract with 162 PIHPs or PAHPs, 19 States that contract with 21 non-emergency transportation PAHPs, and 13 States with 26 PCCM or PCCM entities. The estimates below reflect deduplicated State counts as data permitted.

To estimate the burden for these requirements in part 457, we utilized State submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 4,580,786 Medicaid expansion CHIP and 2,593,827 separate CHIP managed care enrollees. These data also showed that 32 States use managed care entities for CHIP enrollment contracting with 199 MCOs, PIHPs, and PAHPs, as well as 17 PCCMs.

1. ICRs Regarding Standard Contract Requirements (§ 438.3 and 457.1203)

The following proposed changes to § 438.3 will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1203 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.3(i) and 457.1203(f) would require that MCOs, PIHPs, and PAHPs report provider incentive payments based on standard metrics for provider performance. The proposed amendments to § 438.8(e)(2) would define the provider incentive payments that could be included in the MLR calculation; however, the administrative burden for these changes is attributable to the managed care contracting process, so we are attributing these costs to the contracting requirements in § 438.3(i). Approximately half (or 315 Medicaid contracts and 100 CHIP contracts) of all MCO, PIHP, and PAHP contracts would require modification to reflect these changes. For the contract modifications, we estimate it would take 2

hours at $77.28/hr for a business operations specialist and 1 hour at $110.82/hr for a general operations manager. In aggregate for Medicaid for § 438.3(i), we estimate a one-time State burden of 945 hours (315 contracts x 3 hr) at a cost of $83,595 [315 contracts x ((2 hr x $77.28/hr) + (1 hr x $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 315 hours and $9,288. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1203(f) we estimate a one-time State burden of 300 hours (100 contracts x 3 hr) at a cost of $26,538 [100 contracts x ((2 hr x $77.28/hr) + (1 hr x $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 66 hours and $8,819. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

To report provider incentive payment based on standard metrics, MCOs, PIHP, and PAHPs would need to select standard metrics, develop appropriate payment arrangements, and then modify the affected providers' contracts. We estimate it would take 120 hours consisting of: 80 hours x $77.28/hr for a business operations specialist and 40 hours x $110.82/hr for a general and operations manager. In aggregate for Medicaid for § 438.3(i), we estimate a one-time private sector burden of 37,800 hours (315 contracts x 120 hr) at a cost of $3,343,788 [315 contracts x ((80 hr x $77.28/hr) + (40 hr x $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 12,600 hours and $1,114,596. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1203(f) we estimate a one-time private sector burden of

12,000 hours (100 contracts x 120 hr) at a cost of $1,061,520 [100 contracts x ((80 hr x $77.28/hr) + (40 hr x $110.82/hr))].

To do the annual reconciliations needed to make the incentive payments and include the expenditures in their annual report required by 438.8(k), we estimate MCOs, PIHPs, and PAHPs would take 1 hour at $77.28/hr for a business operations specialist. In aggregate for Medicaid we estimate an annual private sector burden of 315 hours (315 contracts x 1 hr) at a cost of $24,343 (315 contracts x 1 hr x $77.28/hr).

In aggregate for CHIP, we estimate an annual private sector burden of 100 hours (100 contracts x 1 hr) and $7,728 (100 contracts x 1 hr x $77.28/hr).

2. ICRs Regarding Special Contract Provisions Related to Payment (§ 438.6)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

The proposed amendments to § 438.6(c)(2) would require all SDP expenditures under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) (that is, the SDPs that require prior written approval under this proposed rule) must be submitted and have written approval by CMS prior to implementation.

Initially, we estimate that 38 States would submit 50 new proposals for minimum/maximum fee schedules, value-based payment, or uniform fee increases. We estimate that it would take 2 hours at $120.48/hr for an actuary, 6 hours at $77.28/hr for a business operations specialist, and 2 hours at $110.82/hr for a general and operations manager for development and submission. We estimate an annual State burden of 500 hours (50 proposals x 10 hr) at a cost of $46,314 [50 proposals x ((2 hr x $120.48/hr) + (6 hr x $77.28/hr) + (2 hr x $110.82/hr))].

Thereafter, we estimate that 38 States would submit 150 renewal or amendment proposals per year. We estimate also it would take 1 hour at $77.28/hr for a business operations specialist, 1 hour at $120.48/hr for an actuary, and 1 hour at $110.82/hr for a general and operations manager for any proposal updates or renewals. In aggregate, we estimate an annual State burden of 450 hours (150 proposals x 3 hr) and $46,287 [150 renewal/amendment proposals x ((1 hr x $77.28/hr) + (1 hr x $110.82/hr) + (1 hr x 120.48/hr))].

The proposed amendments to § 438.6(c)(2)(iii) would require that all SDPs subject to prior approval under paragraphs (c)(1)(i) through (iii) for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center, include a written analysis, showing that the total payment for such services does not exceed the average commercial rate. We estimate that 38 States will develop and submit 60 of these SDPs that include a written analysis to CMS. We also estimate it would take 6 hours at $120.48/hr for an actuary, 3 hours at $110.82/hr for a general and operations manager, and 6 hours at $109.36/hr for a computer programmer for each analysis. In aggregate we estimate an annual State burden of 900 hours (60 SDPs x 15 hr) and at a cost of $102,690 [60 certifications x ((6 hr x $120.48/hr) + (3 hr x $110.82/hr) + (6 hr x $109.36/hr))].

Section 438.6(c)(2)(iv) would require that SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) must prepare and submit a written evaluation plan to CMS. The evaluation plan must include specific components under this proposal and is intended to measure the effectiveness of those State directed payments in advancing at least one of the goals and objectives in the quality strategy on an annual basis and whether specific performance targets are met. We estimate that 38 States would submit 50 written evaluation plans for new proposals. We also estimate it would take 5 hours at $109.36/hour for a computer programmer, 2.5 hours at $110.82/hr for a general and operations manager, and 2.5 hours at $77.28/hr for a business operations specialist for each new evaluation plan. In aggregate, we estimate an annual State burden of 500 hours (50 evaluation plans x 10 hr) and at a cost of $50,853 [50 evaluation plans x

((5 hr x 109.36/hr) + (2.5 hr x $110.82) + (2.5 hr x $77.28/hr))].

Thereafter, we estimate that 38 States would prepare and submit 150 written evaluation plans for amendment and renewal proposals. We also estimate it would take 2 hours at $109.36/hr for a computer programmer, 2 hours at $110.82/hr for a general and operations manager and 2 hours at $77.28/hr for a business operations specialist for each evaluation plan amendment and renewal. In aggregate we estimate an annual State burden of 900 hours (150 evaluation plans x 6 hr) at a cost of $89,238 [150 evaluation plans x ((2 hr x 109.36/hr) + (2 hr x $110.82) + (2 hr x $77.28/hr))].

Section 438.6(c)(2)(v) would require for all SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) that have an actual Medicaid managed care spending percentage greater than 1.5 must complete and submit an evaluation report using the approved evaluation plan to demonstrate whether the SDP results in achievement of the State goals and objectives in alignment with the State's evaluation plan.

We estimate 38 States will submit 47 evaluation reports. We also estimate it would take 3 hours at $109.36/hr for a computer programmer, 1 hour at $110.82/hour for a general and operations manager, and 2 hours at $77.28/hr for a business operations specialist for each report. In aggregate we estimate an annual State burden of 282 hours (47 reports x 6 hr) at a cost of $27,893 [47 reports x ((3 hr x $109.36/hr) + (1hr x $110.82/hr) + (2 hr x $77.28/hr)].

The proposal at § 438.6(c)(7) would require States to submit a final SDP cost percentage as a separate actuarial report concurrently with the rate certification only if a State wishes to demonstrate that the final SDP cost percentage is below 1.5 percent. We anticipate that 10 States would need: 5 hours at $120.48/hr for an actuary, 5 hours at $109.36/hr for a computer programmer, and 7 hours at $77.28/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 170 hours (17 hr x 10 States) at a cost of $16,902 (10 States x [(5 hr x $120.48/hr) + (5 hr x $109.36/hr) + (7 hr x $77.28/hr)]).

3. ICRs Regarding Rate Certification Submission (§ 438.7)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

The proposed amendments to § 438.7 set out revisions to the submission and documentation requirements for all managed care actuarial rate certifications. The certification would be reviewed and approved by CMS concurrently with the corresponding contract(s). Currently, § 438.7(b) details certain requirements for documentation in the rate certifications. We believe these requirements are consistent with actuarial standards of practice and previous Medicaid managed care rules.

We estimate that 44 States would develop 225 certifications at 250 hours for each certification. Of the 250 hours, we estimate that it would take 110 hours at $120.48/hr for an actuary, 15 hours at $110.82/hr for a general and operations manager, 53 hours at $109.36/hr for a computer programmer, 52 hours at $77.28/hr for a business operations specialist, and 20 hours at $37.96/hr for an office and administrative support worker. In aggregate we estimate an annual State burden of 56,250 hours (250 hr x 225 certifications) at a cost of $5,735,012 [225 certifications x ((110 hr x $120.48/hr) + (15 hr x $110.82/hr) + (53 hr x $109.36/hr) + (52 hr x $77.28/hr) + (20 hr x $37.96/hr))].

4. ICRs Regarding Medical Loss Ratio Standards (§§ 438.3, 438.8, 438.74, and 457.1203)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1203 will be submitted to OMB for review under control number 0938-1282 (CMS-

10554).

This rule's proposed amendments to §§ 438.8 and 457.1203 would require that MCOs, PIHPs, and PAHPs report to the State annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs were required to submit to States amount to 629 Medicaid contracts and 199 CHIP contracts. All MCOs, PIHPs, and PAHPs need to report the information specified under §§ 438.8 and 457.1203 regardless of their credibility status.

The proposed amendments to § 438.8(k) would require that MCOs, PIHPs, and PAHPs include expenditures for State directed payments on a separate line in their annual report to the State. We anticipate that the one-time system change would take 4 hr at $77.28/hr for a business operations specialist and 2 hr at $109.36/hr for a computer programmer. In aggregate for Medicaid for § 438.8(k), we estimate a one-time private sector burden of 3,774 hours (629 contracts x 6 hr) at a cost of $332,011 [629 contracts x ((4 hr x $77.28/hr) + (2 hr x $109.36/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 1,258 hours and $110,670. The annualization divides our estimate by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

The proposed amendments to §§ 438.8(k)(1)(vii) and 457.1203(f) would require that MCOs, PIHPs, and PAHPs develop their annual MLR reports compliant with the proposed expense allocation methodology.[149] To meet this requirement we anticipate it would take: 1 hr at $80.74/hr for an accountant, 1 hr at $77.28/hr for a business operations specialist, and 1 hr at $110.82/hr for a general operations manager. In aggregate for Medicaid for § 438.8(k)(1)(vii), we estimate an annual private sector burden of 1,887 hours (629 contracts x 3 hr) at a cost of

149 Methodology(ies) for allocation of expenditures as described at 45 CFR 158.170(b).

$169,100 [629 contracts x ((1 hr x $80.74/hr) + (1 hr x $77.28/hr) + (1 hr x $110.82/hr))]. In aggregate for CHIP for § 457.1203(f), we estimate an annual private sector burden of 597 hours (199 contracts x 3 hr) at a cost of $53,499 [199 contracts x ((1 hr x $80.74/hr) + (1 hr x $77.28/hr) + (1 hr x $110.82/hr))].

The proposed amendments to §§ 438.74 and 457.1203(e) would require States to comply with data aggregation requirements for their annual reports to CMS. We estimate that only 5 States would need to resubmit MLR reports to comply with the proposed data aggregation changes. We anticipate that it would take 5 hours x $77.28/hr for a business operations specialist. In aggregate, for Medicaid for § 438.74, we estimate a one-time State burden of 25 hours (5 States x 5 hr) at a cost of $1,932 (5 States x 5 hr x $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 8 hours and $644. In aggregate for CHIP for § 457.1203(e) we estimate a one-time State burden of 25 hours (5 States x 5 hr) at a cost of $1,932 (5 States x 5 hr x $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates for CHIP to 8 hours and $644. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

The proposed amendments to § 438.74 would require States to submit a summary report of the State directed payment data submitted by their managed care plans under § 438.8(k). The proposed changes to § 438.74 would apply to 43 States. To accommodate the new data from plans resulting from proposed changes to § 438.74, we anticipate it would take 4 hours at $77.28/hr for a business operations specialist to implement the proposed SDP reporting changes in their MLR summary reports. In aggregate, we estimate an annual State burden of 172 hours (43 States x 4 hr) at a cost of $13,292 (43 States x 4 hr x $77.28/hr).

5. ICRs Regarding Information Requirements (§§ 438.10 and 457.1207)

The following proposed changes to § 438.10 will be submitted to OMB for review under

control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1207 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.10(c)(3) and 457.1207 would require States to operate a website that provides the information required in § 438.10(f). We propose to require that States include required information on one page, use clear labeling, and verify correct functioning and accurate content at least quarterly. We anticipate it would take 20 hours at $109.36/hr once for a computer programmer to place all required information on one page and ensure the use of clear and easy to understand labels on documents and links.

In aggregate for Medicaid for § 438.10(c)(3), we estimate a one-time State burden of 900 hours (45 States x 20 hr) at a cost of $98,424 (900 hr x $109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 300 hours and $32,808. In aggregate for CHIP for § 457.1207, we estimate a one-time State burden of 640 hours (32 States x 20 hr) at a cost of $69,990 (640 hr x $109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 213 hours and $23,294. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

We also anticipate that it would take 40 hr at $109.36/hr for a computer programmer to periodically add and verify the function and content on the site at least quarterly (10 hours/quarter). In aggregate for Medicaid for we estimate an annual State burden of 1,800 hours (45 States x 40 hr) at a cost of $196,848 (1,800 hr x $109.36/hr). Due to the additional proposal to post summary enrollee experience survey results by separate CHIP managed care plan on the

State's website, we estimate an additional 1 hour at $109.36/hr for a computer programmer to post these comparative data annually for a total of 41 hours. For CHIP, we estimate an annual State burden of 1,312 hours (32 States x 41 hr) at a cost of $143,480 (1,312 hr x $109.36/hr).

6. ICRs Regarding ILOS Contract and Supporting Documentation Requirements (§§ 438.16 and 457.1201)

The following proposed changes at § 438.16 will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1201 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposals at §§ 438.16 and 457.1201 would require States that provide ILOSs, with the exception of short term IMD stays, to comply with additional information collection requirements. 44 States utilize MCOs, PIHPs and PAHPs in Medicaid managed care programs. We do not have current data readily available on the number of States that utilize ILOSs and the types of ILOSs in Medicaid managed care. We believe it is a reasonable estimate to consider that half of the States with MCOs, PIHPs and PAHPs (22 States) may choose to provide non-IMD ILOSs. Similarly, for CHIP, we estimate that half of the States with MCOs, PIHPs, and PAHPS (16 States) provide ILOSs and would be subject to the additional information collection requirements.

The proposal at § 438.16(c)(4)(i) would require States to submit a projected ILOS cost percentage to CMS as part of the rate certification. The burden for this proposal is accounted for in ICR #2 (above) for § 438.7 Rate Certifications.

The proposal at § 438.16(c)(5)(ii) would require States to submit a final ILOS cost percentage and summary of actual MCO, PIHP and PAHP ILOS costs as a separate actuarial

report concurrently with the rate certification. We anticipate that 22 States would need: 5 hours at $120.48/hr for an actuary, 5 hours at $109.36/hr for a computer programmer, and 7 hours at $77.28/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 374 hours (17 hr x 22 States) at a cost of $37,184 (22 States x [(5 hr x $120.48/hr) + (5 hr x $109.36/hr) + (7 hr x $77.28/hr)]).

Proposals at §§ 438.16(d)(1) and 457.1201(e) would require States that elect to use ILOS to include additional documentation requirements in their managed care plan contracts. We anticipate that 22 States for Medicaid and 16 States for CHIP would need 1 hour at $77.28/hr for a business operations specialist to amend 327 Medicaid MCO, PIHP, and PAHP contracts and 100 CHIP contracts annually. In aggregate for Medicaid for § 438.16(d)(1), we estimate an annual State burden of 327 hours (327 contracts x 1 hr) at a cost of $25,271 (327 hr x $77.28/hr). In aggregate for CHIP for § 457.1201(e) we estimate an annual State burden of 100 hours (100 contracts x 1 hr) at a cost of $7,728 (100 hr x $77.28/hr).

Proposals at §§ 438.16(d)(2) and 457.1201(e) would require some States to provide to CMS additional documentation to describe the process and supporting data the State used to determine each ILOS to be a medically appropriate and cost-effective substitute. This additional documentation would be required for States with a projected ILOS cost percentage greater than 1.5 percent. We anticipate that approximately 5 States may be required to submit this additional documentation. We estimate it would take 2 hours at $77.28/hr for a business operations specialist to provide this documentation. In aggregate for Medicaid for § 438.16(d)(2), we estimate an annual State burden of 10 hours (5 States x 2 hr) at a cost of $773 (10 hr x $77.28/hr). In aggregate for CHIP for § 457.1201(e) we estimate the same annual State burden of 10 hours (5 States x 2 hr) at a cost of $773 (10 hr x $77.28/hr).

Proposals at §§ 438.16(e)(1) and 457.1201(e) would require States with a final ILOS cost percentage greater than 1.5 percent to submit an evaluation for ILOSs to CMS. We anticipate that approximately 5 States may be required to develop and submit an evaluation. We estimate it

would take 25 hours at $77.28/hr for a business operations specialist. In aggregate for Medicaid for § 438.16(e)(1), we estimate an annual State burden of 125 hours (5 States x 25 hr) at a cost of $9,660 (125 hr x $77.28/hr). In aggregate for CHIP for § 457.1201(e), we estimate the same annual State burden of 125 hours (5 States x 25 hr) at a cost of $9,660 (125 hr x $77.28/hr).

An ILOS may be terminated by either a State, a managed care plan, or by CMS. Proposals as §§ 438.16(e)(2)(iii) and 457.1201(e) would require States to develop an ILOS transition of care policy. We believe all States with non-IMD ILOSs should proactively prepare a transition of care policy in case an ILOS is terminated. We estimate both a one-time burden and an annual burden for these proposals. We believe there is a higher one-time burden as all States that currently provide non-IMD ILOSs would need to comply with this proposed requirement by the applicability date, and an annual burden is estimated for States on an on-going basis. We estimate for a one-time burden, it would take: 2 hours at $109.36/hr for a computer programmer and 2 hours at $77.28/hr for a business and operations specialist for initial development of a transition of care policy. In aggregate for Medicaid for § 438.16(e)(2)(iii), we estimate a one-time State burden 88 hours (22 States x 4 hr) at a cost of $8,212 (22 States x [(2 hr x $109.36/hr) + (2 hr x $77.28/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 30 hours and $2,799. In aggregate for CHIP for § 457.1201(e), we estimate a one-time State burden 64 hours (16 States x 4 hr) at a cost of $5,973 (16 States x [(2 hr x $109.36/hr) + (2 hr x $77.28/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 21 hours and $1,991. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

For updates to reflect specific ILOSs, we also estimate that this proposed ILOS transition of care policy would have an annual burden of 1 hour at $77.28/hr for a business operations specialist per State. In aggregate for Medicaid for § 438.16(e)(2)(iii), we estimate an annual State burden of 22 hours (22 States x 1 hr) at a cost of $1,700 (22 hr x $77.28/hr). In aggregate for

CHIP for § 457.1201(e), we estimate an annual State burden of 16 hours (16 States x 1 hr) at a cost of $1,237 (16 hr x $77.28/hr).

For MCOs, PIHPs, or PAHPs that would need to implement a transition policy when an ILOS is terminated, we estimate that on an annual basis, 20 percent of managed care plans (65 plans for Medicaid and 40 plans for CHIP) may need to implement this policy. We estimate an annual managed care plan burden of 2 hours at $77.28/hr for a business operations specialist to implement the policy. In aggregate for Medicaid for § 438.16(e)(2)(iii)(B) we estimate an annual burden of 130 hours (65 plans x 2 hr) at a cost of $10,046 (130 hr x $77.28/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual burden of 80 hours (40 plans x 2 hr) at a cost of $6,182 (80 hr x $77.28/hr).

7. ICRs Regarding State Monitoring Requirements (§ 438.66)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

The proposed amendments to § 438.66(c) would require States to conduct, or contract for, an enrollee experience survey annually. We believe most, if not all, States will use a contractor for this task and base our burden estimates on that assumption. In the first year, for procurement, contract implementation and management, and analysis of results, we estimate 85 hours at $77.28/hr for a business operations specialist and 25 hours at $110.82/hr for general operations manager. In aggregate for § 438.66(c), we estimate a one-time State burden of 5,390 hours (49 States x 110 hr) at a cost of $457,626 (49 States x [(85 hr x $77.28/hr) + (25 hr x $110.20)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1,796 hours and $152,542. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do

not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, for contract management and analysis of experience survey results, we estimate 50 hours at $77.28/hr for a business operations specialist and 15 hours at $110.82/hr for general operations manager. In aggregate, we estimate an annual State burden of 3,185 hr (49 States x 65 hr) at a cost of $270,789 (49 States x [(50 hr x $77.28/hr) + (15 hr x $110.20/hr)]).

Amendments to § 438.66(e)(1) and (2) would require that States submit an annual program assessment report to CMS covering the topics listed in § 438.66(e)(2). The data collected for § 438.66(b) and the utilization of the data in § 438.66(c), including reporting as proposed in § 438.16, would be used to complete the report. We anticipate it would take 80 hours at $77.28/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual State burden of 3,920 hours (49 States x 80 hr) at a cost of $302,938 (3,920 hr x $77.28/hr).

8. ICRs Regarding Network Adequacy Standards (§§ 438.68 and 457.1218)

The following proposed changes to § 438.66 will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1218 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

Sections 438.68(e) and 457.1218 would require States with MCO, PIHP, and PAHPs to develop appointment wait time standards for four provider types. We anticipate it would take: 20 hours at $77.28/hr for a business operations specialist for development and 10 hours at $77.28/hr a business operations specialist for ongoing enforcement of all network adequacy standards. In aggregate for Medicaid for § 438.68(e), we estimate a one-time State burden of 880 hours (44 States x 20 hr) at a cost of $68,006 (880 hr x $77.28/hr) and an annual State burden of 440 hours

(44 States x 10 hr) at a cost of $34,003 (440 hr x $77.28/hr).

In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 640 hours (32 States x 20 hr) at a cost of $49,459 (640 hr x $77.28/hr) and an annual State burden of 320 hours (32 States x 10 hr) at a cost of $24,730 (320 hr x $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 320 hours and $24,729. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Amendments to §§ 438.68(f) and 457.1218 would require States with MCO, PIHPs, or PAHPs to contract with an independent vendor to perform secret shopper surveys of plan compliance with appointment wait times and accuracy of provider directories and send directory inaccuracies to the State within three days of discovery. In the first year, for procurement, contract implementation, and management, we anticipate it would take: 85 hours at $77.28/hr for a business operations specialist and 25 hours at $110.82/hr for general operations manager. In aggregate for Medicaid for § 438.68(f), we estimate a one-time State burden of 4,840 hours (44 States x 110 hr) at a cost of $410,929 (44 States x [(85 hr x $77.28/hr) + (25 hr x $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1,614 hours and $136,976. In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 3,520 hours (32 States x 110 hr) at a cost of $298,858 (32 States x [(85 hr x $77.28/hr) + (25 hr x $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1441 hours and $129,228. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In subsequent years, for contract management and analysis of results, we anticipate it would take 50 hours at $77.28/hr for a business operations specialist and 15 hours at $110.82/hr for general operations manager. In aggregate for Medicaid for § 438.68(c), we estimate an

annual State burden of 2,860 hours (44 States x 65 hr) at a cost of $243,157 (44 States x [(50 hr x $77.28/hr) + (15 hr x $110.82)]).

In aggregate for CHIP for § 457.1218 we estimate an annual State burden of 2,080 hours (32 States x 65 hr) at a cost of $176,842 (32 States x [(50 hr x $77.28/hr) + (15 hr x $110.82/hr)]).

9. ICRs Regarding Assurance of Adequate Capacity and Services (§§ 438.207 and 457.1230)

The following proposed changes to § 438.207 will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1230 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.207(b) and 457.1230(b) would require MCOs, PIHPs, and PAHPs to submit documentation to the State of their compliance with § 438.207(a). As we propose in this rule to add a reimbursement analysis at § 438.207(b)(3) (and at § 457.1230(b) for separate CHIP), we estimate a one-time plan burden of: 50 hours at $77.28/hr for a business operations specialist, 20 hours at $110.82/hr for a general operations manager, and 80 hours at $109.36/hr for a computer programmer. In aggregate for Medicaid for § 438.207(b), we estimate a one-time private sector burden of 94,350 hours (629 MCO, PIHPs, and PAHPs x 150 hr) at a cost of $9,327,567 (629 MCOs, PIHPs, and PAHPs x [(50 hr x $77.28/hr) + (20 hr x $110.20/hr) + (80 hr x $109.36/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 31,450 hours and $3,460,800. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

In aggregate for CHIP for § 457.1230(b), we estimate a one-time private sector burden of 29,850 hours (199 MCO, PIHPs, and PAHPs x 150 hr) at a cost of $2,948,543 (199 MCOs, PIHPs, and PAHPs x [(50 hr x $77.28/hr) + (20 hr x $110.20/hr) + (80 hr x $109.36/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 9,950 hours and $982,848. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

For ongoing analyses and submission of information that would be required by amendments to § 438.207(b), we estimate it would take: 20 hours at $77.28/hr for a business operations specialist, 5 hours at $110.82/hr for a general operations manager, and 20 hours at $109.36/hr for a computer programmer. In aggregate for Medicaid, we estimate a one-time private sector burden of 28,305 hours (629 MCO, PIHPs, and PAHPs x 45 hr) at a cost of $2,696,460 (629 MCO, PIHPs, and PAHPs x [(20 hr x $77.28/hr) + (5 hr x $110.20/hr) + (20 hr x $109.36/hr)]).

In aggregate for CHIP, we estimate a one-time private sector burden of 8,955 hours (199 MCO, PIHPs, and PAHPs x 45 hr) at a cost of $852,476 (199 MCO, PIHPs, and PAHPs x [(20 hr x $77.28 /hr) + (5 hr x $110.20/hr) + (20 hr x $109.36/hr)]).

Amendments to §§ 438.207(d) and 457.1230(b) would require States to submit an assurance of compliance to CMS that their MCOs, PIHPs, and PAHPs meet the State's requirements for availability of services. The submission to CMS must include documentation of an analysis by the State that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP and the accessibility of covered services. Including the proposals in this rule at § 438.68(f) and § 438.208(b)(3), we anticipate it would take 40 hours at $77.28/hr for a business operations specialist. Although States may need to submit a revision to this report at other times during a year (specified at § 438.207(c)), we believe these submissions will be infrequent and require minimal updating to the template; therefore, the burden estimated

here in inclusive of occasional revisions. In aggregate for Medicaid, we estimate an annual State burden of 1,760 hours (44 States x 40 hr) at a cost of $136,013 (1,760 hr x $77.28/hr).

Due to the additional proposal to include enrollee experience survey results in the State's separate CHIP analysis of network adequacy, we anticipate an additional 4 hours at $77.28/hr for a business operations specialist to analyze these data for a total of 44 hours annually. In aggregate for CHIP, we estimate an annual State burden of 1,408 hours (32 States x 44 hr) at a cost of $108,810 (1,408 hr x $77.28/hr).

10. ICRs Regarding External Quality Review Results (§§ 438.364 and 457.1250)

The following proposed changes to § 438.364 will be submitted to OMB under control number 0938-0786 (CMS-R-305), and the proposed changes to § 457.1250 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

Amendments to § 438.360(a)(1) would remove the requirement that plan accreditation must be from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158. Eliminating this requirement would simplify the plan accreditation process. We assume that States would apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we anticipate that this provision would offset the burden associated with § 438.358(b)(1)(i) through (iii) for 65 MCOs, PIHPs, and PAHPs (since these activities will no longer be necessary for these 65 plans). Consistent with the estimates used in § 438.358(b)(1)(i) through (iii), we estimate an aggregated offset of annual State burden of minus 26,606 hours [(-65 MCOs, PIHPs x 409.33 hr)] and minus $2,056,146 (-26,606.45 hr x $77.28/hr).

The proposed amendments to § 438.364(a)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, would (1) require that the EQR technical reports include "any outcomes data and results from quantitative assessments" for the applicable EQR activities in addition to whether or not the data has been validated, and (2) add the mandatory network adequacy validation activity to the types of EQR activities to which the

requirement to include data in the EQR technical report applies. For Medicaid § 438.364, we assume 44 States and 654 MCOs, PIHPs and PAHPs will be subject to the EQR provisions. For CHIP, we assume 32 States and 199 MCOs, PIHPs and PAHPs will be subject to the proposed EQR provisions.

We estimate it would take 1 hour at $77.28/hr for a business operations specialist to describe the data and results from quantitative assessments and 30 minutes at $37.96/hr for an office clerk to collect and organize data. In aggregate for Medicaid we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $62,954 (654 reports x [(1 hr × $77.28/hr) + (0.5 hr x $37.96/hr)]). In aggregate for CHIP for § 457.1250(a), we estimate an annual State burden of 299 hours (199 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $19,156 (199 reports × [(1 hr x $77.28/hr) + (0.5 hr x $37.96/hr)]).

Amendments to § 438.364(c)(1) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, shifts the date in which States must finalize their annual EQR technical report. Previously, EQR annual reports had to be posted by April 30th, but under this new provision, EQR technical reports must be posted on the web site required under §§ 438.10(c)(3) and 457.1207 by December 31st of each year. We estimate it would take 1 hour at $77.28/hr for a business operations specialist and 30 minutes at $110.82/hr a general operations manager to amend vendor contracts to reflect the new reporting date. In aggregate for Medicaid, we estimate an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) at a cost of $86,779 (654 contracts [(1 hr × $77.28/hr) + (0.5 hr x $110.82/hr)]). In aggregate for CHIP, we estimate an annual State burden of 299 hours (199 MCOs, PIHPs, and PAHPs yearly reports × 1.5 hr) and $26,405 (199 contracts [(1 hr × $77.28/hr) + (0.5 hr x $110.82/hr)]).Amendments to § 438.364(c)(2)(i) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, would require States to notify CMS within 14 calendar days of posting their EQR technical reports on their quality website and provide CMS

with a link to the report. Previously States were not required to notify CMS when reports were posted. We estimate it would take 30 minutes at $77.28/hr for a business operations specialist to notify CMS of the posted reports. In aggregate for Medicaid we estimate an annual State burden of 22 hours (44 States × 0.5 hr) at a cost of $1,700 (22 hr × $77.28/hr). In aggregate for CHIP, we estimate an annual State burden of 16 hours (32 States × 0.5 hr) at a cost of $1,236 (16 hr × $77.28/hr).

Amendments to § 438.364(c)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, would require States to maintain an archive of at least the previous 5 years of EQR technical reports on their websites. Currently, almost half of States maintain an archive of at least 2 years' worth of EQR reports. Initially, we assume 75 percent of reports completed within the previous 5 years need to be archived on State websites. We estimate it would take 5 minutes (0.0833 hr) at $77.28/hr for a business operations specialist to collect and post a single EQR technical report to a State website. In aggregate for Medicaid for § 438.364(c)(2)(iii), we estimate a one-time burden of 204 hours (654 MCOs, PIHPs, and PAHPs yearly reports x 0.75 x 5 years x 0.0833 hr) at a cost of $15,765 (204 hr × $77.28/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 68 hours and $5,255. In aggregate for CHIP for § 457.1250(a), we estimate a one-time burden of 62 hours [(199 MCOs, PIHPs, and PAHPs yearly reports x 0.75 x 5 years x 0.0833 hr) at a cost of $4,791 (62 hr × $77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 21 hours and $1,597. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

11. ICRs Regarding Requirements for PCCMs (§§ 438.310(c)(2), 438.350, and 457.1250)

The following proposed changes will be submitted to OMB for review under control number 0938–0786 (CMS-R-305). The following proposed changes to § 457.1250 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.310(c)(2), 438.350, and 457.1250(a) would remove PCCMs from the managed care entities subject to EQR. We estimate the burden on States of completing EQR mandatory and optional activities which include:

Mandatory EQR activities include the validation of performance measures and a compliance review. We assume States validate 3 performance measures each year and conduct a compliance review once every 3 years. We expect it would take 53 hours at $77.28/hr for a business operations specialist to complete each performance measure validation and 361 hours at $77.28/hr for a business operations specialist to conduct a compliance review. Alleviating this burden would result in an annual State Medicaid savings of minus 2,793 hours (10 PCCM entities x [(53 hr/validation x 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus $215,843 (− 2,793 hr x $77.28/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 4,749 hours (17 PCCM entities x [(53 hr/validation x 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus $367,003 (− 4,749 hr x $77.28/hr).

Optional EQR activities include: (1) validation of client level data (such as claims and encounters); (2) administration or validation of consumer or provider surveys; (3) calculation of performance measures; (4) conduct of PIPs; (5) conduct of focused studies; and (6) assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with §§ 438.334 and 457.1240(d). Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent of PCCM entities would be subject to each of the optional EQR-related activities. Regarding the administration or validation of consumer or provider surveys, we assume that half would administer surveys while half (29) would validate surveys. We also estimate that a mix of professionals would work on each optional EQR-related activity: 20 percent by a general and operations manager at $110.82/hr; 25 percent by a computer programmer at $92.92/hr; and 55 percent by a business operations specialist at $77.28/hr. Alleviating this burden would result in an annual State Medicaid savings of minus 999 hours (-

350+-75 hr + -25 hr + -159 hr + -195 hr + -195 hr) and minus $87,810 [(-999 hr x 0.20 x $110.82/hr) + (-999 hr x 0.25 x $92.92/hr) + (-999 hr x 0.55 x $77.28/hr)]. For CHIP, we estimate annual State savings of minus 649 hours (-75 hr + -25 hr + -159 hr + -195 hr + -195 hr) and minus $57,045.80 [(-649 hr x 0.20 x $110.82/hr) + (-649 hr x 0.25 x $92.92/hr) + (-649 hr x 0.55 x $77.28/hr)].

Per § 438.364(c)(2)(ii), each State agency would provide copies of technical reports, uponrequest, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. This change would eliminate the burden on States to provide PCCM EQR reports. We estimate an annual State burden of 5 minutes (on average) or 0.0833 hours at $37.96/hr for an office clerk to disclose the reports (per request), and that a State would receive five requests per PCCM entity. Alleviating this burden would result in an annual Medicaid State savings of minus 4 hours (10 PCCM entities x 5 requests x 0.0833 hr) and minus $152 (−4 hr x $37.96/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 0.833 hours (50 minutes) (2 PCCM entities x 5 requests x 0.833 hr) and minus $32 (−0.833 hr x $37.96/hr).

For the mandatory and optional EQR activities, in aggregate, we estimate an annual State savings of minus 3,796 hours (-2,793 hr + -999 hr + -4 hr) and minus $303,805 ($215,843 + $87,810 + $152).

Additionally, the burden associated with § 438.358(b)(2) also includes the time for a PCCM entity (described in § 438.310(c)(2)) to prepare the information necessary for the State to conduct the mandatory EQR-related activities. Given the estimate of 200 hr for an MCO,PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in § 438.310(c)(2)), we estimate it would take 100 hr to prepare the documentation for these 2 activities, half (50 hr) at $77.28/hr by a business operations specialist and half (50 hr) at $37.96/hr by an office clerk. In aggregate for Medicaid, we estimate an annual private sector

savings of minus 1,000 hours (10 PCCM entities x 100 hr) and minus $57,620 [(− 500 hr x $77.28/hr) + (− 500 hr x $37.96/hr)]. In aggregate for CHIP for § 457.1250(a), we estimate an annual private sector savings of minus 200 hours (2 PCCM entities x 100 hr) and minus $11,524 [(− 100 hr x $77.28/hr) + (− 100 hr x $37.96/hr)].

Amendments to §§ 438.364(c)(7) and 457.1250(a) add a new optional EQR activity to assist in evaluations for In Lieu of Services, quality strategies and State Directed Payments that pertain to outcomes, quality, or access to health care services. Based on our review of recent EQR technical report submissions we estimate and assume that each year 10 percent of MCOs, PIHPs and PAHPs will be subject to each of the optional EQR-related activities, though we note that the exact States and number vary from year to year. We also estimate that a mix of professionals will work on each optional EQR-related activity: 20 percent by a general and operations manager at $110.82/hr; 25 percent by a computer programmer at $109.36/hr; and 55 percent by a business operations specialist at $77.28/hr. To assist in evaluations, we estimate an annual State burden of 80 hours per MCO, PIHP and PAHP. In aggregate for Medicaid, the annual State burden to assist in evaluations is 4,640 hours (58 MCOs, PIHPs and PAHPs x 80 hr) at a cost of $426,917 [(4,640 hr x 0.20 x $110.82/hr) + (4,640 hr x 0.25 x $103.36/hr) + (4,640 hr x 0.55 x $77.28/hr)]. In aggregate for CHIP for § 457.1250(a), the annual State burden to assist in evaluations is 1,600 hours (20 MCOs, PIHPs and PAHPs x 80 hr) at a cost of $147,213 [(1,600 hr x 0.20 x $110.82/hr) + (1,600 hr x 0.25 x $109.36/hr) + (1,600 hr x 0.55 x $77.28/hr)].

12. ICRs Regarding Quality Rating System Measure Collection (§§ 438.515 and 457.1240)

The following proposed changes will be submitted to OMB for review under control number 0938–1281 (CMS–10553). The following proposed changes to § 457.1240 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.515(a)(1) and 457.1240(d) would revise the existing QRS requirements by mandating that the State collect specified data from each managed care plan with which it contracts that has 500 or more enrollees on July 1 of the measurement year.

Based on the data collected, the State would calculate and issue an annual quality rating to each managed care plan. The State would also collect data from Medicare and the State's fee-for-service providers, if all data necessary to issue an annual quality rating cannot be provided by the managed care plans. Annual quality ratings will serve as a tool for States, plans and beneficiaries. The annual quality ratings will hold States and plans accountable for the care provided to Medicaid and CHIP beneficiaries, provide a tool for States to drive improvements in plan performance and the quality of care provided by their programs, and empower beneficiaries with useful information about the plans available to them. States would be required to collect data using the framework of a mandatory QRS Measure Set. We used the proposed mandatory measure set, found in Table 1, as the basis for the measure collection burden estimate. The proposed mandatory measure set consists of 18 measures, including CAHPS survey measures, and reflects a wide range of preventive and chronic care measures representative of Medicaid and CHIP beneficiaries. For Medicaid managed care, we assume 629 MCOs, PIHPs and PAHPs and 44 States to be subject to the proposed mandatory QRS measure set collection and reporting provision. For CHIP managed care, we assume 199 MCOs, PIHPs and PAHPs and 32 States to be subject to the proposed mandatory QRS measure set collection and reporting provision. We assume that plans with CHIP populations will report the subset of QRS measures which apply to beneficiaries under 19 years of age and to pregnant and postpartum adults, where applicable.

For Medicaid, we expect reporting the QRS non-survey measures would take: 680 hours at $109.36/hr for a computer programmer to program and synthesize the data; 212 hours at $77.28/hr for a business operations specialist to manage the data collection process; 232 hours at $37.96/hr for an office clerk to input the data; 300 hours at $79.56/hr for a registered nurse to review medical records for data collection; and 300 hours at $46.46/hr for medical records and health information analyst to compile and process medical records. For Medicaid, for one managed care entity we estimate an annual private sector burden of 1,724 hours (680 hr + 212 hr + 232 hr + 300 hr + 300 hr) at cost of $137,361 ([680 hr x $109.36/hr] + [252 hr x $77.28/hr] +

[328 hr x $37.96/hr] + [300 hr x $79.56/hr] + [300 hr x $46.46/hr]).

For Medicaid, we also estimate that conducting the QRS survey measures comprised of the CAHPS survey would take: 20 hours at $77.28/hr for a business operations specialist to manage the data collection process; 40 hours at $37.96/hr for an office clerk to input the data; and 32 hours at $95.62/hr for a statistician to conduct data sampling. For one Medicaid managed care entity we estimate an annual private sector burden of 92 hours (20 hr + 40 hr + 32 hr) at cost of $6,124 ([20 hr x $77.28/hr] + [40 hr x $37.96/hr] + [32 hr x $95.62]).

For one Medicaid managed care entity, for mandatory QRS non-survey and survey measures we estimate an annual private sector burden of 1,816 hours (1,724 hr +92 hr) at a cost of $143,485 ($137,361 + $6,124). In aggregate, for Medicaid, we estimate an annual private sector burden of 1,142,264 hours (629 Medicaid MCOs, PIHPs and PAHPs × 1,816 hours) and $90,252,065 (629 Medicaid MCOs, PIHPs and PAHPs × $143,485).

For CHIP for § 457.1240(d), we expect reporting non-survey QRS measures would take: 400 hours at $109.36/hr for a computer programmer to program and synthesize the data; 148 hours at $77.28/hr for a business operations specialist to manage the data collection process; 152 hours at $37.96/hr for an office clerk to input the data; 60 hours at $79.56/hr for a registered nurse to review medical records for data collection; and 60 hours at $46.46/hr for medical records specialist to compile and process medical records. For one CHIP managed care entity we estimate an annual private sector burden of 820 hours (400 hr + 148 hr + 152 hr + 60 hr +60 hr) at cost of $68,513 ([400 hr x $109.36/hr] + [148 hr x $77.28/hr] + [152 hr x $37.96/hr] + [60 hr x $79.56/hr] + [60 hr x $46.46/hr])

For CHIP for § 457.1240(d), we also estimate that conducting the survey measures (comprised of the CAHPS survey and secret shopper) would take: 20 hours at $77.28/hr for a business operations specialist to manage the data collection process; 56 hours at $37.96/hr for an office clerk to input the data; and 32 hours at $95.62/hr for a statistician to conduct data sampling. For one CHIP managed care entity we estimate an annual private sector burden of 108

hours (20 hr + 56 hr + 32 hr) at cost of $6,731 ([20 hr x $77.28/hr] + [56 hr x $37.96/hr] + [32 hr x $95.62]).

For one CHIP managed care entity, for mandatory QRS non-survey and survey measures, we estimate an annual private sector burden of 928 hours (820 hr +108 hr) at a cost of $75,244 ($68,513 + $6,731). In aggregate, for CHIP for § 457.1240(d), we estimate an annual private sector burden of 184,672 hours (199 CHIP MCOs, PIHPs and PAHPs × 928 hours) and $14,973,556 (199 CHIP MCOs, PIHPs and PAHPs × $75,244).

The CAHPS survey measures also include a new burden on Medicaid beneficiaries. Beneficiaries complete the survey via telephone or mail. Response rates vary slightly by survey population. The adult CAHPS survey aims for 411 respondents out of a 1,350-person sampling and the Child CAHPS survey aims for 411 respondents out of a 1,650-person sampling. For Medicaid, the survey would be conducted twice, once for children and once for adults. For CHIP, the survey would be conducted once for children and once for pregnant or postpartum adults, as applicable. We estimate it would take 20 minutes (0.33 hr) at $28.01/hr for a Medicaid or CHIP beneficiary to complete the CAHPS Health Plan Survey. For Medicaid, in aggregate, we estimate a new beneficiary burden of 172,346 hours (629 MCOs, PIHPs and PAHPs x 0.33 hr per survey response x 822 beneficiary responses) at a cost of $4,827,411 (172,346 hr x $28.01/hr). For CHIP for § 457.1240(d), in aggregate, we estimate a new beneficiary burden of 27,263 hours (199 MCOs, PIHPs, and PAHPs x 0.33 hr per survey response x 411 beneficiary responses) at a cost of $763,637 (27,263 hr x $28.01/hr).

Additionally, amendments to § 438.515(a)(1)(i), reporting QRS measures would require States to update existing managed care contracts. We estimate it would take 1 hour at $77.28/hr for a business operations specialist and 30 minutes at $110.82/hr a general operations manager to amend vendor contracts to reflect the new reporting requirements. In aggregate for Medicaid, we estimate a one-time State burden of 944 hours (629 MCOs, PIHPs, and PAHPs × 1.5 hours) at a cost of $83,462 (629 contracts x [(1 hr × $77.28/hr) + (0.5 hr x $110.82/hr)]). As this would be a

one-time requirement, we annualize our time and cost estimates to 315 hours and $27,821. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 299 hours (199 MCOs, PIHPs, and PAHPs × 1.5 hours) at a cost of $26,405 (199 contracts x [(1 hr × $77.28/hr) + (0.5 hr x $110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 99 hours and $8,820. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

Amendments to § 438.515(a)(1)(ii) require States to collect data from Medicare and the State's fee-for-service providers, if all data necessary to issue an annual quality rating cannot be provided by the managed care plans and the data are available for collection by the State without undue burden. We expect a that subset of States would need to collect Medicare data or State Medicaid fee-for-service data to report the mandatory quality measures. We assume that plans have access to Medicare data for their members and have included this burden in the cost of data collection described above. However, we assume Medicaid fee-for-service data would need to be provided and that this requirement would impact 5 States. For a State to collect the fee-for-service data needed for QRS reporting, we expect it would take: 120 hours at $109.36/hr for a computer programmer to program and synthesize the data and 20 hours at $77.28/hr for a business operations specialist to manage the data collection process. In aggregate for Medicaid, we estimate an annual State burden of 700 hours (5 States x [120 hr + 20 hr]) at a cost of $73,344 ([120 hr x $109.36/hr] + [20 hr x $77.28/hr]).

Amendments to §§ 438.515(a)(2) and 457.1240(d) require the QRS measure data to be validated. We estimate it would take 16 hours at $77.28/hr for a business operations specialist to review, analyze and validate measure data. In aggregate for Medicaid, we estimate an annual

private sector burden of 10,064 hours (629 MCOs, PIHPs, PAHPs and PCCMs x 16 hr) at a cost of $777,746 (10,064 hr x $77.28/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 3,184 hours (199 MCOs, PIHPs and PAHPs x 16 hr) at a cost of $246,060 (3,184 hr x $77.28/hr).

13. ICRs Regarding Requirements for QRS Website Display (§§ 438.520(a) and 457.1240)

The following proposed changes will be submitted to OMB for review under control number 0938–1281 (CMS–10553). The following proposed changes to § 457.1240 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.520(a) and 457.1240(d) would require the State to prominently post an up-to-date display on its website that provides information on available MCOs, PIHPs and PAHPs. The display must: allow users to view tailored information, compare managed care plans, provide information on quality ratings and directs users to resources on how to enroll in a Medicaid or CHIP plan. Additionally, the display must offer consumer live assistance services. After the display is established, the State would need to maintain the display by populating the display with data collected from the mandatory QRS measure set established as proposed in this proposed rule. The proposed rule outlines a phase-in approach to the QRS website display requirements; however, the burden estimate reflects the full implementation of the website. We recognize this may results is an overestimate during the initial phase of the website display but believe the estimate is representative of the longer-term burden associated with the QRS website display requirements.

To develop the initial display, we estimate it would take: 600 hours at $109.36/hr for a computer programmer to create and test code; 600 hours at $78.18/hr for a web developer to create the user interface; 80 hours at $77.28/hr for a business operations specialist to manage the display technical development process; and 450 hours at $98.50/hr for a database administer to establish the data structure and organization. We estimate that 44 States for Medicaid and 32 States for CHIP will develop QRS website displays. For one State, we estimate a burden of

1,730 hours (600 hr + 600 hr + 80 hr + 450 hr) at a cost of $163,031 ([600 hr x $109.36/hr] + [600 hr x $78.18/hr] + [80 hr x $77.28/hr] + [450 hr x $98.50/hr]). In aggregate for Medicaid, we estimate a one-time State burden of 76,120 hours (44 States x 1,730 hr) at a cost of $7,173,364 (44 States x $163,031). In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 55,360 hours (32 States x 1,730 hr) and $5,216,992 (32 States x $163,031). As this would be a one-time requirement, we annualize our time and cost estimates for CHIP to 18,453 hours and $48,330,202. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires.

To maintain the QRS display annually, we estimate it would take: 384 hours at $109.36/hr for a computer programmer to modify and test code; 256 hours at $78.18/hr to update and maintain the user interface; 120 hours at $77.28/hr for a business operations specialist to manage the daily operations of the display; and 384 hours at $98.50/hr for a database administer to organize data. We estimate that 44 States for Medicaid and 32 States for CHIP will maintain QRS displays annually. For one State, we estimate a burden of 1,144 hours (384 hr + 256 hr + 120 hr + 384 hr) at a cost of $109,106 ([384 hr x $92.92/hr] + [256 hr x $78.18/hr] + [120 hr x $77.28/hr] + [384 hr x $98.50/hr]). In aggregate for Medicaid, we estimate an annual State burden of 50,336 hours (1,144 hours x 44 States) at a cost of $4,800,664 ($109,106 x 44 States). In aggregate for CHIP for § 457.1240(d), we estimate an annual State burden of 103,168 hours (1,144 hr x 32 States) at a cost of $3,491,392 ($109,106 x 32 States).

The amendments to §§ 438.520(a)(2)(iv) and 457.1240(d) would require the display to include quality ratings for mandatory measures which may be stratified by factors determined by CMS. We estimate it would take 24 hours at $109.36/hr for a computer programmer to develop code to stratify plan data. In aggregate for Medicaid (§ 438.520(a)(2)(iv)), we estimate an annual private sector burden of 15,096 hours (629 MCOs, PIHPs and PAHPs x 24 hr) at a cost of

$1,650,899 (15,096 hr x $109.36/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 4,776 hours (199 MCOs, PIHPs and PAHPs x 24 hr) at a cost of $522,303 (4,776 hr x $109.36/hr).

The amendments to § 438.520(a)(3)(v) would require the QRS website display to include certain managed care plan performance metrics, as specified by CMS including the results of the secret shopper survey specified in § 438.68(f). The secret shopper survey is currently accounted for by OMB under control number 0938-TBD (CMS-10856). Plans would complete the secret shopper independent of the QRS requirements. To meet QRS requirements, States would enter data collected from the secret shopper survey and display the results of the survey on the QRS. Since the burden for the secret shopper survey is accounted for under a separate control number, for the purposes of MAC QRS, we account for the incremental burden associated with meeting the QRS requirements. We estimate it would take 16 hours at $37.96/hr for an office clerk to enter the results from the secret shopper survey into the QRS. In aggregate for Medicaid § 438.520(a)(3)(v), we estimate an annual private sector burden of 10,064 hours (629 MCOs, PIHPs and PAHPs x 16 hr) at a cost of $382,029 (10,064 hr x $37.96/hr). In aggregate for CHIP for § 457.1240(d), we estimate an annual private sector burden of 3,184 hours (199 MCOs, PIHPs and PAHPs x 16 hr) at a cost of $120,865 (3,184 hr x $37.96/hr).

14. ICRs Regarding QRS Annual Reporting Requirements (Part 438 Subpart G and §§ 438.520(a) and 457.1240)

The following proposed changes will be submitted to OMB for review under control number 0938–1281 (CMS–10553). The following proposed changes to § 457.1240 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.535(a) and 457.1240(b) would mandate that on an annual basis, the State submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. We estimate that 44 States for Medicaid and 32 States for CHIP will submit annual MAC QRS reports. We estimate it would take 24 hours at $77.28/hr

for a business operations specialist to compile the required documentation to complete this report and attestation that the State is in compliance with QRS standards. In aggregate for Medicaid for § 438.535(a), we estimate an annual State burden of 1,056 hours (44 States x 24 hr) at a cost of $81,608 (1,056 hr x $77.28/hr). In aggregate for CHIP for § 457.1240(b), we estimate an annual State burden of 768 hours (32 States x 24 hr) at a cost of $59,351 (768 hr x $77.28/hr).

The addition of 438 subpart G for Medicaid, and through a proposed amendment at § 457.1240(d) for separate CHIP, would revise the quality rating system requirements and associated burden previously promulgated under § 438.334. Given the QRS requirements have substantively changed, our currently approved burden estimates for making changes to an approved alternative Medicaid managed care QRS are no longer applicable.

Therefore, alleviating this burden would result in an annual Medicaid State reduction of minus 116.7 hours [(10 States x 35 hr) / 3 years] and minus $8,361 (10 States x [(5 hr x $37.96/hr) + (30 x $77.28/hr)] / 3 years). Similarly, we estimate an annual CHIP State savings of minus 116.7 hours [(10 States x 35 hr) / 3 years] and minus $8,361 [(10 States x ((5 hr x $37.96/hr) + (30 x $77.28/hr)) / 3 years)].

To implement an alternative Medicaid managed care QRS, we estimate it would take: 5 hours at $37.96/hr for an office and administrative support worker, 25 hours at $77.28/hr for a business operations specialist to complete the public comment process, and 5 additional hours at $77.28/hr for a business operations specialist to seek and receive approval from CMS for the change. We assume that a subset of States will opt for an alternative QRS and that the subset will revise their QRS once every three years.

15. ICRs Regarding Program Integrity Requirements Under the Contract (§§ 438.608 and 457.1285)

The following proposed changes to § 438.608 will be submitted to OMB for review under control number 0938-TBD (CMS-10856). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection

of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request. The following proposed changes to § 457.1285 will be submitted to OMB for review under control number 0938-1282 (CMS-10554).

The proposed amendments to §§ 438.608 and 457.1285 would require States to update all MCO, PIHP, and PAHP contracts to require managed care plans to report overpayments to the State within 10 business days of identifying or recovering an overpayment. We estimate that the proposed changes to the timing of overpayment reporting (from timeframes that varied by State to 10 business days for all States) would apply to all MCO, PIHP, and PAHP contracts, including contracts for NEMT, that is, a total of 654 contracts for Medicaid, and 199 contracts for CHIP. We estimate it would take: 2 hours at $77.28/hr for a business operations specialist and 1 hour at $110.82/hr for a general and operations manager to modify State contracts with plans. In aggregate for Medicaid for § 438.608, we estimate a one-time State burden of 1,962 hours (654 contracts x 3 hr) at a cost of $173,559 [654 contracts x ((2 hr x $77.28/hr) + (1 hr x $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 654 hours and $57,853.

In aggregate for CHIP for § 457.1285, we estimate a one-time State burden of 597 hours (199 contracts x 3 hr) at a cost of $52,811 [199 contracts x ((2 hr x $77.28/hr) + (1 hr x $110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 199 hours and $17,604. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate that it would take MCOs, PIHPs, and PAHPs 1 hour at $109.36/hr for a computer programmer to update systems and processes already used to meet the previous requirement for "prompt" reporting. In aggregate for Medicaid for § 438.608, we estimate a one-time private sector burden of 654 hours (654 contracts x 1 hr) at a cost of $71,521 (654 hr x

$109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 218 hours and $23,840. In aggregate for CHIP for § 457.1285, we estimate a one-time private sector burden of 199 hours (199 contracts x 1 hr) at a cost of $21,763 (199 contracts x $109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 218 hours and $7,947. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires.

C. Summary of Collection of Information Requirements and Associated Burden Estimates

TABLE 4: Summary of Proposed Medicaid Requirements and Burden

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.3(i)	0938–0920 (CMS–10856)	315	315	2	630	77.28	48,686	Once	210	16,229
438.3(i)	0938–0920 (CMS–10856)	315	315	1	315	110.82	34,908	Once	105	11,636
438.3(i)	0938–0920 (CMS–10856)	315	315	80	25,200	77.28	1,947,456	Once	8,400	649,152
438.3(i)	0938–0920 (CMS–10856)	315	315	40	12,600	110.82	1,396,332	Once	4,200	465,444
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	50	2	100	120.48	12,048	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	50	6	300	77.28	23,184	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	50	2	100	110.82	11,082	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	150	1	150	110.82	16,623	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	30	150	1	150	120.48	18,072	Annual	n/a	n/a
438.6(c)(2)(ii)	0938–0920 (CMS–10856)	38	150	1	150	77.28	11,592	Annual	n/a	n/a
438.6(c)(2)(iii)	0938–0920 (CMS–10856)	38	60	6	360	120.48	43,373	Once	120	14,458
438.6(c)(2)(iii)	0938–0920 (CMS–10856)	38	60	3	180	110.82	19,948	Once	60	6,649
438.6(c)(2)(iii)	0938–0920 (CMS–10856)	38	60	6	360	109.36	39,370	Once	120	13,123
438.6(c)(2)(iv)	0938–0920 (CMS–10856)	38	50	5	250	109.36	27,340	Annual	n/a	n/a
438.6(c)(2)(iv)	0938–0920 (CMS–10856)	38	50	2.5	125	110.82	13,853	Annual	n/a	n/a
438.6(c)(2)(iv)	0938–0920 (CMS–10856)	38	50	2.5	125	77.28	9,660	Annual	n/a	n/a
438.6(c)(2)(v)	0938–0920 (CMS–10856)	38	47	3	141	109.36	15,420	Annual	n/a	n/a
438.6(c)(2)(v)	0938–0920 (CMS–10856)	38	47	1	47	110.82	5,209	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.6(c)(2)(v)	0938–0920 (CMS–10856)	38	47	2	94	77.28	7,264	Annual	n/a	n/a
438.6(c)(7)	0938-0920 (CMS-10856)	10	10	5	15	120.48	6,024	Annual	n/a	n/a
438.6(c)(7)	0938-0920 (CMS-10856)	10	10	5	15	109.36	5,468	Annual	n/a	n/a
438.6(c)(7)	0938-0920 (CMS-10856)	10	10	7	70	77.28	5,410	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	110	24,750	120.48	2,981,880	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	15	3,375	110.82	374,018	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	53	11,925	109.36	1,304,118	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	52	11,700	77.28	904,176	Annual	n/a	n/a
438.7(b)	0938–0920 (CMS–10856)	44	225	20	4,500	37.96	170,820	Annual	n/a	n/a
438.8(k)	0938–0920 (CMS–10856)	629	629	4	2,516	77.28	194,437	Once	839	64,812
438.8(k)	0938–0920 (CMS–10856)	629	629	2	1,258	109.36	137,575	Once	419	45,858
438.8(k)	0938–0920 (CMS–10856)	629	629	1	629	80.74	50,785	Annual	n/a	n/a
438.8(k)	0938–0920 (CMS–10856)	315	315	1	315	77.28	24,343	Annual	n/a	n/a
438.8(k)	0938–0920 (CMS–10856)	629	629	1	629	110.82	69,706	Annual	n/a	n/a
438.8(k)	0938-0920 (CMS-10856)	629	629	1	629	77.28	48,609	Annual	n/a	n/a
438.10(c)(3)	0938–0920 (CMS–10856)	45	45	20	900	109.36	98,424	Once	300	32,808
438.10(c)(3)	0938–0920 (CMS–10856)	45	45	40	1800	109.36	196,848	Annual	n/a	n/a
438.16(c)(5)(ii)	0938–0920 (CMS–10856)	22	22	5	110	120.48	13,253	Annual	n/a	n/a
438.16(c)(5)(ii)	0938–0920 (CMS–10856)	22	22	7	154	77.28	11,901	Annual	n/a	n/a
438.16(c)(5)(ii)	0938–0920 (CMS–10856)	22	22	5	110	109.36	12,030	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.16(d)(1)	0938–0920 (CMS–10856)	22	327	1	327	77.28	25,271	Annual	n/a	n/a
438.16(d)(2)	0938–0920 (CMS–10856)	5	5	2	10	77.28	773	Annual	n/a	n/a
438.16(e)(1)	0938–0920 (CMS–10856)	5	5	25	125	77.28	9,660	Annual	n/a	n/a
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	22	22	2	44	77.28	3,400	Once	15	1,159
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	22	22	2	44	109.36	4,812	Once	15	1,640
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	22	22	1	44	77.28	1,700	Annual	n/a	n/a
438.16(e)(2)(iii)	0938–0920 (CMS–10856)	65	65	2	130	77.28	10,046	Annual	n/a	n/a
438.66(c)	0938–0920 (CMS–10856)	49	49	85	4,165	77.28	321,871	Once	1,388	107,290
438.66(c)	0938–0920 (CMS–10856)	49	49	25	1,225	110.82	135,755	Once	408	45,252
438.66(c)	0938–0920 (CMS–10856)	49	49	50	2,450	77.28	189,336	Annual	n/a	n/a
438.66(c)	0938–0920 (CMS–10856)	49	49	15	735	110.82	81,453	Annual	n/a	n/a
438.66(e)	0938–0920 (CMS–10856)	49	49	80	3,920	77.28	302,938	Annual	n/a	n/a
438.68(e)	0938–0920 (CMS–10856)	44	44	20	880	77.28	68,006	Once	293	22,669
438.68(e)	0938–0920 (CMS–10856)	44	44	10	440	77.28	34,003	Annual	n/a	n/a
438.68(f)	0938–0920 (CMS–10856)	44	44	85	3,740	77.28	289,027	Once	1,247	96,342
438.68(f)	0938–0920 (CMS–10856)	44	44	25	1,100	110.82	121,902	Once	367	40,634
438.68(f)	0938–0920 (CMS–10856)	44	44	50	2,200	77.28	170,016	Annual	n/a	n/a
438.68(f)	0938–0920 (CMS–10856)	44	44	15	660	110.82	73,141	Annual	n/a	n/a
438.74	0938–0920 (CMS–10856)	5	5	5	25	77.28	1,932	Once	8	644
438.74	0938–0920 (CMS–10856)	43	43	4	172	77.28	13,292	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	50	31,450	77.28	3,485,289	Once	10,483	1,161,763
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	20	12,580	110.82	1,394,116	Once	4,193	464,705
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	80	50,320	109.36	5,502,995	Once	16,773	1,834,332
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	20	12,580	77.28	972,182	Annual	n/a	n/a
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	5	3,145	110.82	348,529	Annual	n/a	n/a
438.207(b)(3)	0938–0920 (CMS–10856)	629	629	20	12,580	109.36	1,375,749	Annual	n/a	n/a
438.207(d)	0938–0920 (CMS–10856)	44	44	40	1,760	77.28	136,013	Annual	n/a	n/a
438.310(c)(2), 438.350	0938-0786 (CMS-R-305)	10	10	379.6	-3,796	varies	-303,805	Annual	n/a	n/a
438.334(c)(1)(a)	0938-0786 (CMS-R-305)	10	-10	-35	-117	varies	-8,361	Annual	n/a	n/a
438.358(b)(2)	0938-0786 (CMS-R-305)	10	-10	-100	-1000	varies	-57,620	Annual	n/a	n/a
438.360(a)(1)	0938-0786 (CMS-R-305)	65	-65	-409.33	-26,606	77.28	-2,056,146	Annual	n/a	n/a
438.364(a)(2)(iii)	0938-0786 (CMS-R-305)	654	654	1.5	981	varies	62,954	Annual	n/a	n/a
438.364(c)(1)	0938-0786 (CMS-R-305)	44	654	1.5	981	Varies	86,779	Once	327	28,926
438.364(c)(2)(i)	0938-0786 (CMS-R-305)	44	44	0.5	22	77.28	1,700	Annual	n/a	n/a
438.364(c)(2)(iii)	0938-0786 (CMS-R-305)	44	2452.5	0.0833	204	77.28	15,765	Once	68	5,255
438.364(c)(7)	0938-0786 (CMS-R-305)	58	58	80	4640	Varies	426,917	Annual	n/a	n/a
438.515(a)(1)	0938-1282 (CMS-10553)	629	629	1816	1,142,264	Varies	90,252,065	Annual	n/a	n/a
438.515(a)(1)(i)	0938-1282 (CMS-10553)	44	629	1.5	944	Varies	83,462	Once	315	27,821
438.515(a)(1)(ii)	0938-1282 (CMS-10553)	5	5	140	700	varies	73,344	Annual	n/a	n/a
438.515(a)(2)	0938-1282 (CMS-10553)	629	629	16	10,064	77.28	777,745	Annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Costs ($)
438.520(a)	0938-1282 (CMS-10553)	44	44	1730	76120	varies	7,173,364	Once	25,373	2,391,121
438.520(a)	0938-1282 (CMS-10553)	44	44	1,144	50336	varies	4,800,664	Annual	n/a	n/a
438.520(a)(2)(iv)	0938-1282 (CMS-10553)	629	629	24	15,096	109.36	1,650,899	Annual	n/a	n/a
438.520(a)(3)(v)	0938-1282 (CMS-10553)	629	629	16	10,064	37.96	382,029	Annual	n/a	n/a
438.540(a)	0938-1282 (CMS-10553)	44	44	24	1056	77.28	81,608	Annual	n/a	n/a
438.608(a)(2)	0938–0920 (CMS–10856)	654	654	2	1308	77.28	101,082	Once	436	33,694
438.608(a)(2)	0938–0920 (CMS–10856)	654	654	1	654	110.82	72,476	Once	218	24,159
438.608(a)(2)	0938–0920 (CMS–10856)	654	654	1	654	109.36	71,521	Once	218	23,840
Total		Varies	20,977	Varies	1,538,197	Varies	129,072,871	Varies	76,918	7,631,425

TABLE 5: Summary of Proposed CHIP Requirements and Burden

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1201(e)	0938-1282 (CMS-10554)	16	100	1	100	77.28	7,728	annual	n/a	n/a
457.1201(e)	0938-1282 (CMS-10554)	5	5	2	10	77.28	773	annual	n/a	n/a
457.1201(e)	0938-1282 (CMS-10554)	5	5	25	125	77.28	9,660	annual	n/a	n/a
457.1201(e)	0938-1282 (CMS-10554)	16	16	2	32	109.36	3,500	once	11	1167
457.1201(e)	0938-1282 (CMS-10554)	16	16	2	32	77.28	2,473	once	11	824
457.1201(e)	0938-1282 (CMS-10554)	16	16	1	16	77.28	1,236	annual	n/a	n/a
457.1203(f)	0938-1282 (CMS-10554)	32	100	2	100	77.28	15,456	once	33	5,125
457.1203(f)	0938-1282 (CMS-10554)	32	100	1	100	110.82	11,082	once	33	3,694
457.1203(e)	0938-1282 (CMS-10554)	32	5	5	25	77.28	1,932	once	8	644
457.1207	0938-1282 (CMS-10554)	32	32	20	640	109.36	69,990	once	213	23,294
457.1207	0938-1282 (CMS-10554)	32	32	41	1,312	109.36	143,480	annual	n/a	n/a
457.1218	0938-1282 (CMS-10554)	32	32	20	640	77.28	49,459	once	213	16,486
457.1218	0938-1282 (CMS-10554)	32	32	10	320	77.28	24,730	once	107	8,243
457.1218	0938-1282 (CMS-10554)	32	32	85	2,720	77.28	210,202	once	1174	99,676
457.1218	0938-1282 (CMS-10554)	32	32	25	800	110.82	88,656	once	267	29,552
457.1218	0938-1282 (CMS-10554)	32	32	50	1,600	77.28	123,648	annual	n/a	n/a
457.1218	0938-1282 (CMS-10554)	32	32	15	480	110.82	53,194	annual	n/a	n/a
457.1230(b)	0938-1282 (CMS-10554)	32	32	44	1,408	77.28	108,810	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	32	199	1	199	77.28	15,379	once	66	5,126
457.1240(d)	0938-1282 (CMS-10554)	32	199	.5	100	110.82	11,082	once	33	3,694

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1240(d)	0938-1282 (CMS-10554)	32	32	600	19,200	109.36	2,099,712	once	6,400	699,904
457.1240(d)	0938-1282 (CMS-10554)	32	32	600	19,200	78.18	1,501,056	once	6,400	500,352
457.1240(d)	0938-1282 (CMS-10554)	32	32	80	2,560	77.28	197,837	once	853	65,946
457.1240(d)	0938-1282 (CMS-10554)	32	32	450	14,400	98.50	141,192,000	once	4,800	47,064,000
457.1240(d)	0938-1282 (CMS-10554)	32	32	384	12,288	109.36	1,343,816	once	4,096	447,939
457.1240(d)	0938-1282 (CMS-10554)	32	32	256	8,192	78.18	640,451	once	2,731	213,484
457.1240(d)	0938-1282 (CMS-10554)	32	32	120	3,840	78.28	300,595	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	32	32	384	12,288	98.50	1,210,368	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	32	32	24	768	77.28	59,351	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	(10)	(10)	(5)	(50)	(37.96)	(1,898)	annual	n/a	n/a
457.1240(d)	0938-1282 (CMS-10554)	(10)	(10)	(30)	(300)	(77.28)	(23,184)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	199	1	199	77.28	15,379	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	199	.5	100	37.96	3,777	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	32	.5	16	77.28	1,236	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	149	.0833	62	77.28	4,791	once	21	1597
457.1250(a)	0938-1282 (CMS-10554)	32	199	1	199	77.28	15,379	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	32	199	.5	100	110.82	11,027	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(17)	(17)	(1298)	(22066)	(110.82)	(2,445,354)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(17)	(17)	(162)	(2758)	(92.92)	(256,297)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(17)	(17)	(357)	(6068)	(77.28)	(468,947)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	(3)	(17)	(279.33)	(4,749)	(77.28)	(366,977)	annual	n/a	n/a

Regulatory Section in Title 42 of the CFR	OMB Control Number (CMS ID No.)	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate ($/hr)	Total cost ($)	Frequency	Annualized Time (hours)	Annualized Cost ($)
457.1250(a)	0938-1282 (CMS-10554)	(2)	(10)	(.0833)	(0.833)	(37.96)	(32)	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	20	20	16	320	110.82	35,462	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	20	20	20	400	109.36	43,744	annual	n/a	n/a
457.1250(a)	0938-1282 (CMS-10554)	20	20	44	880	77.28	68,006	annual	n/a	n/a
457.1285	0938-1282 (CMS-10554)	32	199	2	398	77.28	30,757	once	133	10,252
457.1285	0938-1282 (CMS-10554)	32	199	1	199	110.82	22,053	once	66	7,351
Total		Varies	2,674	Varies	70376	Varies	146,186,578	Varies	27,382	49,198,887

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS Web site at *www.cms.hhs.gov/PaperworkReductionActof1995*, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the DATES and ADDRESSES section of this proposed rule and identify the rule (CMS-2439-P), the ICR's CFR citation, and OMB control number.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would advance CMS' efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and CHIP managed care enrollees. The proposed rule would specifically address standards for timely access to care and States' monitoring and enforcement efforts, reduce burden for State directed payments and certain quality reporting requirements, add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and identify the scope and

nature of ILOS, specify medical loss ratio (MLR) requirements, and establish a quality rating system (QRS) for Medicaid and CHIP managed care plans.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 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), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (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 major rules. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is "significant" under Section 3(f)(1) as measured by the $200 million threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of

1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

We have examined the proposed provisions in this rule and determined that most of the proposed revisions to part 438 and part 457 outlined in this proposed rule are expected to minimally or moderately increase administrative burden and associated costs as we note in the COI (see section II. of this proposed rule). Aside from our analysis on burden in the COI, we believe that certain provisions in this proposed rule should specifically be analyzed in this regulatory impact analysis as potentially having a significant economic impact. Those proposed provisions include State directed payments, MLR reporting standards, and ILOS due to the impact these proposed provisions could have on the associated and corresponding managed care payments.

1. State Directed Payments (SDPs) (§§ 438.6, 438.7)

Neither the May 6, 2016 final rule (81 FR 27830) nor the November 13, 2020 final rule (85 FR 72754) included a regulatory impact analysis that discussed the financial and economic effects of SDPs. At the time the 2016 final rule was published and adopted regulations explicitly governing State directed payments, we believed that States would use the SDPs in three broad ways to: (1) transition previous pass-through payments into formal arrangements as SDPs; (2) add or expand provider payment requirements to promote access to care; and (3) implement quality or value payment models that include Medicaid managed care plans. However, since § 438.6(c) was issued in the 2016 final rule, States have requested approval for an increasing number of SDPs. The scope, size, and complexity of the SDPs being submitted by States for approval has also grown steadily. In calendar year 2017, CMS received 36 preprints for our review and approval from 15 States; in calendar year 2021, CMS received 223 preprints from 39

States. For calendar year 2022, CMS received 309 preprints from States. As of March 2023, CMS has reviewed more than 1,100 SDP proposals and approved more than 1,000 proposals since the 2016 final rule was issued. To accommodate these requests from States, CMS applied discretion in interpreting and applying § 438.6(c) in reviewing and approving SDPs. The 2016 final rule required criteria to determine if provider payment rates are "reasonable, appropriate, and attainable" and that SDPs must relate to utilization, quality, or other goals described in § 438.6(c). CMS has interpreted these sections of the regulation broadly, and therefore, the amount of SDP payments has grown significantly over time.

SDPs also represent a substantial amount of State and Federal spending. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported that CMS approved SDPs in 37 States, with spending exceeding more than $25 billion.[150] The U.S. Government Accountability Office (GAO) also reported that at least $20 billion has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 proposals.[151]

We have tracked SDP spending trends as well. Using the total spending captured for each SDP through the end of fiscal year 2022, we calculate that SDP payments in 2022 were at least $52.2 billion. there may be some SDPs for which CMS does not have projected or actual spending data. In addition, our data reporting and collection is not standardized, and in some cases may be incomplete, so spending data for some SDP approvals may be less accurate. CMS began collecting total dollar estimates for SDPs incorporated through adjustments to base rates as well as those incorporated through separate payment terms with the revised preprint form published in January 2021; States were required to use the revised preprint form for rating periods beginning on or after July 1, 2021. We estimate that SDP spending comprises approximately 11.3 percent of total managed care payments in 2022 ($461.6 billion) and 6.6

150 Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP," June 2022, available at *https://www.macpac.gov/wp-content/uploads/2022/06/MACPAC_June2022-WEB-Full-Booklet_FINAL-508-1.pdf*.
151 U.S. Government Accountability Office, "Medicaid: State Directed Payments in Managed Care," June 28, 2022, available at *https://www.gao.gov/assets/gao-22-105731.pdf*.

percent of total Medicaid benefit expenditures ($794.5 billion). SDP spending varies widely across States. Thirty-nine (39) States reported the use of one or more SDPs in 2022. In these States, the percentage of Medicaid managed care spending paid through SDPs ranged from 1 percent to 58 percent, with a median of 8 percent; as a share of total Medicaid spending, SDPs ranged from 0 percent to 33 percent, with a median of 3 percent.

From 2016 through 2022, SDPs were a significant factor in Medicaid expenditure growth. Total benefit spending increased at an average annual rate of 6.3 percent per year from 2016 through 2022; excluding SDPs, benefit spending grew at an average rate of 5.1 percent. Managed care payments grew 9.2 percent on average over 2016 to 2022, but excluding SDPs, the average growth rate was 7.0 percent. While some SDP spending may have been included in managed care payments prior to 2016 (either as a pass-through payment or some other form of payment), by 2022 we expect that much of this is new spending.

In 2022, we estimate that about 75 percent of SDP spending went to hospitals for inpatient and outpatient services, and another 5 percent went to academic medical centers. The remaining 20 percent of SDP spending went to nursing facilities, primary care physicians, specialty physicians, HCBS and personal care service providers, behavioral health service providers, and dentists.

The data available do not allow us to determine how much of this baseline SDP spending was incorporated into managed care expenditures prior to the 2016 final rule, or reflected historical transfers from prior payment arrangements. For example, States transitioned pass-through payments to SDPs or transferred spending from fee-for-service payments (for example, supplemental payments) to SDPs. Some States indicate that the SDP has had no net impact on rate development while other States have reported all estimated spending for the services and provider class affected by the SDP. Based on our experience working with States, we believe much of the earlier SDP spending was largely existing Medicaid spending that was transitioned to managed care SDPs. However, in more recent years, we believe that most SDP spending

reflects new expenditures. For context, States reported $6.7 billion in pass-through payments after the 2016 final rule.[152] States also have reported only a small decrease in fee-for-service supplemental payments since 2016 (from $28.7 billion in 2016 to $27.5 billion in 2022).[153] SDP spending in 2022 significantly exceeds the originally reported pass-through payments and the changes in fee-for-service supplemental payments.

The proposals in this rule are intended to ensure the following policy goals: (1) Medicaid managed care enrollees receive access to high-quality care under SDPs; (2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDPs; and (3) CMS has the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and feasibility of SDPs.

The proposal expected to have the most significant economic impact is setting a payment ceiling at 100 percent of the ACR for SDPs for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers. As discussed in section I.B.2.f. of this proposed rule, we have used the ACR as a benchmark for total payment levels for all SDP reviews since 2018 and have not knowingly approved an SDP that includes payment rates that are projected to exceed the ACR. Based on the available data, we estimate that $11.6 billion of SDPs in 2022 reflect payments at or near the ACR. It is difficult to determine the amounts of these payments due to data quality and inconsistent reporting of these details. For example, if payment data are aggregated across multiple providers or provider types, it can be difficult to determine if providers are being paid at different levels. Additionally, many SDPs report payment rates relative to Medicare instead of ACR; for some SDPs, the payment rates relative to Medicare suggest effective payment rates

152 Our data reflects documentation provided from 15 States with pass-through payments in rating periods beginning from July 1, 2017 through June 30, 2018.
153 CMS-64. *https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html*.

would be near the ACR. These would include SDPs with effective payment rates of 150 percent or more of the Medicare rate (with several over 200 percent and as high as 450 percent).

Under current policy, we project that SDP spending would increase from $52 billion in 2022 (or 11.3 percent of managed care spending) to about $91 billion by 2028 (or 15 percent of managed care spending).

TABLE 6: Projected Medicaid Managed Care and State Directed Spending Under Current Policy, FY 2022-2028 (in billions of dollars)

	2022	2023	2024	2025	2026	2027	2028
Managed care spending	$461.6	$502.2	$479.4	$502.9	$536.6	$571.1	$607.7
SDP spending	$52.2	$66.1	$67.5	$73.1	$79.2	$85.7	$91.2
SDP as share of managed care	11.3%	13.2%	14.1%	14.5%	14.8%	15.0%	15.0%

Estimating the impact of the proposed SDP provisions is challenging for several reasons. First, as noted previously, the projected and actual spending data that we collect from States is not standardized, and in some cases aggregated across providers. It is also often difficult to determine how payment rates compare, especially when States use different benchmarks for payment (for example, comparing SDPs using Medicare payment rates to those using ACR payment rates). In addition, there is frequently limited information on ACR payment rates. It is difficult to determine how the ACR may be calculated and how the calculation may vary across different States and providers. Furthermore, it may be difficult to determine how many more providers are not paid under SDPs and how much they could be paid if SDPs were expanded to them.

Second, it is difficult to determine how much providers are paid in managed care programs without SDPs. These data appear to be less frequently reported, and we have virtually no information about provider payments when the State does not use an SDP. This information is important when estimating the impact of changes in SDPs, because the initial payment rate matters as much as the final rate. In some cases, the initial payment rates for existing SDPs are

significantly low (for example, there are several SDPs where the reported initial payment rates are 10 to 20 percent of ACR or commercial rates, 25 to 30 percent of Medicare rates, or 10 to 35 percent of Medicaid State plan rates). In other cases, the initial payment rates are relatively higher. Thus, it may be difficult to determine how large new SDPs would be.

Third, there is significant variation in the use of SDPs across States. States have significant discretion in developing SDPs (including which providers receive SDPs and the amounts of the payments), and it is challenging to predict how States would respond to changes in policy. Some States may add more SDPs or expand spending in existing SDPs. Moreover, as many SDPs are funded through sources other than State general revenues (such as intergovernmental transfers or provider taxes), decisions about SDPs may be dependent on the availability of these funding sources.

For these reasons, we believe it is prudent to provide a range of estimated impacts for this section of the proposed rule. The following estimates reflect a reasonable expectation of the impacts of this proposed rule on Medicaid expenditures, but do not include all possible outcomes.

We estimate that the low end of the range for the proposed changes would have zero impact on Medicaid expenditures. That is, we assume that the new policies in the rule would have no bearing on States' future decisions on SDPs. Future growth in Medicaid spending on SDPs would be the same as currently projected. This estimate also assumes that there would be no reduction in expenditures from limiting effective payment rates to ACR rates.

We believe this is a reasonable estimate of the low end of this range. SDPs are already growing rapidly and several States already have SDPs with effective payment rates at or near the ACR. In addition, SDP spending is projected to continue to grow as a share of Medicaid managed care spending over the next several years, which suggests that other States may add SDPs or increase the payment rates within the SDPs. Thus, one possible outcome is that States would use SDPs the same way under current policy and under the proposed rule.

The estimate of the upper end of the range is based on the expectation that the provisions of the proposed rule would prompt States to increase SDP spending. We believe that by setting the payment limit at the ACR rates for certain services, States may increase the size and scope of future SDPs to approach this limit. In particular, there are many SDPs that currently have effective reimbursement rates at or around 100 percent of Medicare reimbursement rates, and others with rates below 100 percent of ACR, and that States may potentially increase payments associated with these SDPs.

For the high scenario, we assume that Medicaid SDP spending would increase at a faster rate than projected under current law. Under current law, Medicaid SDP spending is projected to reach 15 percent of managed care spending by 2027; we assume in the high scenario that SDP spending would reach about 17.5 percent of managed care spending in 2027. Under this scenario, SDP spending would increase by approximately 20 percent by 2027 (or about $16 billion). From 2024 through 2026, SDP spending would increase somewhat faster than assumed under current law to reach those levels. This increase would include additional spending from current SDPs increasing payment rates to the ACR, and may also include new or expanded SDPs. We would also expect that this would occur mostly among SDPs for hospitals and academic medical centers, as those are currently the providers that receive the majority of SDPs. We have not estimated a breakdown of impacts by provider type or by State in this analysis. The estimated impacts are provided in Table 7.

TABLE 7: Projected Medicaid State Directed Payment Spending Under Proposed Rule, High Scenario, FY 2024-2028 (in billions of dollars)

	2024	2025	2026	2027	2028
Current law	$67.5	$73.1	$79.2	$85.7	$91.2
Proposed rule	$72.2	$81.7	$91.8	$101.9	$108.5
Impact	$4.7	$8.6	$12.6	$16.2	$17.3

In Table 8, we provide estimates of the impacts on the Federal government and on States.

TABLE 8: Projected Medicaid State Directed Payment Spending Under Proposed Rule By Payer, High Scenario, FY 2024-2028 (in billions of dollars)

	2024	2025	2026	2027	2028
Total impact	$4.7	$8.6	$12.6	$16.2	$17.3
Federal government	$3.1	$5.6	$8.2	$10.5	$11.1
States	$1.6	$3.0	$4.4	$5.7	$6.2

We project that the Federal government would pay an additional $11.1 billion in 2028, with the States paying an additional $6.2 billion in the high scenario. We would note that for the States, they would have discretion of whether or not to increase SDP spending (through existing or new SDPs), and that the source of the non-Federal share may vary. Many States already use sources other than State general revenues (such as IGTs and provider taxes, as noted previously), and therefore the direct impact to State expenditures may be less than projected.

As noted previously, there is a wide range of possible outcomes of this proposed rule on SDP expenditures. The actual changes in spending may be difficult to determine, as there is uncertainty in the future amount of spending through SDPs in the baseline. The specific impacts could also vary over time, by State, and by provider type. We believe actual impacts can reasonably be expected to fall within the range shown here.

There are additional proposals in this rule that may also slightly increase SDP spending. This includes allowing States to:

(1) Direct expenditures for non-network providers;

(2) Set the amount and frequency for VBP SDPs;

(3) Recoup unspent funds for VBP SDPs; and

(4) Exempting minimum fee schedules at the Medicare rate from prior approval.

We do not have quantitative data to analyze the impact of these provisions. However, based on a qualitative analysis of our work with States, we believe these regulatory changes would have much more moderate effects on the economic impact in comparison to the ceiling on payment levels described above. Allowing States to direct expenditures for non-network providers will

likely increase the number of State contract provisions; however, we anticipate that most States will want to require minimum fee schedules tied to State plan rates, which will likely result in very small changes from existing rate development practices. Regarding the proposal to remove the existing regulatory requirements for setting the amount and frequency for VBP SDPs and recouping unspent funds for VBP SDPs, we anticipate this will change the types of SDPs States seek, encouraging them to pursue VBP models, that would replace existing VBPs, though a few States may pursue new models. The proposed regulatory requirement to exempt minimum fee schedules tied to Medicare rates will likely cause some increase in spending as more States may take up this option, but again, we do not anticipate this to have as significant impact on rate development.

There are a few proposals in this rule that are likely to exert some minor downward pressure on the rate of growth in SDP spending, such as the enhanced evaluation requirements, requirements related to financing of the non-Federal share, and eliminating States' ability to use reconciliation processes. We expect that these provisions would not have any significant effect on Medicaid expenditures.

Aside from spending, we believe many of the proposals in section I.B.2. of this proposed rule would have significant qualitative impacts on access, quality, and transparency. One example is our proposal to permit the use of SDPs for non-network providers (section I.B.2.d. of this proposed rule). One of the most frequently used non-network provider types is family planning. Permitting States to use SDPs for family planning providers could greatly improve access and ease access for enrollees consistent with the statutory intent of section 1902(a)(23)(B) of the Act. Our proposal to permit States to set the frequency and amount of SDP payments (section I.B.2.h. of this proposed rule) should remove unnecessary barriers for States implementing VBP SDPs. This should have direct impacts on quality of care as States will be more inclined to use VBP SDPs. It will allow the payments to be more closely linked to the services provided in a timely fashion, and it will allow States to establish strong parameters and

operational details that define when and how providers will receive payment to support robust provider participation. Lastly, our proposal (section I.B.2.b. of this proposed rule) to require specific information in managed care plan contracts would improve accountability to ensure that the additional funding included in the rate certification is linked to a specific service or benefit provided to a specific enrollee covered under the contract.

Taken together, we believe our SDP related proposals in this rule would enable us to ensure that SDPs would be used to meet State and Federal policy goals to improve access and quality, used for the provision of services to enrollees under the contract, and improve fiscal safeguards and transparency. The proposals in this rule would provide a more robust set of regulations for SDPs and are informed by six years of experience reviewing and approving SDP preprints. We believe the resulting regulations would enable more efficient and effective use of Medicaid managed care funds.

2. Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.74, 457.1201, 457.1203, 457.1285)

We propose to amend §§ 438.3(i), 438.8(e)(2), 457.1201, and 457.1203 to specify that only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers may be included in incurred claims for MLR reporting. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. If managed care plans currently include (in reported incurred claims) payments to providers that significantly reduce or eliminate remittances while providing no value to consumers, the proposed clarification would result in transfers from such managed care plans to States in the form of higher remittances or lower capitation rates. Although we do not know how many managed care plans currently engage in such reporting practices or the amounts improperly included in MLR calculations, using information from a prior CCIIO RIA analysis,[154]

154 87 FR 703.

we estimate the impact of the proposed clarification by assuming that provider incentive and bonus payments of 1.06 percent or more paid claims (the top 5 percent of such observations) may represent incentives based on MLR or similar metrics. Based on this assumption and the Medicaid MLR data for 2018, *the proposed clarification would increase remittances paid by managed care plans to States by approximately $12 million per year* (total computable).

We propose to amend §§ 438.8(e)(3) and 457.1203(c) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where the remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. This proposed change would result in transfers from managed care plans that currently include indirect expenses in QIA to States in the form of higher remittances or lower capitation rates. Although we do not know how many managed care plans include indirect expenses in QIA, using information from a previous CCIIO RIA analysis[155], we estimate the impact of the proposed change by assuming that indirect expenses inflate QIA by 41.5 percent (the midpoint of the 33 percent to 50 percent range observed during CCIIO MLR examinations) for half of the issuers that report QIA expenses (based on the frequency of QIA-related findings in CCIIO MLR examinations). Based on these assumptions and the Medicaid MLR data for 2018, *the proposed clarification would increase remittances paid by managed care plans to States by approximately $49.8 million per year*.

We propose to amend §§ 438.608(a)(2) and (d)(3), and 457.1285 to require States' contracts with managed care plans to include a provision requiring managed care plans to report any overpayment (whether identified or recovered) to the State. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and where the remittance calculations are based on the MLR standards in § 438.8, the remittance amounts may be affected. Given that States do not provide this level of payment reporting to CMS, we are

155 87 FR 703.

unable to quantify the benefits and costs of this proposed change; however, this proposed change may result in transfers from managed care plans to States in the form of higher remittances or lower capitation rates.

We propose to amend 438.8(k) to require managed care plans to report SDPs to States as a line item in their MLR reports. In States that require managed care plans to pay remittances back to the State for not meeting a minimum MLR, and the remittance calculation arrangements are based on § 438.8, the remittance amounts may be affected. Given that CMS does not have data on actual revenue and expenditure amounts for SDPs that would allow for modeling the effect of the line item reporting on remittances, we are unable to quantify the benefits and costs of this proposed change. We expect that this proposed change may result in transfers from States to managed care plans in the form of lower remittances or higher capitation rates.

3. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120)

In the May 6, 2016 final rule (81 FR 27830), the regulatory impact analysis addressed the financial and economic effects of allowing FFP for capitation payments made for enrollees that received inpatient psychiatric services during short-term stays in an institution for mental disease (IMD) as an ILOS; however, it did not address other potential ILOS (see 81 FR 27840 and 27841 for further details). When we analyzed the May 6, 2016 final rule for the regulatory impact analysis, we concluded that the financial and economic effects of all other ILOSs would be offset by a decrease in expenditures for the State plan-covered services and settings for which ILOSs are a medically appropriate and cost effective substitute. The use of ILOSs is a longstanding policy in managed care given the flexibility that managed care plans have historically had in furnishing care in alternate settings and services in a risk-based delivery system, if cost effective, on an optional basis and to the extent that the managed care plan and the enrollee agree that such setting or service would provide medically appropriate care. States and managed care plans historically have utilized ILOSs that are immediate substitutes for covered services and settings under the State plan, such as a Sobering Center as a substitute for an emergency department visit.

More recently, a few States and managed care plans have begun utilizing ILOSs as longer term substitutes for covered services and settings under the State plan. On January 7, 2021, CMS published a State Health Official (SHO) letter (SHO# 21-001)[156] that described opportunities under Medicaid and CHIP to better address social determinants of health (SDOH). Additionally, on January 4, 2023, CMS published a State Medicaid Director (SMD) letter (SMD# 23-001)[157] that outlined additional guidance for ILOSs in Medicaid managed care. Since CMS published this guidance, States have been working to implement changes in their Medicaid managed care programs to meet the HRSNs of Medicaid beneficiaries more effectively, including partnering with community-based organizations that routinely address HRSNs.

We believe that expanding the definition of what is allowable as ILOSs in Medicaid managed care would likely lead to an increase in Medicaid expenditures. Many of these services intended to address HRSNs may not have been previously eligible for coverage under Medicaid as an ILOS. While guidance requires these to be cost effective, the proposed rule does not require cost effectiveness to be "budget neutral." Moreover, for ILOSs that are intended to be in lieu of some future service, the cost effectiveness may need to be measured over years.

Data on ILOS is extremely limited, and CMS does not currently collect any data (outside of ILOS spending for IMDs as part of the managed care rate contract). Moreover, there is limited information on the additional ILOSs that States may use. Therefore, we are providing a range of potential impacts for this section as well.

At the low end of the range, we project that there would be no impact on Medicaid expenditures. In these cases, we would assume (1) the use of new ILOSs are relatively lower; and (2) additional ILOS spending is offset by savings from other Medicaid services.

At the high end of the range, we project that there would be some increase in Medicaid

156 Opportunities in Medicaid and CHIP to Address Social Determinants of Health, *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf*.
157 Additional Guide on Use of In Lieu of Services and Settings in Medicaid Managed Care, *https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf*.

spending. We make the following assumptions for the high scenario: (1) half of States would use new ILOSs; (2) States would increase use of ILOSs to 2 percent of total Medicaid managed care spending; and (3) additional ILOSs would offset 50 percent of new spending. Table 9 shows the impacts in the high scenario.

TABLE 9: Projected Medicaid ILOS spending under proposed rule by payer, high scenario, FY 2024-2028 (in billions of dollars)

	2024	2025	2026	2027	2028
Total impact	$2.4	$2.5	$2.7	$2.9	$3.0
Federal government	$1.6	$1.6	$1.7	$1.9	$2.0
States	$0.8	$0.9	$1.0	$1.0	$1.0

We also believe it is important for CMS to begin to capture data on ILOS expenditures as a portion of total capitation payments that are eligible for FFP to ensure appropriate fiscal oversight, as well as detail on the managed care plans' ILOS costs. Therefore, we proposed reporting related to the final ILOS cost percentage and actual MCO, PIHP and PAHP ILOS costs in §§ 438.16(c) and 457.1201(c). This will also aid us in future regulatory impact analyses.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the 2016 final rule will be the number of reviewers of this proposed rule. We received 879 unique comments on the 2016 final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the 2016 rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually

exclusive sections of this proposed rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $115.22 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 20 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is $2,304. Therefore, we estimate that the total cost of reviewing this regulation is $2 million.

D. Alternatives Considered

1. State Directed Payments (SDPs)

As discussed in section I.B.2.f. of this proposed rule on provider payment limits, we are considering alternatives to the ACR as a total payment rate limit for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center for each SDP. The alternatives we are considering include the Medicare rate, some level between Medicare and the ACR, or a Medicare equivalent of the ACR. We are also considering an alternative that would establish a total payment rate limit for any SDPs described in paragraphs (c)(1)(i) and (ii) that are for any of these four services, at the ACR, while limiting the total payment rate for any SDPs described in paragraph § 438.6(c)(1)(iii)(C) through (E), at the Medicare rate. We are also considering and seek public comment on establishing a total payment rate limit for all services for all SDP arrangements described in § 438.6 (c)(1)(i) and (ii), and 438.6(c)(1)(iii)(C) through (E) at the Medicare rate. For each of these alternatives, we acknowledge that some States currently have SDPs that have total payment rates up to the ACR. Therefore, these alternative proposals could be more restrictive, and States could need to reduce funding from current levels, which could have a negative impact on access to care and health equity initiatives.

2. Medical Loss Ratio (MLR) Standards

For all MLR-related proposed changes, except those relating to SDP reporting, the only alternative considered was no change. We considered alternatives to requiring actual SDP amounts as part of MLR reports, including creating a new separate reporting process for SDPs or modifying existing reporting processes to include SDPs. We determined that creating a new separate reporting process specific to SDPs would impose significant burden on States as it would require State staff to learn a new process and complete an additional set of documents for SDP reporting. We considered modifying other State managed care reporting processes, for example, MCPAR, to include SDPs but, unlike MLR reporting, those processes were not specific to reporting financial data. We propose integrating SDP reporting in the MLR as the current MLR process requires reporting of financial data from managed care plans, and in turn, States provide a summary of these reports to CMS in the form of the annual MLR summary report. The integration of managed care plan and State SDP reporting using current MLR processes will encourage States to add the monitoring and oversight of SDPs as a part of a State's established MLR reporting process.

3. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120)

One alternative we considered was leaving the 2016 final rule as it is today; however, since the rule was finalized in 2016, we continue to hear of increased State and plan utilization and innovation in the use of ILOSs, and we do not believe the current regulation ensures appropriate enrollee and fiscal protections. As a result, we propose many additional safeguards in this rule. The ILOS proposals seek to ensure appropriate safeguards while also specifying that States and managed care plans can consider both short term and longer term substitutes for State plan-covered services and settings. Additionally, we considered including enrollee protections and ILOS transparency without the 5 percent limit on the ILOS cost percentage and the ILOS evaluation, when applicable. However, we have concerns regarding the potential unrestrained growth of ILOS expenditures.

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 10 showing the classification of the impact associated with the provisions of this proposed rule. In the case *of* SDPs, we categorize these *as transfers* from the Federal government *and* States to health care providers. For ILOSs, we categorize these as transfers from the Federal government and States to beneficiaries in the form of additional services. Finally, for MLR requirements, we categorize these as transfers from managed care organizations to the Federal government and States.

This provides our best estimates of the transfer payments outlined in the "Section C. Detailed Economic Analysis" above. We detail our estimates of the low and high end of the ranges in this section, and the primary estimate is the average of the low and high scenario impacts. This reflects a wide range of possible outcomes, but given the uncertainty *in* the ways and degrees to which States may use the SDPs and ILOSs, we believe that *this* is a reasonable estimate of the potential impacts under this proposed rule. For the MLR provisions, we have not provided a range given the relatively small size of the estimated impact.

These impacts are discounted at seven percent and three percent, respectively, as reflected in Table 10.

TABLE 10: Accounting Statement [in millions of 2024 dollars]

Benefits						
Non-Quantified	This proposed rule would support many benefits to the Medicaid program, including to align State and Federal efforts to improve timely access to care for Medicaid managed care enrollees, enhance and improve quality-based provider payments to better support care delivery, and support better quality improvement throughout the Medicaid managed care program.					
Transfers						
Annual Monetized **Transfers**	Primary Estimate	Low Estimate	High Estimate	Units		
				Year Dollars	Discount Rate	Period Covered
From Federal Government to Providers	3,384	0	6,767	2024	7%	2024-2028
	3,449	0	6,899	2024	3%	2024-2028
From States to Providers	1,846	0	3,692	2024	7%	2024-2028
	1,882	0	3,764	2024	3%	2024-2028
From Federal Government to Beneficiaries	809	0	1,617	2024	7%	2024-2028
	809	0	1,619	2024	3%	2024-2028
From States to Beneficiaries	428	0	856	2024	7%	2024-2028
	429	0	858	2024	3%	2024-2028
From Managed Care Plans to Federal Government	62	62	62	2024	7%	2024-2028
	62	62	62	2024	3%	2024-2028
From Managed Care Plans to States	34	34	34	2024	7%	2024-2028
	34	34	34	2024	3%	2024-2028

F. Regulatory Flexibility Act (RFA)

Effects on MCOs, PIHPs or PAHPs (referred to as "managed care plans") will not have a significant economic impact. As outlined in section II.B. of this proposed rule, we utilized data submitted by States for enrollment in Medicaid managed care plans for CY 2020. The enrollment data reflected 58,521,930 enrollees in MCOs, 37,692,501 enrollees in PIHPs or PAHPs, and

6,089,423 enrollees in PCCMs, for a total of 67,836,622 Medicaid managed care enrollees.[158] This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. This data also showed 43 States that contract with 467 MCOs, 11 States that contract with 162 PIHPs or PAHPs, 19 States that contract with 21 non-emergency transportation PAHPs, and 13 States with 26 PCCM or PCCM entities. For CHIP, we utilized State submitted data for enrollment in managed care plans for CY 2017. The enrollment data reflected 4,580,786 Medicaid expansion and 2,593,827 separate CHIP managed care enrollees.[159] These data also showed that 32 States use managed care entities for CHIP enrollment contracting with 199 managed care entities.[160]

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 some managed care plans may be small entities as that term is used in the RFA. We believe that only a few managed care plans may qualify as small entities. Specifically, we believe that approximately 14-25 managed care plans may be small entities. We believe that the remaining managed care plans have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of $41.5 million; therefore, we do not believe that this proposed rule will have a significant economic impact on a substantial number of small businesses.

For purposes of the RFA, approximately 0.04 percent of Medicaid managed care plans may be considered small businesses according to the Small Business Administration's size standards with total revenues of $8 million to $41.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. The cost impact on Medicaid managed care

158 Medicaid Managed Care Enrollment and Program Characteristics (2020).
159 Centers for Medicare and Medicaid Services, Statistical Enrollment Data System (2017), Quarterly Enrollment Data Form 21E: Number of Children Served in Separate CHIP Program/Quarterly Enrollment Data Form 64.21E: Number of Children Served in CHIP Medicaid Expansion Program/Quarterly Enrollment Data Form 21PW: Number of Pregnant Women Served, accessed December 5, 2022.
160 Results of managed care survey of States completed by Centers for Medicare and Medicaid Services, Center for Medicaid and CHIP Services, Children and Adults Health Programs Group, Division of State Coverage Programs, 2017.

plans on a per entity basis is approximately $54,500. This proposed 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.

The proposed rule would specifically address standards for (1) timely access to care and States' monitoring and enforcement efforts; (2) reduce burden for State directed payments (SDPs) and certain quality reporting requirements; (3) add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and identify the scope and nature of ILOS; (4) specify medical loss ratio (MLR) requirements; and (5) establish a quality rating system (QRS) for Medicaid and CHIP managed care plans. As outlined, these efforts do not impact small entities.

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. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

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 603 of the RFA. 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. We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on most hospitals, including small rural hospitals. Provisions include some proposed new standards for State governments and managed care plans but no direct requirements on providers, including hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with Medicaid managed care plans, but any additional burden on small rural hospitals should be negligible. We invite comment on our proposed analysis of the

impact on small rural hospitals regarding the provisions of this proposed rule. We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

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 is approximately $177 million. This proposed rule does not contain any Federal mandate costs resulting from (A) imposing enforceable duties on State, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs. We have determined that this proposed rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $177 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We believe this proposed regulation gives States appropriate flexibility regarding managed care standards (for example, setting network adequacy standards, setting credentialing standards, EQR activities), while also aligning Medicaid and CHIP managed care standards with those for plans in the Marketplace and MA to better streamline the beneficiary experience and to reduce administrative and operational burdens on States and health plans across publicly-funded programs and the commercial market. We have determined that this proposed rule would not significantly affect States' rights, roles, and responsibilities.

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 proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $177 million in any one year.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 24, 2023.

List of Subjects

42 CFR Part 430

Administrative practice and procedure, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 430— GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 is revised to read as follows:

Authority: 42 U.S.C. 1302.

2. Amend § 430.3 by revising the introductory text and adding paragraph (d) to read as follows:

§ 430.3 Appeals under Medicaid.

Four distinct types of disputes may arise under Medicaid.

* * * * *

(d) Disputes that pertain to disapproval of written prior approval by CMS of State directed payments under 42 CFR 438.6(c)(2)(i) are also heard by the Board in accordance with procedures set forth in 45 CFR part 16. 45 CFR part 16, appendix A, lists all the types of disputes that the Board hears.

PART 438—MANAGED CARE

3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

4. Amend § 438.2 by—

a. Adding the definition of "In lieu of service or setting (ILOS)" in alphabetical order; and

b. Revising paragraph (9) in the definition of "Primary care case management entity (PCCM entity)".

The addition and revision read as follows:

§ 438.2 Definitions.

* * * * *

In lieu of service or setting (ILOS) is a service or setting that is provided to an enrollee as

a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2). An ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize the covered service or setting under the State plan.

* * * * *

Primary care case management entity (PCCM entity) * * *

(9) Coordination with mental and substance use disorder health systems and providers.

* * * * *

5. Amend § 438.3 by:

a. Revising paragraphs (c)(1)(ii) and (e)(2);

b. Adding paragraphs (i)(3) and (4); and

c. Revising paragraph (v).

The additions and revisions read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(c) * * *

(1) * * *

(ii) The final capitation rates must be based only upon services covered under the State plan, ILOS, and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

* * * * *

(e) * * *

(2) An MCO, PIHP or PAHP may cover, for enrollees, an ILOS as follows:

(i) The State determines that the ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the ILOS, and the MCO, PIHP or PAHP must comply with the following requirements:

(A) An enrollee who is offered or utilizes an ILOS offered as a substitute for a covered service or setting under the State plan retains all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option; and

(B) An ILOS may not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and an MCO, PIHP or PAHP may not deny access to a service or setting covered under the State plan, on the basis that the enrollee has been offered an ILOS as an optional substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past;

(iii) The approved ILOS is authorized and identified in the MCO, PIHP or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP or PAHP;

(iv) The utilization and actual cost of the ILOS is taken into account in developing the component of the capitation rates that represents the covered State plan services and settings, unless a statute or regulation explicitly requires otherwise; and

(v) With the exception of a short term stay as specified in § 438.6(e) in an Institution for Mental Diseases (IMD), as defined in § 435.1010 of this chapter, for inpatient mental health or substance use disorder treatment, an ILOS must also comply with the requirements in § 438.16.

* * * * *

(i) * * *

(3) The State, through its contracts with an MCO, PIHP, and PAHP must require that incentive payment contracts between the MCO, PIHP, and PAHP and network providers:

(i) Have a defined performance period that can be tied to the applicable MLR reporting periods.

(ii) Be signed and dated by all appropriate parties before the commencement of the applicable performance period.

(iii) Include well-defined quality improvement or performance metrics that the provider must meet to receive the incentive payment.

(iv) Specify a dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a date of payment.

(4) The State through its contracts with an MCO, PIHP, and PAHP must:

(i) Define the documentation that must be maintained by the MCO, PIHP, and PAHP to support the provider incentive payments.

(ii) Prohibit the use of attestations as supporting documentation for data that factor into the MLR calculation.

(iii) Require the MCO, PIHP, and PAHP to make incentive payment contracts, and any documentation in paragraph (e)(4)(i), available to the State upon request and at any routine frequency established in the State's contract with the MCO, PIHP, and PAHP.

* * * * *

(v) *Applicability date*. Paragraphs (e)(2)(v), (i)(3), and (i)(4) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following [EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

§ 438.6 Special contract provisions related to payment.

6. Amend § 438.6—

a. In paragraph (a) by:

i. Revising the introductory text;

ii. Adding definitions for “Academic medical center”, “Average commercial rate”, “Condition-based payment”, “Final State directed payment cost percentage”, “Inpatient hospital services”, “Maximum fee schedule”, “Minimum fee schedule”, “Outpatient hospital services”, “Nursing facility services”, “Performance measure”, “Population-based payment”, “Qualified practitioner services at an academic medical center”, “Separate payment term”, “Total payment rate”, “Total published Medicare payment rate”, and “Uniform increase” in alphabetical order;

b. By revising paragraph (c) paragraph heading and paragraphs (c)(1)(iii), (c)(2) and (c)(3).

c. By adding paragraphs (c)(4) through (8); and

d. By revising paragraph (e).

The revisions and additions read as follows:

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Academic medical center means a facility that includes a health professional school with an affiliated teaching hospital.

Average commercial rate means the average rate paid for services by the highest claiming third-party payers for specific services as measured by claims volume.

* * * * *

Condition-based payment means a prospective payment for a defined set of Medicaid covered service(s) that are tied to a specific condition and delivered to Medicaid managed care enrollees.

Final State directed payment cost percentage means the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section and for each managed care program.

* * * * *

Inpatient hospital services means the same as specified at § 440.10.

Maximum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no more than a certain amount for a covered service(s).

Minimum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s).

Outpatient hospital services means the same as specified in § 440.20(a).

Nursing facility services means the same as specified in § 440.40(a).

* * * * *

Performance measure means, for State directed payments, a quantitative measure with a numerator and denominator that is used to monitor performance at a point in time or track performance over time, of provider service delivery, quality of care, or outcomes as defined in § 438.320 for enrollees.

Population-based payment means a prospective payment for a defined set of Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group.

Qualified practitioner services at an academic medical center means professional services provided by both physicians and non-physician practitioners affiliated with or employed by an academic medical center.

* * * * *

Separate payment term means a pre-determined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a State directed payment for which the State has received written prior approval under § 438.6(c)(2)(i). Payments made from this funding pool are made by the State to the MCOs, PIHPs or PAHPs exclusively for State directed payments for which the State has received written prior approval under §

438.6(c)(2)(i) and are made separately and in addition to the capitation rates identified in the contract as required under § 438.3(c)(1)(i).

State directed payment (SDP) means a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section.

* * * * *

Total payment rate means the aggregate for each managed care program of:

(i) The average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the State directed payment;

(ii) The effect of the State directed payment on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section;

(iii) The effect of any and all other State directed payments on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section; and

(iv) The effect of any and all allowable pass-through payments, as defined in paragraph (a) of this section, paid to any and all providers included in the provider class specified in the State directed payment for which the State is seeking prior approval under paragraph (c)(2)(i) of this section on the average payment rate to providers in the specified provider class.

Total published Medicare payment rate means amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B.

Uniform increase means any State directed payment that directs the MCO, PIHP, or PAHP to pay the same amount (the same dollar amount or the same percentage increase) per Medicaid covered service(s) in addition to the rates the MCO, PIHP or PAHP negotiated with the providers included in the specified provider class for the service(s) identified in the State directed payment.

* * * * *

(c) *State directed payments under MCO, PIHP, or PAHP contracts* -

(1) * * *

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for providers that provide a particular service under the contract using State plan approved rates.

(B) Adopt a minimum fee schedule for providers that provide a particular service under the contract using a total published Medicare payment rate that was in effect no more than 3 years prior to the start of the rating period and the minimum fee schedule to be used by the MCO, PIHP, or PAHP is equivalent to 100 percent of the specified total published Medicare payment rate.

(C) Adopt a minimum fee schedule for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in paragraph (c)(1)(iii)(B) of this section.

(D) Provide a uniform dollar or percentage increase for providers that provide a particular service under the contract.

(E) Adopt a maximum fee schedule for providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Standards for State directed payments*. (i) State directed payments specified in paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) of this section must have written prior approval that the standards and requirements in this section are met.

(ii) Each State directed payment must meet the following standards. Specifically, each State directed payment must:

(A) Be based on the utilization and delivery of services;

(B) Direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expect to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Have an evaluation plan that measures the degree to which the State directed payment advances at least one of the goals and objectives in the quality strategy in § 438.340 and includes all of the elements outlined in paragraph (c)(2)(iv) of this section;

(E) Not condition provider participation in State directed payments on the provider entering into or adhering to intergovernmental transfer agreements;

(F) Result in achievement of the stated goals and objectives in alignment with the State's evaluation plan;

(G) Comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR 433, subpart B;

(H) Ensure that each provider receiving payment under a State directed payment attests that it does not participate in any hold harmless arrangement with respect to any health care-related tax as specified in § 433.68(f)(3) of this subchapter in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount, and ensure that such attestations are available upon CMS request;

(I) Ensure that the total payment rate for each service and provider class included in the State directed payment must be reasonable, appropriate and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class; and

(J) Be developed in accordance with § 438.4, and the standards specified in §§ 438.5, 438.7, and 438.8.

(iii) The total payment rate projected for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section for inpatient hospital services,

outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center must not exceed the average commercial rate. To demonstrate compliance with this paragraph, States must submit:

(A) The average commercial rate demonstration, for which States must use payment data that:

(*1*) Is specific to the State;

(*2*) Is no older than from the three most recent and complete years prior to the rating period of the initial request following the applicability date of this section;

(*3*) Is specific to the service(s) addressed by the State directed payment;

(*4*) Includes the total reimbursement by the third-party payer and any patient liability, such as cost sharing and deductibles;

(5) Excludes payments to FQHCs, RHCs, and from any non-commercial payers, such as Medicare; and

(*6*) Excludes any payment data for services or codes that the applicable Medicaid MCOs, PIHPs, or PAHPs do not cover.

(B) A total payment rate comparison*,* for which States must provide a comparison of the total payment rate for these services included in the State directed payment to the average commercial rate that:

(*1*) Is specific to each managed care program that the State directed payment applies to;

(*2*) Is specific to each provider class to which the State directed payment applies;

(*3*) Is projected for the rating period for which the State is seeking prior approval under paragraph (c)(2)(i) of this section;

(*4*) Uses payment data that are specific to each service included in the State directed payment; and

(*5*) Describes each of the components of the total payment rate as a percentage of the average commercial rate (demonstrated by the State as provided in paragraph (c)(2)(iii)(A) of this section) for each of these services included in the State directed payment.

(C) The ACR demonstration described in paragraph (c)(2)(iii)(A) of this section must be included with the initial documentation submitted for written prior approval of the State directed payment under paragraph (c)(2)(i) of this section, and then subsequently updated at least once every 3 years thereafter as long as the State continues to include the State directed payment that requires prior approval under paragraph (c)(2)(i) of this section in any MCO, PIHP, or PAHP contract. The total payment rate comparison described in paragraph (c)(2)(iii)(B) of this section must be included with the documentation submitted for written prior approval under paragraph (c)(2)(i) of this section and updated with each amendment and subsequent renewal.

(iv) For State directed payments for which written prior approval under paragraph (c)(2)(i) of this section is required, the State must include a written evaluation plan with its submission for written prior approval under paragraph (c)(2)(i) of this section and an updated written evaluation plan with each amendment and subsequent renewal. The evaluation plan must include the following elements:

(A) Identification of at least two metrics that will be used to measure the effectiveness of the State directed payment in advancing at least one of the goals and objectives in the quality strategy on an annual basis, which must:

(*1*) Be specific to the State directed payment, and when practicable and relevant, attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the State directed payment applies; and

(*2*) Include at least one performance measure as defined in § 438.6(a) as part of the metrics used to measure the effectiveness of the State directed payment;

(B) Include baseline statistics on all metrics that will be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section;

(C) Include performance targets for all metrics to be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section that demonstrate either maintenance or improvement over the baseline statistics and not a decline relative to baseline. The target for at least one performance measure, as defined in § 438.6(a), must demonstrate improvement over baseline; and

(D) Include a commitment by the State to submit an evaluation report in accordance with § 438.6(c)(2)(v) if the final State directed payment cost percentage exceeds 1.5 percent.

(v) For any State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section that has a final State directed payment cost percentage greater than 1.5 percent, the State must complete and submit an evaluation report using the evaluation plan outlined during the prior approval process under paragraph (c)(2)(iv) of this section.

(A) This evaluation report must:

(*1*) Include all of the elements in paragraph (c)(2)(iv) of this section as specified in the approved evaluation plan;

(*2*) Include three most recent and complete years of annual results for each metric as required in paragraph (c)(2)(iv)(A) of this section; and

(*3*) Be published on the public facing website as required under § 438.10(c)(3).

(B) States must submit the initial evaluation report as described in paragraph (c)(2)(v)(A) of this section to CMS no later than 2 years after the conclusion of the 3-year evaluation period. Subsequent evaluation reports must be submitted to CMS every 3 years.

(vi) Any State directed payments described in paragraph (c)(1)(i) or (ii) of this section must:

(A) Make participation in the value-based purchasing, delivery system reform, or performance improvement initiative available using the same terms of performance to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) If the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section conditions payment upon performance, the payment to providers under the State directed payment:

(*1*) Cannot be conditioned upon administrative activities, such as the reporting of data nor upon the participation in learning collaboratives or similar administrative activities.

(*2*) Must use a common set of performance measures across all of the payers and providers specified in the State directed payment;

(*3*) Must define and use a performance measurement period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered;

(*4*) Must identify baseline statistics on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP; and

(*5*) Must use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the State directed payment applies, that demonstrate improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP.

(C) If the State directed payment is a population-based or condition-based payment, the State directed payment must:

(*1*) Be conditioned upon the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution of a covered enrollee to a provider for the rating period for treatment;

(*2*) If conditioning payment on the attribution to a provider, have an attribution methodology using data that are no older than the three most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; accounts for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers;

(*3*) Replace the negotiated rate between an MCO, PIHP, or PAHP and providers for the Medicaid covered service(s) included in the population or condition-based payment; no other payment may be made by an MCO, PIHP, or PAHP to the same provider on behalf of the same enrollee for the same services included in the population or condition-based payment; and

(*4*) Include at least one metric in the evaluation plan required under paragraph (c)(2)(iv) of this section that measures performance at the provider class level; the target for this performance measure, as defined in § 438.6(a), must be set to demonstrate improvement over baseline.

(vii) Any State directed payment described in paragraph (c)(1)(iii) of this section must:

(A) Condition payment from the MCO, PIHP, or PAHP to the provider on the utilization and delivery of services under the contract for the rating period for which the State is seeking written prior approval only; and

(B) Not condition payment from the MCO, PIHP, or PAHP to the provider on utilization and delivery of services outside of the rating period for which the State is seeking written prior approval and then require that payments be reconciled to utilization during the rating period.

(viii) A State must submit all required documentation for all State directed payments for which written prior approval is required under (c)(2)(i) of this section no later than:

(A) Ninety days before the end of the rating period for any State directed payments that begins at least 90 days before the end of the rating period.

(B) Before the end of the rating period for any State directed payment that begins less than 90 days before the end of the rating period.

(C) For any State directed payments that are approved for multiple rating periods as provided in paragraph (c)(3) of this section, the same time frames described in paragraphs (c)(2)(viii)(A) and (B) of this section apply to the first rating period for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section.

(ix) States seeking to amend State directed payments after CMS has issued written prior approval under paragraph (c)(2)(i) of this section must obtain written prior approval of the amendment(s). States must submit all required documentation for written prior approval of such amendment(s):

(A) Prior to the end of the rating period to which the State directed payment applies to amend the State directed payment; and

(B) For any State directed payments that are approved for multiple rating periods as provided in paragraph (c)(3) of this section, within 120 days of the start of the rating period for amendments to the State directed payment for either the second or third rating period. States cannot amend State directed payments that are approved on a multi-year basis as defined in paragraph (c)(3) of this section for rating periods that have concluded.

(3) *Approval and renewal timeframes.* (i) Approval of a State directed payment described in paragraphs (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval of up to three rating periods is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the State directed payment in the contract as a multi-year State directed payment, including a description of the State directed payment by year and if the State directed payment varies by year.

(B) The State has developed and described its plan for implementing a multi-year State directed payment, including the State's plan for multi-year evaluation, and the impact of a multi-year State directed payment on the State's goals and objectives in the State's quality strategy in § 438.340.

(C) The State has affirmed that it will not make any changes to the State directed payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year State directed payment without CMS written prior approval. If the State determines that changes to the State directed payment methodology, or magnitude of the payment, are necessary, the State must obtain written prior approval of such changes under paragraph (c)(2) of this section.

(ii) Written prior approval of a State directed payment described in paragraph (c)(1)(iii)(C) through (E) of this section is for one rating period.

(iii) State directed payments are not automatically renewed.

(4) *Reporting requirements.* The State must submit to CMS no later than 180 days after each rating period, data to the Transformed Medicaid Statistical Information System, and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for State directed payments, including amounts paid to individual providers. The initial report will be due after the rating period following the release of reporting instructions by CMS. Minimum data fields to be collected include the following:

(i) Provider identifiers.

(ii) Enrollee identifiers.

(iii) MCO, PIHP or PAHP identifiers.

(iv) Procedure and diagnosis codes.

(v) Allowed, billed, and paid amounts. Paid amounts include the amount that represents the MCO's, PIHP's or PAHP's negotiated payment amount, the amount of the State directed payment, the amount for any pass-through payments under paragraph (d) of this section, and any other amounts included in the total amount paid to the provider.

(5) *Requirements for Medicaid Managed Care contract terms for State directed payments.* State directed payments must be specifically described and documented in the MCO's,

PIHP's, or PAHP's contracts. The MCO's, PIHP's or PAHP's contract must include, at a minimum, the following information for each State directed payment:

(i) The State directed payment start date and, if applicable, the end date within the applicable rating period;

(ii) A description of the provider class eligible for the State directed payment and all eligibility requirements;

(iii) A description of the State directed payment, which must include at a minimum:

(A) For State directed payments described in paragraphs (c)(1)(iii)(A), (B), and (C) of this section:

(*1*) The required fee schedule;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies;

(*4*) For State directed payments that specify State plan approved rates, the contract must also reference the State plan page, when it was approved, and a link to the currently approved State plan page when possible; and

(*5*) For State directed payments that specify a Medicare-referenced fee schedule, the contract must also include information about the Medicare fee schedule(s) that is necessary to implement the State directed payment, including identifying the specific Medicare fee schedule, the time period for which the Medicare fee schedule is in effect, and any material adjustments due to geography or provider type that need to be applied.

(B) For State directed payments described in paragraphs (c)(1)(iii)(D) of this section, the contract must include the following:

(*1*) Whether the uniform increase will be a specific dollar amount or a percentage increase of negotiated rates;

(*2*) The procedure and diagnosis codes to which the uniform dollar or percentage increase applies;

(*3*) The specific dollar amount or percentage increase that the MCO, PIHP or PAHP must apply or the methodology to establish the specific dollar amount or percentage increase;

(*4*) The applicable dates of service within the rating period for which the uniform increase applies; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, and other significant relevant information.

(C) For State directed payments described in paragraph (c)(1)(iii)(E) of this section, the contract must include the following:

(*1*) The fee schedule the MCO, PIHP, or PAHP must ensure that payments are below;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(3) The applicable dates of service within the rating period for which the fee schedule applies; and

(*4*) Details of the State's exemption process for MCOs, PIHPs, or PAHPs and providers to follow if they are under contractual obligations that result in the need to pay more than the maximum fee schedule.

(D) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section that condition payment based upon performance:

(*1*) The approved performance measures upon which payment will be conditioned;

(*2*) The approved measurement period for those measures;

(*3*) The approved baseline statistics for all measures against which performance will be measured;

(*4*) The performance targets that must be achieved on each measure for the provider to obtain the performance-based payment;

(*5*) The methodology to determine if the provider qualifies for the performance-based payment as well as the amount of the payment; and

(*6*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, what to do with any unearned payments, and other significant relevant information.

(E) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section using a population-based or condition-based payment as defined in paragraph (a) of this section:

(*1*) The Medicaid covered service(s) that the population or condition-based payment is for;

(*2*) The time period that the population or condition-based payment covers;

(*3*) When the population or condition-based payment is to be made and how frequently;

(*4*) A description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how the attribution methodology will be communicated to providers; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP in operationalizing the attribution methodology if an attribution methodology is used.

(iv) Any encounter reporting and separate reporting requirements necessary for auditing the State directed payment in addition to the reporting requirements in paragraph (c)(4) of this section; and

(v) If the State will be using a separate payment term as defined in paragraph (a) of this section to implement the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section.

(vi) All State directed payments must be specifically described and documented in the MCO's, PIHP's, and PAHP's contracts no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval or 120 days after the date CMS issued written prior approval of the State directed payment under (c)(2) of this section, whichever is later.

(6) *Separate payment term requirements.* All separate payment terms must:

(i) Be reviewed and approved as part of the review of the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section;

(ii) Not be used to implement a State directed payment described in paragraphs (c)(1)(iii)(A) and (B) of this section;

(iii) Be specific to each Medicaid managed care program and specific to the individual State directed payment for which the State has obtained written prior approval under paragraph (c)(2) of this section;

(iv) Not exceed the total amount documented in the written prior approval for each State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section and for each Medicaid managed care program; and

(v) Be documented in the State's contracts with the MCOs, PIHPs, or PAHPs no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section or 120 days after the date CMS issued written prior approval of the State directed payment under (c)(2)(i) of this section, whichever is later.

(A) The separate payment term cannot be amended except to account for a payment methodology that is first approved by CMS as an amendment to the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(B) The documentation in the MCO's, PIHP's, or PAHP's contract must include:

(*1*) The total dollars that the State will pay to the MCOs, PIHPs, or PAHPs for the individual State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(*2*) The timing and frequency of payments that will be made under the separate payment term from the State to the MCO, PIHP, or PAHP;

(*3*) A description or reference to the specific State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section for which the separate payment term is to be used; and

(*4*) Any separate reporting requirements that the State requires to ensure appropriate reporting of the separate payment term for the purposes of MLR reporting under § 438.8.

(7) *Final State directed payment cost percentage.* For each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section, unless the State voluntarily submits the evaluation report per paragraph (c)(2)(v) of this section, the State must calculate the final State directed payment cost percentage and if the final State directed payment cost percentage is below 1.5 percent the State must provide a final State directed payment cost percentage report to CMS as follows:

(i) *State directed payment cost percentage calculation*. The final State directed payment cost percentage must be calculated on an annual basis and recalculated annually.

(ii) *State directed payment cost percentage certification*. The final State directed payment cost percentage must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(iii) *Calculation of the final State directed payment cost percentage.* The final State directed payment cost percentage is the result of dividing the amount determined in paragraph (c)(7)(iii)(A) of this section by the amount determined in paragraph (c)(7)(iii)(B) of this section.

(A) The actual total amount that is paid as a separate payment term described in paragraph (c)(6) of this section and portion of the actual total capitation payments that is attributable to the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section, for each managed care program.

(B) The actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through

payments in effect under § 438.6(d), and the actual total amount of all State directed payments that are paid as separate payment terms as described in paragraph(c)(6).

(iv) *Annual CMS review of the final State directed payment cost percentage.* The State must submit the final State directed payment cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes a State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(8) *Applicability dates*. States must comply with:

(i) Paragraphs (a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) and (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv) of this section beginning on [EFFECTIVE DATE OF THE FINAL RULE].

(ii) Paragraphs (c)(2)(iii), (c)(2)(vi)(B), and (c)(2)(vi)(C)(*1*) and (*2*) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after [insert the effective date of the final rule].

(iii) Paragraphs (c)(2)(ii)(H), (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(vii), (c)(2)(viii), (c)(2)(ix) and (c)(5)(i) through (v) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after [insert the effective date of the final rule].

(iv) Paragraphs (c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v) and (c)(7) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after [insert the effective date of the final rule].

(v) Paragraphs (c)(5)(vi) and (c)(6)(v) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule].

(vi) Paragraph (c)(4) of this section no later than the first rating period following the release of reporting instructions by CMS.

* * * * *

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease*. The State may make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21-64 receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is a hospital providing mental health or substance use disorder inpatient care or a sub-acute facility providing mental health or substance use disorder crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. The provision of inpatient mental health or substance use disorder treatment in an IMD must meet the requirements for in lieu of services at § 438.3(e)(2)(i) through (iii). For purposes of rate setting, the State may use the utilization of services provided to an enrollee under this section when developing the inpatient mental health or substance use disorder component of the capitation rate, but must price utilization at the cost of the same services through providers included under the State plan.

7. Amend § 438.7 by--

a. Revising paragraph (b)(6); and

b. Adding paragraphs (c)(4) through (6) and (f) and (g).

The revisions and additions read as follows:

§ 438.7 Rate certification submission.

* * * * *

(b) * * *

(6) *Special contract provisions*. A description of any of the special contract provisions related to payment in § 438.6 and ILOS in § 438.3(e)(2) that are applied in the contract.

(c) * * *

(4) The State must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under paragraph (a) of this section for any special contract provisions related to payment described in § 438.6 and ILOS in § 438.3(e)(2) not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.

(5) Retroactive adjustments to the capitation rates, as outlined in paragraph (c)(2), resulting from a State directed payment described in § 438.6(c) must be a result of adding or amending any State directed payment consistent with the requirements in § 438.6(c), or a material error in the data, assumptions or methodologies used to develop the initial capitation rate adjustment such that modifications are necessary to correct the error.

(6) The rate certification or retroactive adjustment to capitation rates resulting from any State directed payments for which the State has obtained written prior approval under § 438.6(c)(2)(i) must be submitted no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under § 438.6(c)(2)(i) of this section or 120 days after the date CMS issued written prior approval of the State directed payment under § 438.6(c)(2)(i) of this section, whichever is later.

* * * * *

(f) *State certification*. The State, through its actuary, must certify the total dollar amount for each separate payment term included in the State's MCO, PIHP or PAHP contracts in alignment with the requirements of § 438.6(c)(6).

(1) The State may pay each MCO, PIHP or PAHP a different amount under the separate payment term that is different than the amount paid to another MCO, PIHP or PAHP, so long as the aggregate total dollars paid to all MCOs, PIHPs and PAHPs does not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract.

(2) As part of the State's rate certification documentation for a separate payment term, the State, through its actuary, must provide an estimate of the impact of the separate payment term on a rate cell basis, as paid per the State directed payment approved by CMS under § 438.6(c)(2)(i).

(3) No later than 12 months following the end of the rating period, the State must submit documentation to CMS that demonstrates the impact of the separate payment term by rate cell for which the State has obtained written prior approval under § 438.6(c)(2)(i) consistent with the distribution methodology described in the State directed payment for which the State obtained written prior approval under § 438.6(c)(2)(i) in the manner and form required by CMS.

(4) Once CMS has issued written prior approval under § 438.6(c)(2)(i), the State must submit a rate certification or a rate certification amendment incorporating the separate payment term no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under § 438.6(c)(2)(i) or 120 days after the date CMS issued written prior approval of the State directed payment under § 438.6(c)(2)(i), whichever is later.

(g) *Applicability dates*. (1) Paragraph (b)(6) of this section applies to the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following [insert the effective date of the final rule]. Until that applicability date, States are required to continue to comply with paragraph (b)(6) of this section contained in 42 CFR, parts 430 to 481, edition most recently published prior to the final rule.

(2) Paragraphs (c)(4), (c)(5), (f)(1), (f)(2) and (f)(3) of this section applies beginning on [insert the effective date of the final rule].

(3) Paragraphs (c)(6) and (f)(4) of this section apply no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule].

8. Amend § 438.8 by –

a. Revising paragraph (e)(2)(iii)(A);

b. Adding paragraph (e)(2)(iii)(C);

c. Revising paragraph (e)(3)(i);

d. Adding paragraph (f)(2)(vii);

e. Revising paragraphs (h)(4) introductory text and (k)(1)(vii);

f. Adding paragraphs (k)(1)(xiv) through (xvi); and

g. Revising paragraph (m).

The revisions and additions read as follows:

§ 438.8 Medical loss ratio (MLR) standards.

* * * * *

(e) * * *

(2) * * *

(iii) * * *

(A) The amount of incentive and bonus payments made, or expected to be made, to network providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

* * * * *

(C) The amount of payments made under all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures as specified in § 438.6(c)(1)(i) through (iii).

* * * * *

(3) * * *

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(a) and (b) and is not excluded under 45 CFR 158.150(c).

* * * * *

(f) * * *

(2) * * *

(vii) Payments to the MCO, PIHP, or PAHP for expenditures approved under § 438.6(c)(1)(i) through (iii).

* * * * *

(h) * * *

(4) CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

* * * * *

(k) * * *

(1) * * *

(vii) Methodology(ies) for allocation of expenditures, which must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described in 45 CFR 158.170(b).

* * * * *

(xiv) The amount of payments made to providers under all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures as described in § 438.6(c)(1)(i) through (iii).

(xv) Payments to the MCO, PIHP, or PAHP from the State for expenditures approved under § 438.6(c)(1)(i) through (iii).

(xvi) Paragraphs (k)(1)(xiv) and (xv) of this section apply to the rating period for contracts with MCOs. PIHPs, and PAHPs beginning on or after 60 days following [EFFECTIVE DATE OF THE FINAL RULE].

* * * * *

(m) *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation rates for an MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected

by the retroactive rate change and submit a new report meeting the requirements in paragraph (k) of this section.

* * * * *

9. Amend § 438.10 by –

a. Revising paragraphs (c)(3), (d)(2), (g)(2)(ix), (h)(1) introductory text;

b. Adding paragraph (h)(1)(ix);

c. Revising paragraph (h)(2)(iv);

d. Adding paragraph (h)(3)(iii); and

e. Revising paragraph (j).

The revisions and additions read as follows:

§ 438.10 Information requirements.

* * * * *

(c) * * *

(3) The State must operate a website that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity webpages, specified at § 438.602(g) and elsewhere in this part. States must:

(i) Include all content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity Web sites, on one web page;

(ii) Include clear and easy to understand labels on documents and links;

(iii) Verify no less than quarterly, the accurate function of the website and the timeliness of the information presented; and

(iv) 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.

* * * * *

(d) * * *

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees and experience surveys for enrollees must include taglines in the prevalent non-English languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

* * * * *

(g) * * *

(2) * * *

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100 and, if applicable, § 438.3(e)(2)(ii).

* * * * *

(h) * * *

(1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and searchable electronic form, the following information about its network providers:

* * * * *

(ix) Whether the provider offers covered services via telehealth.

(2) * * *

(iv) Mental health and substance use disorder providers; and

* * * * *

(3) * * *

(iii) MCOs, PIHPs, or PAHPs must use the information received from the State pursuant to § 438.68(f)(1)(iii) to update provider directories no later than the timeframes specified in (h)(3)(i) and (ii).

* * * * *

(j) *Applicability.* States will not be held out of compliance with the requirements of paragraph (c)(3) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (c)(3) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. States will not be held out of compliance with the requirements of paragraph (d)(2) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after the [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraphs (d)(2) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. States will not be held out of compliance with the requirements of paragraph (h)(1) of this section prior to July 1, 2025, so long as they comply with the corresponding standard(s) codified in paragraph (h)(1) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. States will not be held out of compliance with the requirements of paragraph (h)(1)(ix) of this section prior to July 1, 2025. Paragraph (h)(3)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule].

* * * * *

10. Add § 438.16 to read as follows:

§ 438.16 In lieu of services and settings (ILOS) requirements.

(a) *Definitions*. As used in this part, the following terms have the indicated meanings:

Final ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(3) of this section, specific to each managed care program that includes ILOS.

Projected ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(2) of this section, specific to each managed care program that includes ILOS.

Summary report of actual MCO, PIHP, and PAHP ILOS costs is the report calculated, in accordance with paragraph (c)(4) of this section, specific to each managed care program that includes ILOS.

(b) *General rule*. An ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i), or 1915(k) of the Act.

(c) *ILOS Cost Percentage and summary report of actual MCO, PIHP, and PAHP ILOS costs*.

(1) General rule. (i) The projected ILOS cost percentage calculated as required in paragraph (c)(2) of this section may not exceed 5 percent and the final ILOS cost percentage calculated as required in paragraph (c)(3) of this section may not exceed 5 percent.

(ii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be calculated on an annual basis and recalculated annually.

(iii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(2) *Calculation of the projected ILOS cost percentage*. The projected ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(2)(i) of this section by the amount determined in paragraph (c)(2)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The projected total capitation payments for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the projected total State directed payments in effect under § 438.6(c) that are paid as a separate payment term as described in § 438.6(c)(6).

(3) *Calculation of the final ILOS cost percentage.* The final ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(3)(i) of this section by the amount determined in paragraph (c)(3)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d), and the actual total State directed payments in effect under § 438.6(c) that are paid as a separate payment term as described in § 438.6(c)(6).

(4) *Summary report of actual MCO, PIHP, and PAHP ILOS costs.* The State must submit to CMS a summary report of the actual MCO, PIHP and PAHP costs for delivering ILOSs based on the claims and encounter data provided by the MCO(s), PIHP(s) and PAHP(s).

(5) *CMS review of the projected ILOS cost percentage, the final ILOS cost percentage and the summary report of actual MCO, PIHP and PAHP ILOS costs*.

(i) The State must annually submit the projected ILOS cost percentage to CMS for review as part of the rate certification required in § 438.7(a).

(ii) The State must submit the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes an ILOS.

(d) *Documentation requirements*--(1) *State requirements.* All States that include an ILOS in an MCO, PIHP, or PAHP contract are required to include, at minimum, the following:

(i) The name and definition of each ILOS;

(ii) The covered service or setting under the State plan for which each ILOS is a medically appropriate and cost-effective substitute;

(iii) The clinically defined target populations for which each ILOS is determined to be medically appropriate and cost effective;

(iv) The process by which a licensed network or MCO, PIHP, or PAHP staff provider, determines and documents in the enrollee's records that each identified ILOS is medically appropriate for the specific enrollee;

(v) The enrollee rights and protections, as defined in § 438.3(e)(2)(ii); and

(vi) A requirement that the MCO, PIHP, or PAHP will utilize specific codes established by the State that identify each ILOS in encounter data, as required under § 438.242.

(2) *Additional documentation requirements*. A State with a projected ILOS cost percentage that exceeds 1.5 percent is also required to provide the following documentation concurrent with the contract submission for review and approval by CMS under § 438.3(a).

(i) A description of the process and supporting evidence the State used to determine that each ILOS is a medically appropriate service or setting for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(ii) A description of the process and supporting data the State used to determine that each ILOS is a cost-effective substitute for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(3) *Provision of additional information.* At the request of CMS, the State must provide additional information, whether part of the MCO, PIHP or PAHP contract, rate certification or supplemental materials, if CMS determines that the requested information is pertinent to the review and approval of a contract that includes ILOS.

(e) *Monitoring, evaluation and oversight*. (1) *Retrospective evaluation*. A State with a final ILOS cost percentage that exceeds 1.5 percent, is required to submit at least one retrospective evaluation of ILOS to CMS. The retrospective evaluation must:

(i) Be completed separately for each managed care program that includes an ILOS.

(ii) Be completed using the 5 most recent years of accurate and validated data for the ILOS. The State must utilize these data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS.

(iii) Evaluate at least:

(A) The impact each ILOS had on utilization of State plan approved services or settings, including any associated cost savings;

(B) Trends in MCO, PIHP, or PAHP and enrollee use of each ILOS;

(C) Whether encounter data supports the State's determination that each ILOS is a medically appropriate and cost-effective substitute for the identified covered service and setting under the State plan or a cost-effective measure to reduce or prevent the future need to utilize the covered service and setting under the State plan;

(D) The impact of each ILOS on quality of care;

(E) The final ILOS cost percentage for each year consistent with the report in paragraph (c)(5)(ii) of this section with a declaration of compliance with the allowable threshold in paragraph (c)(1)(i) of this section;

(F) Appeals, grievances, and State fair hearings data, reported separately, related to each ILOS, including volume, reason, resolution status, and trends; and

(G) The impact each ILOS had on health equity efforts undertaken by the State to mitigate health disparities.

(iv) The State must submit the retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included ILOS.

(v) CMS reserves the right to require the State to submit additional retrospective evaluations to CMS.

(2) *Oversight*. Oversight for each ILOS must include the following:

(i) *State notification requirement*. The State must notify CMS within 30 calendar days if:

(A) The State determines that an ILOS is no longer a medically appropriate or cost effective substitute for the covered service or setting under the State plan identified in the contract as required in paragraph (d)(1)(ii) of this section; or

(B) The State identifies noncompliance with requirements in this section.

(ii) *CMS oversight process*. If CMS determines that a State is out of compliance with any requirement in this part or receives a State notification in paragraph (e)(2)(i) of this section, CMS may require the State to terminate the use of an ILOS.

(iii) *Process for termination of ILOS.* When a State decides to terminate an ILOS, an MCO, PIHP or PAHP decides to cease offering an ILOS to its enrollees, or CMS makes the decision to require the State to terminate an ILOS, the State must submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision. The transition plan must include at least the following:

(A) A process to notify enrollees of the termination of an ILOS that they are currently receiving as expeditiously as the enrollee's health condition requires.

(B) A transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to care to any enrollee who is currently receiving the ILOS that will be terminated. The State must make the transition of care policy publicly available.

(C) An assurance the State will submit the modification of the MCO, PIHP, or PAHP contract to remove the ILOS and submission of the modified contracts to CMS as required in § 438.3(a), and a reasonable timeline for submitting the contract amendment.

(D) An assurance the State and its actuary will submit an adjustment to the actuarially sound capitation rate, as needed, to remove utilization and cost of the ILOS from capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2), and a reasonable timeline for submitting the revised rate certification.

(f) *Applicability date*. Section 438.16 applies to the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following [insert the effective date of the final rule].

11. Amend § 438.66 by revising paragraphs (b)(4), (c)(5), (e)(2)(vi) and (vii), and (e)(3)(i), and (f) to read as follows:

§ 438.66 State monitoring requirements.

* * * * *

(b) * * *

(4) Enrollee materials, enrollee experience, and customer services, including the activities of the beneficiary support system.

* * * * *

(c) * * *

(5) Results from an annual enrollee experience survey conducted by the State and any provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.

* * * * *

(e) * * *

(2) * * *

(vi) Availability and accessibility of covered services, including any ILOS, within the MCO, PIHP, or PAHP contracts, including network adequacy standards.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures and results of an enrollee experience survey, including as applicable, consumer report card, provider surveys, or other reasonable measures of performance.

* * * * *

(3) * * *

(i) Posted on the Web site required under § 438.10(c)(3) within 30 calendar days of submitting it to CMS.

* * * * *

(f) With respect to applicability, States will not be held out of compliance with the requirements of paragraphs (b) through (c) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in § 438.66 contained in the 42 CFR, parts 430 to 481, edition most recently published prior to the final rule.

12. Amend § 438.68 by--

a. Revising paragraphs (b)(1) introductory text, (b)(1)(iii), (d)(1), (d)(2) and (e); and

b. Adding paragraphs (f) through (h).

The revisions and additions read as follows:

§ 438.68 Network adequacy standards.

* * * * *

(b) * * *

(1) *Provider types.* At a minimum, a State must develop a quantitative network adequacy standard, other than appointment wait times, for the following provider types, if covered under the contract:

* * * * *

(iii) Mental health and substance use disorder, adult and pediatric.

* * * * *

(d) * * *

(1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must:

(i) Be specified in the MCO, PIHP or PAHP contract.

(ii) Be based, at a minimum, on the number of providers in that specialty practicing in the MCO, PIHP, or PAHP service area.

(iii) Include consideration of the payment rates offered by the MCO, PIHP, or PAHP to the provider type for which an exception is being requested.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to an MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66(e).

(e) *Appointment wait time standards*. States must establish and enforce appointment wait time standards.

(1) *Routine appointments*. Standards must be established for routine appointments with the following provider types and within the specified limits:

(i) If covered in the MCO's, PIHP's, or PAHP's contract, outpatient mental health and substance use disorder, adult and pediatric, within State-established time frames but no longer than 10 business days from the date of request.

(ii) If covered in the MCO's, PIHP's, or PAHP's contract, primary care, adult and pediatric, within State-established time frames but no longer than 15 business days from the date of request.

(iii) If covered in the MCO's, PIHP's, or PAHP's contract, obstetrics and gynecological within State-established time frames but no longer than 15 business days from the date of request.

(iv) State-selected, other than those listed in paragraphs (e)(1)(i) through (iii) of this section, chosen in an evidence-based manner within State-established time frames.

(2) *Minimum compliance*. MCOs, PIHPs, and PAHPs will be deemed compliant with the standards established in paragraph (e)(1) of this section when secret shopper results, consistent with paragraph (f)(2) of this section, reflect a rate of appointment availability that meets the standards established at paragraph (e)(1)(i) through (iv) of at least 90 percent.

(3) *Selection of additional types of providers*. After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of providers to be added to paragraph (e)(1) of this section.

(f) *Secret shopper surveys*. States must contract with an entity, independent of the State Medicaid agency and any of its contracted MCOs, PIHPs and PAHPs subject to the survey, to conduct annual secret shopper surveys of each MCO's, PIHP's, and PAHP's compliance with the provider directory requirements in § 438.10(h) as specified in paragraph (f)(1) of this section and appointment wait time requirements as specified in paragraph (f)(1) of this section.

(1) *Provider directories*. (i) A secret shopper survey must be conducted to determine the accuracy of the information specified in paragraph (f)(1)(ii) of this section in each MCO's, PIHP's, and PAHP's most current electronic provider directories, as required at § 438.10(h), for the following provider types:

(A) Primary care providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(B) Obstetric and gynecological providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(C) Outpatient mental health and substance use disorder providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory; and

(D) The provider type chosen by the State in (e)(1)(iv).

(ii) A secret shopper survey must assess the accuracy of the information in each MCO's, PIHP's, and PAHP's most current electronic provider directories for at least:

(A) The active network status with the MCO, PIHP, or PAHP;

(B) The street address(es) as required at § 438.10(h)(1)(ii);

(C) The telephone number(s) as required at § 438.10(h)(1)(iii); and

(D) Whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi).

(iii) States must receive information, sufficient to facilitate correction by the MCO, PIHP, or PAHP, on errors in directory data identified in secret shopper surveys from the entity conducting the secret shopper survey no later than 3 business days from the day the error is identified by the entity conducting the secret shopper survey.

(iv) States must send information required in paragraph (f)(1)(iii) of this section to the applicable MCO, PIHP, or PAHP no later than 3 business days from receipt.

(2) *Timely appointment access*. A secret shopper survey must be used to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards in paragraph (e)(1) of this section.

(i) After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of appointments to be added to a secret shopper survey.

(ii) Appointments offered via telehealth can only be counted toward compliance with the appointment wait time standards in paragraph (e)(1) of this section if the provider being surveyed also offers in-person appointments to the MCO's, PIHP's, or PAHP's enrollees and must be identified separately from in-person appointments in survey results.

(3) *Independence*. An entity will be considered independent of the State as specified in paragraph (f)(3)(i) of this section and independent of the MCOs, PIHPs, or PAHPs subject to the surveys as specified in paragraph (f)(3)(ii) of this section.

(i) An entity will be considered independent of the State if it is not part of the State Medicaid agency.

(ii) An entity will be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if the entity is not an MCO, PIHP, or PAHP, is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.

(4) *Methodological standards*. Secret shopper surveys required in this paragraph must :

(i) Use a random sample;

(ii) Include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract; and

(iii) For secret shopper surveys required in paragraph (f)(2) of this section for appointment wait time standards, be completed for a statistically valid sample of providers.

(5) *Results reporting*. Results of the secret shopper surveys conducted pursuant to paragraphs (f)(1) and (2) of this section must be analyzed, summarized, and:

(i) Reported to CMS using the content, form, and submission times as specified at § 438.207(d); and

(ii) Posted on the State's website required at § 438.10(c)(3) within 30 calendar days of submission to CMS.

(g) *Publication of network adequacy standards.* States must publish the standards developed in accordance with paragraphs (b)(1) and (2), and (e) of this section on the website required by § 438.10(c)(3). Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

(h) *Applicability.* States will not be held out of compliance with the requirements of paragraph (b)(1) and of this section prior to the first rating period beginning on or after 3 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraphs (b) of this section contained in the 42 CFR, parts 430 to 481,

most recently published before the final rule. Paragraph (d)(1)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after [insert the effective date of the final rule]. Paragraph (e) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after [insert the effective date of the final rule]. Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after [insert the effective date of the final rule]. States will not be held out of compliance with the requirements of paragraph (g) of this section prior to the first rating period that begins on or after 3 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (g) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule.

13. Amend § 438.74 by revising paragraph (a) to read as follows:

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement.* (1) The State must annually submit to CMS a summary description of each report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to § 438.8(k), with the rate certification required in § 438.7.

(2) The summary description must be provided for each MCO, PIHP, or PAHP under contract with the State and must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

(3) The summary description must also include line items for:

(i) The amount of payments made under all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures as specified in § 438.6(c)(1)(i) through (iii); and

(ii) Payments to the MCO, PIHP, or PAHP for expenditures approved under § 438.6(c)(1)(i) through (iii).

(4) Paragraph (a)(3) of this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following [insert the effective date of the final rule].

* * * * *

14. Amend § 438.206 by revising paragraphs (c)(1)(i) and (d) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(1) * * *

(i) Meet and require its network providers to meet State standards for timely access to care and services taking into account the urgency of the need for services as well as appointment wait times specified in § 438.68(e).

* * * * *

(d) *Applicability date.* States will not be held out of compliance with the requirements of paragraphs (c)(1)(i) of this section prior to the first rating period that begins on or after 4 years after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (c)(1)(i) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule.

* * * * *

15. Amend § 438.207 --

a. In paragraph (b)(1), by removing the "." at the end of the paragraph and adding in its place ";".

b. In paragraph (b)(2), by removing the "." at the end of the paragraph and adding in its place "; and";

c. By adding paragraph (b)(3);

d. By revising paragraphs (d) and (e);

e. By revising paragraph (f) and adding paragraph (g).

The revisions and additions read as follows:

§ 438.207 Assurances of adequate capacity and services.

* * * * *

(b) * * *

(3) Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO's, PIHP's, or PAHP's contract, provides a payment analysis using paid claims data from the immediately prior rating period that demonstrates each MCO's, PIHP's, or PAHP's level of payment as specified in paragraphs (b)(3)(i) and (ii) of this section.

(i) The payment analysis must provide the total amount paid for evaluation and management current procedural terminology codes in the paid claims data from the prior rating period for primary care, OB/GYN, mental health, and substance use disorder services, as well as the percentage that results from dividing the total published Medicare payment rate for the same services.

(A) A separate total and percentage must be reported for primary care, obstetrics and gynecology, mental health, and substance use disorder services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(ii) For homemaker services, home health aide services, and personal care services, the payment analysis must provide the total amount paid 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 services.

(A) A separate total and percentage must be reported for homemaker services, home health aide services, and personal care services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(iii) Payments by MCOs, PIHPS, and PAHPs for the services specified in § 438.207(b)(3)(i) but for which the MCO, PIHP, or PAHP is not the primary payer are excluded from the analysis required in this paragraph.

(iv) Services furnished by a Federally-qualified health center as defined in section 1905(l)(2) and services furnished by a rural health clinic as defined in section 1905(l)(1) are excluded from the analysis required in this paragraph.

* * * * *

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP as specified in paragraph (b) of this section and the secret shopper evaluation results as required at § 438.68(f), the State must submit an assurance of compliance to CMS, in the format prescribed by CMS, that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in §§ 438.68 and 438.206.

(1) The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(2) The analysis in paragraph (d)(1) of this section must include the payment analysis submitted by each MCO, PIHP, or PAHP, as required in paragraph (b)(3) of this section, and contain:

(i) The data provided by each MCO, PIHP, and PAHP in paragraph (b)(3) of this section; and

(ii) A State level payment percentage for each service type specified in paragraphs (b)(3)(i) and (ii) of this section produced by using the number of member months for the applicable rating period to weight each MCO’s, PIHP’s, or PAHP’s reported percentages, as required in paragraph (b)(3) of this section.

(3) States must submit the assurance of compliance required in paragraph (d) of this section as specified in paragraphs (i) through (iii) of this section and post the report on the State's website required in § 438.10(c)(3) within 30 calendar days of submission to CMS.

(i) At the time it submits a completed readiness review, as specified at § 438.66(d)(1)(iii).

(ii) On an annual basis and no later than 180 calendar days after each rating period.

(iii) At any time there has been a significant change as specified in paragraph (c)(3) of this section and with the submission of the associated contract, as required at § 438.3(a).

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP as well as documentation from all secret shopper surveys required at § 438.68(f).

(f) *Remedy plans to improve access*. (1) When the State, MCO, PIHP, PAHP, or CMS identifies an area in which an MCO's, PIHP's, or PAHP's access to care under the access standards in this part could be improved, including the standards at §§ 438.68 and 438.206, the State must:

(i) Submit to CMS for approval a remedy plan as specified in paragraph (f)(ii) of this section no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue;

(ii) Develop a remedy plan that addresses the identified access issue within 12 months and that identifies specific steps with timelines for implementation and completion, and responsible parties. State's and managed care plans' actions may include a variety of approaches, including, but not limited to: increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization;

(iii) Ensure that improvements in access are measurable and sustainable; and

(iv) Submit quarterly progress updates to CMS on implementation of the remedy plan.

(2) If the remedy plan required in paragraph(f)(1) of this section does not result in addressing the MCO's, PIHP's, or PAHP's access issue by improving access within 12 months, CMS may require the State to continue the remedy plan for another 12 months and may require revision to the remedy plan required in paragraph (f)(1) of this section.

(g) *Applicability date*. Paragraphs (b)(3) and (d)(2) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after [insert the effective date of the final rule]. Paragraph (d)(3) of this section applies to the first rating period beginning on or after 1 year after [insert the effective date of the final rule]. States will not be held out of compliance with the requirements of paragraph (e) of this section prior to the rating period beginning on or after 4 year after [insert the effective date of the final rule], so long as they comply with the corresponding standard(s) codified in paragraph (e) of this section contained in the 42 CFR, parts 430 to 481, most recently published before the final rule. Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after [EFFECTIVE DATE OF THE FINAL RULE].

16. Amend § 438.214 is amended by--

a. Revising paragraph (b)(1); and

b. Adding paragraph (d)(2).

The revision and addition read as follows:

§ 438.214 Provider Selection.

* * * * *

(b) * * *

(1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, mental health, substance use disorders, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies.

* * * * *

(d) * * *

(2) States must ensure through its contracts that MCOs, PIHPs, and PAHPs terminate any providers of services or persons terminated (as described in section 1902(kk)(8) of the Social Security Act) from participation under this title, title XVIII, or title XXI from participating as a provider in any network.

* * * * *

17. Amend § 438.310 by revising paragraphs (b)(5) introductory text, (c)(2), and (d) to read as follows:

§ 438.310 Basis, scope, and applicability.

* * * * *

(b) * * *

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, PAHP including –

* * * * *

(c) * * *

(2) The provisions of § 438.330(b)(2) and (3), (c), and (e), and § 438.340 apply to States contracting with PCCM entities whose contracts with the State provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes.

* * * * *

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in 42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of [insert effective date of final rule]:

(1) States must comply with § 438.330(d)(4) no later than the rating period for contracts beginning after [insert the effective date of the final rule].

(2) States must comply with updates to § 438.340 no later than 1 year from [insert the effective date of the final rule].

(3) States must comply with updates to §§ 438.358 and 438.364(c)(2)(iii) no later than December 31, 2025.

(4) States must comply with § 438.364(a)(2)(iii) no later 1 year from the issuance of the associated protocol.

18. Amend § 438.330 by revising paragraph (d)(4) to read as follows:

§ 438.330 Quality assessment and performance improvement program.

* * * * *

(d) * * *

(4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA organization chronic care improvement program conducted under § 422.152(c) of this chapter for one or more of the performance improvement projects otherwise required under this section.

* * * * *

§ 438.334 [Removed and reserved]

19. Section 438.334 is removed and reserved.

20. Amend § 438.340 by revising paragraphs (b)(4), (c)(1) introductory text, (c)(2)(ii), and (c)(3) to read as follows:

§ 438.340 Managed care State quality strategy.

* * * * *

(b) * * *

(4) Arrangements for annual, external independent reviews, in accordance with § 438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, and PAHP contract.

* * * * *

(c) * * *

(1) Make the strategy available for public comment before submitting the strategy to CMS for review in accordance with paragraph (c)(3) of this section, including:

* * * * *

(2) * * *

(ii) The State must make the results of the review, including the evaluation conducted pursuant to paragraph (c)(2)(i) of this section, available on the Web site required under § 438.10(c)(3).

* * * * *

(3) Prior to adopting as final, submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback.

(ii) A copy of the strategy –

(A) Every 3 years following the review in paragraph (c)(2) of this section;

(B) Whenever significant changes, as defined in the State's quality strategy per paragraph (b)(10) of this section, are made to the document;

(C) Whenever significant changes occur within the State's Medicaid program.

* * * * *

§ 438.344 [Removed and reserved]

21. Remove and reserve 438.344.

22. Amend § 438.350 by revising the introductory text and paragraph (a) to read as follows:

§ 438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs must ensure that -

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, or PAHP.

* * * * *

23. Amend § 438.354 by revising paragraph (c)(2)(iii) to read as follows:

§ 438.354 Qualifications of external quality review organizations.

* * * * *

(c) * * *

(2) * * *

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)) services that it will review as an EQRO, except for the related activities specified in § 438.358;

* * * * *

24. Amend § 438.358 by--

a. Revising paragraph (a)(1);

b. Adding paragraph (a)(3);

c. Revising paragraphs (b)(1) introductory text, (b)(1)(i), (ii), and (iv);

d. Removing and reserving paragraph (b)(2);

e. Revising paragraph (c) introductory text and (c)(6); and

f. Adding paragraph (c)(7).

The revisions read as follows:

§ 438.358 Activities related to external quality review.

(a) * * *

(1) The State, its agent that is not an MCO, PIHP, or PAHP or an EQRO may perform the mandatory and optional EQR-related activities in this section.

* * * * *

(3) For the EQR-related activities described in § 438.350(b)(1) and (c) of this subpart (except § 438.350(b)(1)(iii)), the review period begins on the first day of the most recently

concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity, and is 12 months in duration.

(b) * * *

(1) For each MCO, PIHP, or PAHP the following EQR-related activities must be performed in the 12 months preceding the finalization of the annual report:

(i) Validation of performance improvement projects required in accordance with § 438.330(b)(1) that were underway during the EQR review period per paragraph (a)(3) of this section.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with § 438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the EQR review period described in paragraph (a)(3) of this section.

* * * * *

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the EQR review period per paragraph (a)(3) of this section to comply with requirements set forth in § 438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, § 438.14(b)(1).

(2) [Reserved]

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed in the 12 months preceding the annual report by using information derived during the EQR review period described in paragraph (a)(3) of this section:

* * * * *

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with 42 CFR part 438, subpart G.

(7) Assist with evaluations required under §§ 438.16(e)(1), 438.340(c)(2)(i), and 438.6(c)(2)(iv) and (v) pertaining to outcomes, quality, or access to health care services

* * * * *

25. Amend § 438.360 by revising paragraph (a)(1) to read as follows:

§ 438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) * * *

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS;

* * * * *

26. Amend § 438.362 by revising paragraph (b)(2) paragraph heading and (b)(2)(i) to read as follows:

§ 438.362 Exemption from external quality review.

* * * * *

(b) * * *

(2) *Medicare information from a private accrediting organization*. (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used to fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

* * * * *

27. Amend § 438.364 by revising paragraphs (a)(1), (a)(2)(iii), (a)(3) through (6), (c)(1) and (c)(2) to read as follows:

§ 438.364 External quality review results.

(a) * * *

(1) A description of the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, or PAHP.

(2) * * *

(iii) The data and a description of data obtained, including validated performance measurement, any outcomes data and results from quantitative assessments, for each activity conducted in accordance with § 438.358(b)(1)(i), (ii) and (iv) of this subpart; and

* * * * *

(3) An assessment of each MCO's, PIHP's, or PAHP's strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, or PAHP, including how the State can target goals and objectives in the quality strategy, under § 438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, or PAHPs, consistent with guidance included in the EQR protocols issued in accordance with § 438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, or PAHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

* * * * *

(c) * * *

(1) The State must contract with a qualified EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The State must finalize the annual technical report by December 31st of each year.

(2) The State must –

(i) Post the most recent copy of the annual EQR technical report on the Web site required under § 438.10(c)(3) by December 31st of each year and notify CMS, in a form and manner determined by CMS, within 14 calendar days of the Web posting.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, or PAHP beneficiary advocacy groups, and members of the general public.

(iii) Maintain at least the previous 5 years of EQR technical reports on the on the Web site required under § 438.10(c)(3).

* * * * *

28. Subpart G is added to part 438 to read as follows:

Subpart G – Medicaid Managed Care Quality Rating System

Sec.

§ 438.500 Definitions.

(a) Definitions. As used in this subpart, the following terms have the indicated meanings:

Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.

Measurement year means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.

Medicaid managed care quality rating system framework (QRS framework) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.

Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system) means the rating system described in subpart D of parts 422 of 423 of this chapter.

Qualified health plan rating system (QHP quality rating system) means the health plan quality rating system developed in accordance with 45 CFR 156.1120.

Quality rating means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.

Technical resource manual means the guidance described in § 438.530.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.505 General rule and applicability.

(a) *General rule*. As part of its quality assessment and improvement strategy for its managed care program, each State contracting with an applicable managed care plan, as described in paragraph (b) of this section, to furnish services to Medicaid beneficiaries must—

(1)(i) Adopt the QRS framework developed by CMS; or

(ii) Adopt an alternative managed care quality rating system in accordance with § 438.525 of this subpart.

(2) Implement such managed care quality rating system by the end of the fourth calendar year following [the effective date of the final rule published in the Federal Register], unless otherwise specified in this subpart.

(3) Use the State's beneficiary support system implemented under § 438.71 to provide the services identified at § 438.71(b)(1)(i) and (ii) to beneficiaries, enrollees, or both seeking assistance using the managed care quality rating system implemented by the State under this subpart.

(b) *Applicability*. The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The provisions of this

subpart do not apply to States contracting with Medicare Advantage Dual Eligible Special Needs Plans for only Medicaid coverage of Medicare cost sharing.

(c) *Continued alignment.* To maintain the QRS framework, CMS aligns the mandatory measure set and methodology described in § 438.510 and § 438.515 of this subpart, to the extent appropriate, with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the MA and Part D quality rating system, and other similar CMS quality measurement and rating initiatives.

§ 438.510 Mandatory QRS measure set for Medicaid managed care quality rating system.

(a) *Measures required.* The quality rating system implemented by the State must include the measures in the mandatory QRS measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual, and may include other measures identified by the State as described in § 438.520(b).

(b) *Subregulatory process to update mandatory measure set.* Subject to paragraph (d) of this section, CMS will update the mandatory measure set at least every other year, including the addition, removal or updating of mandatory measures after:

(1) Engaging with States and other interested parties (such as State officials, measure experts, health plans, beneficiary advocates, tribal organizations, health plan associations, and external quality review organizations) to evaluate the current mandatory measure set and make recommendations to add, remove or update existing measures based on the criteria and standards in paragraph (c) of this section; and

(2) Providing public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) on any planned modifications to the mandatory measure set following the engagement described in paragraph (b)(1) of this section.

(c) *Standards for adding mandatory measures*. Based on available relevant information, including the input received during the process described in paragraph (b) of this section, CMS will add a measure in the mandatory measure set when each of the following standards are met:

(1) The measure meets at least 5 of the following criteria:

(i) Is meaningful and useful for beneficiaries or their caregivers when choosing a managed care plan;

(ii) Aligns with other CMS programs described in § 438.505(c);

(iii) Measures health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity;

(iv) Presents an opportunity for managed care plans to influence their performance on the measure;

(v) Is based on data that are available without undue burden on States and plans such that it is feasible to report by many States and managed care plans;

(vi) Demonstrates scientific acceptability, meaning that the measure, as specified, produces consistent and credible results;

(2) The proposed measure contributes to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a concise mandatory measure set, and

(3) The burdens associated with including the measure does not outweigh the benefits to the overall quality rating system framework of including the new measure based on the criteria listed in paragraph (c)(1).

(d) *Removing mandatory measures*. CMS may remove existing mandatory measures from the mandatory measure set if--

(1) After following the process described in paragraph (b) of this section, CMS determines that the measure no longer meets the standards described in paragraph (c) of this section;

(2) The measure steward (other than CMS) retires or stops maintaining a measure;

(3) CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes; or

(4) CMS determines that the measure shows low statistical reliability under the standard identified in §§ 422.164(e) and 423.184(e) of this chapter.

(e) *Updating existing mandatory measures*. CMS will modify the existing mandatory measures that undergo measure technical specifications updates as follows—

(1) *Non-substantive updates*. CMS will update changes to the technical specifications for a measure made by the measure steward; such changes will be in the technical resource manual issued under paragraph (f) of this section and § 438.530. Examples of non-substantive updates include, but are not limited to, those that:

(i) Narrow the denominator or population covered by the measure.

(ii) Do not meaningfully impact the numerator or denominator of the measure.

(iii) Update the clinical codes with no change in the target population or the intent of the measure.

(iv) Provide additional clarifications such as:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(D) Adding alternative data sources or expanding of modes of data collection to calculate a measure.

(2) *Substantive updates*. CMS may adopt substantive updates to a mandatory measure not subject to paragraph (e)(1)(i) through (iv) of this section only after following the process specified in paragraph (b) of this section.

(f) *Finalization and display of mandatory measures and updates.* CMS will finalize modifications to the mandatory measure set and the timeline for State implementation of such modifications in the technical resource manual. For new or substantively updated measures,

CMS will provide each State with at least 2 calendar years from the start of the measurement year immediately following the release of the annual technical resource manual in which the modification to the mandatory measure set is finalized to display measurement results and ratings using the new or updated measure(s).

§ 438.515 Medicaid managed care quality rating system methodology.

(a) For each measurement year, the State—

(1) Must collect the data necessary to calculate quality ratings for each quality measure described in § 438.510(a) of this subpart from:

(i) The State's contracted managed care plans that have 500 or more enrollees from the State's Medicaid program on July 1 of the measurement year; and

(ii) Sources of Medicare data (including Medicare Advantage plans, Medicare providers, and CMS), the State's Medicaid fee-for-service providers, or both if all data necessary to calculate a measure cannot be provided by the managed care plans described in paragraph (a)(1) of this section and such data are available for collection by the State without undue burden.

(2) Must ensure that all data collected under paragraph (a)(1) of this section are validated.

(3) Must use the validated data described in paragraph (a)(2) of this section and the methodology described in paragraph (b) of this section to calculate for each quality measure described in § 438.510(a) of this subpart, a measure performance rate for each managed care plan whose contract includes a service or action assessed by the measure, as determined by the State.

(4) Must issue quality ratings to each managed care plan for each measure calculated for the plan under paragraph (a)(3) of this section.

(b) Subject to § 438.525, the State must ensure that the quality ratings issued under paragraph (a)(4) of this section:

(1) Include data for all enrollees who receive coverage through the managed care plan for a service or action for which data are necessary to calculate the quality rating for the managed

care plan, including data for enrollees who are dually eligible for both Medicare and Medicaid, subject to the availability of data under paragraph (a)(1)(ii) of this section.

(2) Are issued to each managed care plan at the plan level, by managed care program, so that a plan participating in multiple managed care programs is issued distinct ratings for each program in which it participates resulting in quality ratings that are representative of services provided only to those beneficiaries enrolled in the plan through the rated program.

(c) After engaging with States, beneficiaries, and other interested parties, CMS will propose to implement domain-level quality ratings, including care domains for which States would be required to calculate and assign domain-level quality ratings for managed care plans, a methodology to calculate such ratings, and website display requirements for displaying such ratings on the MAC QRS website display described in § 438.520.

§ 438.520 Website display.

(a) In a manner that complies with the accessibility standards outlined in § 438.10(d) of this part and in a form and manner specified by CMS, the State must prominently display on the website required under § 438.10(c)(3):

(1) Information necessary for users to understand and navigate the contents of the QRS website display, including:

(i) A statement of the purpose of the Medicaid managed care quality rating system, relevant information on Medicaid, CHIP and Medicare and an overview of how to use the information available in the display to select a quality managed care plan;

(ii) Information on how to access the beneficiary support system described in § 438.71 to answer questions about using the State's managed care quality rating system to select a managed care plan; and

(iii) If users must input user-specific information to access or use the QRS, an explanation of why the information is requested, how it will be used, and whether it is optional or required.

(2) Information that allows beneficiaries to identify managed care plans available to them that align with their coverage needs and preferences including:

(i) All available managed care programs and plans for which a user may be eligible based on the user's age, geographic location, and dually eligible status, if applicable, as well as other demographic data identified by CMS;

(ii) A description of the drug coverage for each managed care plan, including the formulary information specified in § 438.10(i) and other similar information as specified by CMS;

(iii) Provider directory information for each managed care plan including all information required by § 438.10(h)(1) and (2) and such other provider information as specified by CMS;

(iv) Quality ratings described at § 438.515(a)(4) that are calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS in the technical resource manual, and

(v) The quality ratings described in § 438.520(a)(2)(iv) calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, stratified by dual eligibility status, race and ethnicity, and sex.

(3) Standardized information identified by CMS that allows users to compare available managed care plans and programs, including:

(i) The name of each managed care plan;

(ii) An internet hyperlink to each managed care plan's website and each available managed care plan's toll-free customer service telephone number;

(iii) Premium and cost-sharing information including differences in premium and cost-sharing among available managed care plans within a single program;

(iv) A summary of benefits including differences in benefits among available managed care plans within a single program;

(v) Certain metrics, as specified by CMS, of managed care plan performance that States must make available to the public under subparts B and D of this part, including data most recently reported to CMS on each managed care program pursuant to § 438.66(e) of this part and the results of the secret shopper survey specified in § 438.68(f) of this part;

(vi) If a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D-SNP (as those terms are defined in § 422.2 of this chapter), an indication that an integrated plan is available and a link to the integrated plan's most recent rating under the Medicare Advantage and Part D 5-Star Rating System.

(4) Information on quality ratings displayed in accordance with paragraph (a)(2)(iv) of this section in a manner that promotes beneficiary understanding of and trust in the ratings, including:

(i) A plain language description of the importance and impact of each quality measure assigned a quality rating;

(ii) The measurement period during which the data used to calculate the quality rating was produced; and

(iii) Information on quality ratings data validation, including a plain language description of when, how and by whom the data were validated.

(5) Information or hyperlinks directing users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan.

(6) By a date specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in § 438.505:

(i) A search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user;

(ii) A search tool that enables users to identify available managed care plans that include a provider identified by the user in the plan's network of providers; and

(iii) The quality ratings described in § 438.520(a)(iv) calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, including the display of such measures stratified by dual eligibility status, race and ethnicity, sex, age, rural/urban status, disability, language of the enrollee, or other factors specified by CMS in the annual technical resource manual.

(iv) An interactive tool that enables users to view the quality ratings described at § 438.520(a)(iv), stratified by the factors described in paragraph (a)(6)(iii) of this section.

(b) If the State chooses to display quality ratings for additional measures not included in the mandatory measures set described in § 438.510(a), the State must:

(1) Obtain input on the additional measures, prior to their use, from prospective users, including beneficiaries, caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy; and

(2) Document the input received from prospective users required under paragraph (b)(1) of this section, including modifications made to the additional measure(s) in response to the input and rationale for input not accepted.

(c) CMS will periodically consult with States and interested parties including Medicaid managed care quality rating system users to evaluate the website display requirements described in this section for continued alignment with beneficiary preferences and values.

§ 438.525 Alternative quality rating system.

(a) A State may implement an alternative Medicaid managed care quality rating system that applies an alternative methodology from that described in § 438.510(a)(3) provided that—

(1) The alternative quality rating system includes the mandatory measures identified by CMS under § 438.510(a)(1);

(2) The ratings generated by the alternative quality rating system yield information regarding managed care plan performance which, to the extent feasible, is substantially

comparable to that yielded by the methodology described in § 438.515, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

(3) The State receives CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(b) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(1) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and

(2) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(c) To receive CMS approval for an alternative quality rating system, a State must:

(1) Submit a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS in a form and manner and by a date determined by CMS; and

(2) Include the following in the State’s request for or modification of an alternative quality rating system:

(i) The alternative methodology to be used in generating plan ratings;

(ii) Documentation of the public comment process specified in paragraph (b)(1) and (2) this section, including discussion of the issues raised by the Medical Care Advisory Committee and any policy revisions or modifications made in response to the comments and rationale for comments not accepted;

(iii) Other information or documentation specified by CMS to demonstrate compliance with paragraph (a) of this section; and

(iv) Other supporting documents and evidence that the State believes demonstrates compliance with the requirements of (a)(2) of this section.

§ 438.530 Annual technical resource manual.

(a) No later than August 1, 2025, CMS will publish a Medicaid managed care quality rating system technical resource manual, and update it annually thereafter. The technical resource manual must include all of the following:

(1) Identification of all Medicaid managed care quality rating system measures, including:

(i) A list of the mandatory measures; and

(ii) Any measures newly added or removed from the prior year's mandatory measure set.

(iii) The subset of mandatory measures that must be displayed and stratified by factors such as race and ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the CMS in accordance with §§ 438.520(a)(2)(iv) and 438.520(a)(6)(iii).

(2) Guidance on the application of the methodology used to calculate and issue quality ratings as described in § 438.515.

(3) Measure steward technical specifications for mandatory measures.

(4) A summary of interested party engagement and public comments received during the public notice and comment process described in § 438.510(b) using the process identified in § 438.510(c) for the most recent modifications to the mandatory measure set including:

(i) Discussion of the feedback and recommendations received on potential modifications to mandatory measures;

(ii) The final modifications and the timeline by which such modifications must be implemented; and

(iii) The rationale for not accepting or implementing specific recommendations or feedback submitted during the consultation process.

(b) In developing and issuing the manual content described in paragraphs (a)(1) and (2) of this section, CMS will take into account whether stratification is currently required by the measure steward or other CMS programs and by which factors when issuing guidance that identifies which measures, and by which factors, States must stratify mandatory measures.

§ 438.535 Reporting.

(a) Upon CMS' request, but no more frequently than annually, the State must submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. Such report must include:

(1) A list of all mandatory measures displayed as required under § 438.520(a)(1)(i) and any additional measures the State chooses to include in the Medicaid managed care quality rating system as permitted under § 438.510(a).

(2) An attestation that all displayed quality ratings for mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate ratings for any additional measures, if such methodology deviates from the methodology in § 438.515.

(3) The documentation required under § 438.520(b)(2), if including additional measures in the State's Medicaid managed care quality rating system in accordance with § 438.520(c)(3).

(4) The date on which the State publishes or updates the quality ratings for the State's managed care plans.

(5) A link to the State's website for their Medicaid managed care quality rating system.

(6) The application of any technical specification adjustments used to calculate and issue quality ratings described in § 438.515(a)(3) and (4), at the plan- or State-level, that are outside a measure steward's allowable adjustments for a mandatory measure but that the measure steward has approved for use by the State.

(7) A summary of each alternative QRS approved by CMS, including the effective dates for each approved alternative QRS.

(b) States will be given no less than 90 days to submit such a report to CMS on their Medicaid managed care quality rating system.

29. Amend § 438.602 by adding paragraphs (g)(5) through (13) and (j) to read as follows:

§ 438.602 State responsibilities.

* * * * *

(g) * * *

(5) Enrollee handbooks, provider directories, and formularies required at § 438.10(g), (h), and (i).

(6) The information on rate ranges required at § 438.4(c)(2)(iv), if applicable.

(7) The reports required at § 438.66(e) and § 438.207(d).

(8) The network adequacy standards required at § 438.68(b)(1) through (2) and (e).

(9) The results of secret shopper surveys required at § 438.68(f).

(10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C).

(11) Information on all required Application Programming Interfaces including as specified in § 431.60(d) and (f).

(12) Quality related information as required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i).

(13) Documentation of compliance with requirements in Subpart K - Parity in Mental Health and Substance Use Disorder Benefits.

* * * * *

(j) *Applicability*. Paragraphs (g)(5) through (13) apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after [EFFECTIVE DATE OF THE FINAL RULE].

30. Amend § 438.608 by revising paragraphs (a)(2) and (d)(3) and adding paragraph (e) to read as follows:

§ 438.608 Program integrity requirements under the contract.

(a) * * *

(2) Provision for reporting within 10 business days all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

* * * * *

(d) * * *

(3) Each MCO, PIHP, or PAHP must report annually to the State on all overpayments identified or recovered.

* * * * *

(e) *Standards for provider incentive or bonus arrangements*. The State, through its contract with the MCO, PIHP or PAHP, must require that incentive payment contracts between managed care plans and network providers meet the requirements as specified in §§ 438.3(i)(3) and (4).

PART 457 - ALLOTMENTS AND GRANTS TO STATES

31. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

32. Amend § 457.10 by adding the definition of "In lieu of service or setting (ILOS)" in alphabetical order to read as follows:

§ 457.10 Definitions and use of terms.

* * * * *

In lieu of service or setting (ILOS) is defined as provided in § 438.2 of this chapter.

* * * * *

33. Amend § 457.1200 by adding paragraph (d) to read as follows:

§ 457.1200 Basis, scope, and applicability.

* * * * *

(d) *Applicability dates.* States must comply with the requirements of this subpart by the dates established at §§ 438.3(v), 438.16(f), 438.68(h), 438.206(d) and 438.310(d) of this chapter.

34. Amend § 457.1201 by revising paragraphs (c), (e), and (n)(2) to read as follows:

§ 457.1201 Standard contract requirements.

* * * * *

(c) *Payment.* The final capitation rates for all MCO, PIHP or PAHP contracts must be identified and developed, and payment must be made in accordance with §§ 438.3(c) and 438.16(c)(1) through (3) of this chapter, except that the requirement for preapproval of contracts, certifications by an actuary, annual cost reports, contract arrangements described in § 438.6(c), and references to pass through payments do not apply, and contract rates must be submitted to CMS upon request of the Secretary.

* * * * *

(e*) Services that may be covered by an MCO, PIHP, or PAHP.* An MCO, PIHP, or PAHP may cover, for enrollees, services that are not covered under the State plan in accordance with §§ 438.3(e) and 438.16(b), (d), and (e) of this chapter, except that references to § 438.7, IMDs, and rate certifications do not apply and that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part.

* * * * *

(n) * * *

(2) Contracts with PCCMs must comply with the requirements of paragraph (o) of this section; § 457.1207; § 457.1240(b) (cross-referencing § 438.330(b)(2), (b)(3), (c), and (e) of this chapter); § 457.1240(e) (cross-referencing § 438.340 of this chapter).

* * * * *

35. Amend § 457.1203 by revising paragraphs (e) and (f) to read as follows:

§ 457.1203 Rate development standards and medical loss ratio.

* * * * *

(e) The State must comply with the requirements related to medical loss ratios in accordance with the terms of § 438.74 of this chapter, except contract arrangements described in § 438.6(c) do not apply and the description of the reports received from the MCOs, PIHPs and PAHPs under § 438.8(k) of this chapter will be submitted independently, and not with the rate certification described in § 438.7 of this chapter.

(f) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the requirements in § 438.8 of this chapter, except that contract arrangements described in § 438.6(c) do not apply.

36. Revise § 457.1207 to read as follows:

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM, and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter, except that the terms of § 438.10(c)(2), (g)(2)(xi)(E), and (g)(2)(xii) of this chapter do not apply and that references to enrollee rights and protections under part 438 should be read to refer to the rights and protections under subparts K and L of this part. The State must annually post comparative summary results of enrollee experience surveys by managed care plan on the State's website as described at § 438.10(c)(3) of this chapter.

37. Amend § 457.1230 by revising paragraph (b) to read as follows:

§ 457.1230 Access standards.

* * * * *

(b) *Assurances of adequate capacity and services*. The State must ensure, through its contracts, that each MCO, PIHP and PAHP has adequate capacity to serve the expected enrollment in accordance with the terms of § 438.207 of this chapter, except that the reporting requirements in § 438.207(d)(3)(i) of this chapter do not apply. The State must evaluate the most recent annual enrollee experience survey results as required at section 2108(e)(4) of the Act as part of the State's analysis of network adequacy as described at § 438.207(d) of this chapter.

* * * * *

38. Amend § 457.1240 by revising paragraphs (d) and (f) to read as follows:

§ 457.1240 Quality measurement and improvement.

* * * * *

(d) *Managed care quality rating system*. The State must determine a quality rating or ratings for each MCO, PIHP, and PAHP in accordance with the requirements set forth subpart G of part 438 of this chapter, except that references to dually eligible beneficiaries, a beneficiary support system, and the terms of § 438.525(b)(1) and (c)(2)(ii) of this chapter related to consultation with the Medical Care Advisory Committee do not apply.

* * * * *

(f) *Applicability to PCCM entities.* For purposes of paragraphs (b) and (e) of this section, a PCCM entity described in this paragraph is a PCCM entity whose contract with the State provides for shared savings, incentive payments or other financial reward for improved quality outcomes.

39. Amend § 457.1250 by revising paragraph (a) to read as follows:

§ 457.1250 External quality review.

(a) Each State that contracts with MCOs, PIHPs, or PAHPs must follow all applicable external quality review requirements as set forth in §§ 438.350 (except for references to § 438.362), 438.352, 438.354, 438.356, 438.358 (except for references to § 438.6), 438.360 (only with respect to nonduplication of EQR activities with private accreditation) and 438.364 of this chapter.

* * * * *

40. Revise § 457.1285 to read as follows:

§ 457.1285 Program integrity safeguards.

The State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2), 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Dated: April 24, 2023.

Xavier Becerra,

Secretary,

Department of Health and Human Services

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