

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 430, 438, and 457**

[CMS–2439–F]

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: Final rule.

SUMMARY: This final rule will advance CMS’s 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 final rule addresses standards for timely access to care and States’ monitoring and enforcement efforts, reduces State burdens for implementing some State directed payments (SDPs) and certain quality

reporting requirements, adds new standards that will apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and that specify the scope and nature of ILOSs, specifies medical loss ratio (MLR) requirements, and establishes a quality rating system for Medicaid and CHIP managed care plans.

DATES:

Effective Dates: These regulations are effective on July 9, 2024.

Applicability Dates: In the **SUPPLEMENTAL INFORMATION** section of this final rule, we provide a table (Table 1), which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

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SUPPLEMENTARY INFORMATION:**Applicability and Compliance Timeframes**

States are required to comply by the effective date of the final rule or as otherwise specified in regulation text.

States will not be held out of compliance with the changes adopted in this final rule until the applicability date indicated in regulation text for each provision so long as they comply with the corresponding standard(s) in 42 CFR parts 438 and 457 contained in the 42 CFR, parts 430 to 481, effective as of October 1, 2023. The following is a summary of the applicability dates in this final rule:

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TABLE 1: Applicability Dates

| Regulation Text | Applicability Date |
|---|--|
| §§ 438.6(c)(2)(iii); 438.6(c)(2)(vi)(B); 438.6(c)(2)(vi)(C)(I) and (2) | Applicable for the first rating period beginning on or after July 9, 2024. |
| §§ 438.3(e)(2)(v); 438.7(b)(6); 438.16; 457.1201(c) and (e) | Applicable for the first rating period beginning on or after September 9, 2024. |
| §§ 438.340(c)(1) and (c)(3); 438.340(c)(2)(ii); 457.1240(e) | Applicable no later than July 9, 2025. |
| §§ 438.3(i)(3) and (4); 438.207(d)(3); 438.608(a)(2) and (d)(3); 438.608(e); 457.1201(h); 457.1285 | Applicable for the first rating period beginning on or after July 9, 2025. |
| §§ 457.1207; 457.1230(b) | Applicable no later than July 9, 2026. |
| §§ 438.6(c)(2)(vi)(C)(3) and (4); 438.6(c)(2)(viii); 438.6(c)(5)(i) through (iv); 438.10(c)(3); 438.68(d)(1)(iii); 438.68(d)(2); 438.207(b)(3) and (d)(2); 438.602(g)(5)-(13); 457.1207 (transparency provisions); 457.1218 (network adequacy standards); 457.1230(b); 457.1285 (transparency). | Applicable for the first rating period beginning on or after July 9, 2026. |
| §§ 438.6(c)(2)(ii)(D); 438.6(c)(2)(ii)(F); 438.6(c)(2)(iv); 438.6(c)(2)(v); 438.6(c)(2)(vii); 438.6(c)(6); 438.6(c)(7); 438.10(d)(2); 438.66(b)(4), 438.66(c)(5); 438.66(e)(2)(vii); 438.68(b)(1); 438.68(e); 438.68(g); 438.206(c)(1)(i); 457.1207 (secret shopper surveys criteria); 457.1218 (qualitative standard, appointment wait time standards, and publication of network adequacy standards provisions); 457.1230(a). | Applicable for the first rating period beginning on or after July 9, 2027. |
| §§ 438.6(c)(5)(v); 438.7(c)(6); 438.10(h)(3)(iii); 438.68(f); 438.207(e) and (f); 457.1207 (information from secret shopper surveys on provider directories); 457.1218 (secret shopper surveys); 457.1230(b). | Applicable for the first rating period beginning on or after July 10, 2028 |
| §§ 438.10(h)(1); 438.10(h)(1)(ix); 457.1207 (electronic provider directories) | Applicable on July 1, 2025. |
| §§ 438.358(a)(3); 438.358(b)(1); 438.364(c)(2)(iii); 457.1250(a) (EQR archiving requirement) | Applicable on December 31, 2025. |
| §§ 438.364(a)(2)(iii); 457.1250(a) (EQR information) | Applicable no later than 1 year after the issuance of the associated protocol. |
| § 438.6(c)(4) | Applicable by the first rating period beginning on or after the release of reporting instructions. |

| Regulation Text | Applicability Date |
|---|---|
| §§ 438.505(a)(1); 457.1240(d) | Applicable by the end of the fourth calendar year following [inset the effective date of the final rule]. |
| §§ 438.520(a)(6); 457.1240(d) (QRS website display) | Applicable 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 §§ 438.520(a)(6); 457.1240(d) (QRS website display). |
| § 438.6(c)(2)(ii)(H) | Applicable by the first rating period beginning on or after January 1, 2028. |
| § 457.1200(d) | See applicability dates at 438.3(v), 438.10(j), 438.16(f), 438.68(h), 438.206(d), 438.207(g), 438.310(d), 438.505(a)(2), 438.602(j), and 438.608(f). |

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I. Medicaid and CHIP Managed Care**A. Background**

As of September 2023, the Medicaid program provided essential health care coverage to more than 88 million¹ individuals, and, in 2021, had annual outlays of more than \$805 billion. In 2021, the Medicaid program accounted for 18 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 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 2021, 74.6 percent⁶ of Medicaid beneficiaries were enrolled in comprehensive managed care plans; the remaining individuals received all or some services 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 high-quality 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 CHIP payments are sufficient to enlist enough providers. Some of the most common feedback we received through the RFI related to 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 knows if they are or may be eligible for Medicaid, is aware of Medicaid coverage options, and is 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. 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, Marketplace 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, Enrollment, and*

¹ September 2023 Medicaid and CHIP Enrollment Snapshot. Accessed at <http://www.medicaid.gov/sites/default/files/2023-10/september-2023-medicaid-chip-enrollment-trend-snapshot.pdf>.

² CMS National Health Expenditure Fact Sheet. Accessed at <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet>.

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/hiv/aids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/>.

⁶ <https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html>.

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>.

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, or the Basic Health Program (BHP).⁸ This rule was finalized on March 27, 2024.⁹

The third dimension is access to services and supports and was addressed in a proposed rule published on May 3, 2023 (88 FR 28092); we are finalizing it in this final rule. This final 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.¹⁰

In addition to the three above referenced rulemakings (the Streamlining Eligibility & Enrollment proposed rule, this final rule on managed care, and the Ensuring Access to Medicaid Services proposed rule), we are also engaged in non-regulatory activities to improve access to health care services across Medicaid delivery systems. Examples of these activities include best practices toolkits and other resources for States, such as the “Increasing Access, Quality, and Equity in Postpartum Care in Medicaid and CHIP” Toolkit¹¹ and direct technical assistance to States through learning collaboratives, affinity groups and individual coaching to implement best practices, including the Infant Well-Child Learning Collaborative¹² and the Foster Care Learning Collaborative.¹³ 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 final rule, and this final rule involving managed care, we outline additional steps to address the third dimension of the health care access continuum: access to services. This rule also addresses quality and financing of services in the managed care context. We sought to address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all its delivery systems.

The volume of Medicaid beneficiaries enrolled in a managed care program in Medicaid has grown from 81 percent in 2016 to 85 percent in 2021, with 74.6 percent of Medicaid beneficiaries enrolled in comprehensive managed care organizations in 2021.¹⁴ 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 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 may employ a managed care delivery system as long as such coverage meets the requirements of section 2103 of the Act. Specific statutory references to managed care programs are set out at sections 2103(f)(3) and 2107(e)(1)(N) and (R) of the Act, which apply specific provisions of sections 1903 and 1932 of the Act related to Medicaid managed care to separate CHIPs. States that elect Medicaid expansion CHIPs that operate within a managed care delivery system

⁸ We finalized several provisions from the proposed rule in a September 2023 *Federal Register* publication entitled *Streamlining Medicaid; Medicare Savings Program Eligibility Determination and Enrollment*. See 88 FR 65230.

⁹ <https://www.federalregister.gov/public-inspection/2024-06566/medicaid-program-streamlining-the-medicaid-childrens-health-insurance-program-and-basic-health>.

¹⁰ Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. “Proposed Medicaid Access Measurement and Monitoring Plan.” Washington, DC: The Urban Institute. August 2016. Accessed at <https://www.medicaid.gov/sites/default/files/2019-12/monitoring-plan.pdf>.

¹¹ <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/postpartum-care/index.html>.

¹² <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/well-child-care/index.html>.

¹³ <https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/foster-care-learning-collaborative/index.html>.

¹⁴ <https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html>.

are subject to 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.

On July 29, 2016, we published the CMCS Informational Bulletin (CIB) concerning “The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems.”¹⁵ 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 2017 final rule, we finalized changes to the transition periods for pass-through payments. Pass-through payments are defined 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. The 2017 final rule codified the information in the CIB and gave States the option to eliminate physician and nursing facility payments immediately or phase down these pass-through 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 (E.O.) 14009, *Strengthening Medicaid and the Affordable Care Act*, was signed establishing 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. It directed executive departments and agencies to review existing regulations, orders, guidance documents, policies, and any other similar agency actions to determine whether such agency actions are inconsistent with this policy. On April 25, 2022, Executive Order 14070, *Continuing To Strengthen Americans’ Access to Affordable, Quality Health Coverage*, was signed directing 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 final 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.

This rule finalizes new standards to help States improve their monitoring of access to care by requiring the 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 monitor plans’ network adequacy more closely. It finalizes standards that will apply when States use in lieu of services and settings to promote effective utilization and that specify the scope and nature of these services and settings. It also finalizes provisions that 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 (known as State directed payments), enhance quality, fiscal and program integrity of State directed payments, 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 finalizes State website requirements for content and ease of use. Lastly, this final rule will make quality reporting more transparent and meaningful for driving quality improvement, reduce burden of 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 final rule. Medicaid and CHIP provided coverage for nearly 55 million people from racial and ethnic minority backgrounds in 2020. In 2020, Medicaid enrollees were also more likely to live in a rural community and over ten percent of enrollees spoke a

¹⁵ <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib072916.pdf>.

primary language other than English, while approximately eleven percent qualified for benefits based on disability status.¹⁶ Consistent with Executive Order 13985¹⁷ *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, 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 2022–2032¹⁸ and the HHS Equity Action Plan.¹⁹ 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, age, rural/urban status, disability, language, sex, sexual orientation, and gender identity, as well as social determinants of health (SDOH).

The “Medicaid Program and CHIP; Mandatory Medicaid and Children’s Health Insurance Program (CHIP) Core Set Reporting” final rule (hereinafter referred to as the “Mandatory Medicaid and CHIP Core Set Reporting final rule”) was published in the August 31, 2023 **Federal Register** (88 FR 60278). In that rule, we finalized 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 will 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 finalized a phased-in timeline for stratification of measures in these Core Sets. In the Medicaid Program; Ensuring Access to Medicaid Services final rule, published elsewhere in the **Federal Register**, we also finalized 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 our approach to advancing health equity and aligning with the CMS Strategic Priorities.²⁰ In this final rule, we establish our intent to align with the stratification factors required for Core Set measure reporting, which we believe will minimize State and managed care plan burden to report stratified measures. To further reduce burden on States, we will permit States to report using the same measurement and stratification methodologies and classifications as those in the Mandatory Medicaid and CHIP Core Set Reporting final rule and the Ensuring Access to Medicaid Services final rule. We believe these measures and methodologies are appropriate to include in States’ Managed Care Program Annual Report (MCPAR) because § 438.66(e)(2) requires information on and an assessment of the operation of each managed care program, including an evaluation of managed care plan performance on quality measures. Reporting these measures in the 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 anticipate publishing additional subregulatory guidance and adding specific fields in MCPAR to accommodate this measure and data stratification reporting to simplify the process for States.

Finally, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

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

For convenience, 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, which is a subset of what is ordinarily included under the term PAHP. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it is specifically identified 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) (as defined above) and is used only when the provision under discussion applies to all three arrangements. An explicit reference is used in the preamble if the provision applies to primary care case managers (PCCMs) or PCCM entities.

For CHIP, the preamble uses “CHIP” when referring collectively to separate child health programs and title XXI 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. In this final rule, all proposed changes to Medicaid managed care regulations are equally applicable to title XXI Medicaid expansion managed care programs as described at § 457.1200(c).

We received a total of 415 timely comments from State Medicaid and CHIP agencies, advocacy groups, health care providers and associations, health insurers, managed care plans, health care associations, and the general public. The following sections, arranged by subject area, include a summary of the comments we received and our responses to those comments. In response to the May 3, 2023 proposed rule, some commenters chose to raise issues that were beyond the scope of our proposals. In this final rule, we are not summarizing or responding to those comments.

¹⁶ CMS Releases Data Briefs That Provide Key Medicaid Demographic Data for the First Time, <https://www.cms.gov/blog/cms-releases-data-briefs-provide-key-medicare-demographic-data-first-time>.

¹⁷ Executive Order 13985, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-or-underserved-communities-through-the-federal-government/>.

¹⁸ CMS Framework for Health Equity 2022–2032: <https://www.cms.gov/files/document/cmsframework-health-equity.pdf>.

¹⁹ HHS Equity Action Plan, <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf>.

²⁰ CMS Strategic Plan 2022, <https://www.cms.gov/cms-strategic-plan>.

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, and 457.1285)

a. Enrollee Experience Surveys (§§ 438.66(b), 438.66(c), 457.1230(b) and 457.1207)

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 are 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 (MA) organizations, is the Consumer Assessment of Healthcare Providers and Systems (CAHPS®).²¹

CAHPS experience surveys are available for health plans, dental plans, and HCBS programs, as well as for patient experience with providers such as home health, condition specific care such as behavioral health, or facility-based care such as in a hospital. Surveys specially designed to measure the impact of LTSS on the quality of life and outcomes of enrollees are the National Core Indicators-Aging and Disabilities (NCI-AD®) Adult Consumer Survey™²² and the National Core Indicators—Intellectual and Developmental Disabilities (NCI-I/DD). 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 proposed to revise § 438.66(b)(4) to explicitly include "enrollee experience" as something that must be addressed under a State's managed care monitoring system. 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 proposed to revise § 438.66(c)(5) to require that States conduct an annual enrollee experience survey. To reflect this, we proposed to revise § 438.66(c)(5) to add "an annual" before "enrollee" and add "experience survey conducted by the State" after "enrollee." We also proposed 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 did not propose to mandate them at this time. We believe other proposals in the proposed rule, such as enrollee surveys and secret shopper surveys, may yield information that will inform our decision on the use of provider surveys in the future. We invited 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.

To reflect these proposals in MCPAR requirements at § 438.66(e), we proposed conforming edits in § 438.66(e)(2)(vii). We proposed 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.g. of this final rule, we proposed 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 will 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 proposed to add enrollee experience surveys as a document subject to the requirements in § 438.10(d)(2). This will ensure that enrollees that receive a State's enrollee experience survey will be fully notified that oral interpretation in any language and written translation in the State's prevalent languages will 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 each managed care organization to demonstrate adequate capacity and services by providing assurances to the State and CMS that they have the capacity to serve the expected enrollment in their service area, including assurances that they offer 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 maintain 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

²¹ The acronym "CAHPS" is a registered trademark of the Agency for Healthcare Research and Quality.

²² NCI-AD Adult Consumer Survey™ is a copyrighted tool.

regulations based on our authority under section 1902(a)(4) of the Act. Because enrollee experience survey results will 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 they provide a sufficient number, mix, and geographic distribution of providers to meet their enrollees' needs. Enrollee experience survey data will enable managed care plans to assess whether their networks are providing sufficient capacity as experienced by their enrollees and that assessment will 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 will 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 will also inform the development and maintenance of States' quality assessment and improvement strategies and will 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 requested 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 proposed 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 proposed this applicability date in § 438.66(f).

Since we did not adopt MCPAR for separate CHIPs, 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 believed 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 proposed 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 will likely not need the same timeframe to implement as needed for implementing the proposed Medicaid enrollee experience surveys requirement, we proposed 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 invited 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 proposed 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 sought 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.

We summarize and respond to public comments received on Enrollee experience surveys (§§ 438.66(b) and (c), and 457.1230(b)) below.

Comment: We received many supportive comments on our proposal for States to conduct an annual enrollee experience survey. Commenters agreed that enrollees are often the best source of information about their care and best able to provide insights about how to improve the quality of the care they receive. Many commenters were particularly supportive of requiring written survey materials to comply with the interpretation, translation, and tagline criteria in § 438.10(d)(2) so that surveys are fully accessible and easy to read and understand. Many commenters also supported reporting the results in the MCPAR and requiring States to post them on their website within 30 days of submission.

Response: We appreciate the comments in support of our proposal for annual enrollee surveys and the applicability of § 438.10(d)(2) to facilitate participation by enrollees that require reasonable accommodations and interpretation or translation. We believe this will be critical to helping enrollees respond to the surveys and produce more robust and actionable results. We also appreciate the confirmation that including the survey results in the MCPAR and posting them on the State's website timely is the best option to make the results consistently presented and available.

Comment: A few commenters encouraged CMS to require States to include a representative sample of enrollees who are dually eligible for Medicaid and Medicare, in marginalized populations, or had chronic conditions in the experience surveys and require that results be disaggregated by population and other key demographics. Several commenters recommended that we ensure that surveys are not too long, the questions are not too complex, and that the survey is distributed and available in multiple ways (mailing, phone, or email).

Response: We thank commenters for these thoughtful suggestions and encourage States to utilize them to improve the comprehensiveness and utility of the survey results. We may consider some of these suggestions in future rulemaking.

Comment: Some commenters stated that the proposed annual enrollee

experience survey would be duplicative of other surveys currently done by States and would contribute to enrollee survey fatigue. Commenters offered several suggestions, including not requiring an annual survey and letting States choose the cadence, as well as aligning Medicare and Medicaid surveys particularly for aligned plans. One commenter suggested that States be permitted to use surveys administered by their managed care plans while another recommended that States use independent survey vendors.

Response: We understand commenters' concerns about survey fatigue for enrollees and the downward impact that could have on response rates. After considering the comments, we are finalizing § 438.66(c)(5) with an exemption for Medicaid managed care plans in which all enrollees are enrolled in a Medicare Advantage (MA) dual eligible special needs plan (D-SNP) subject to the condition in § 422.107(e)(1)(i). In such circumstances, we already require annual CAHPS surveys for enrollees in D-SNPs, and all enrollees sampled for the CAHPS survey would be dually eligible individuals within the same State. Where States choose not to conduct an experience survey based on this exemption, the requirement still applies at § 438.66(c) that States use data to improve the performance of their Medicaid managed care programs, but when all enrollees are enrolled in a D-SNP subject to the condition in § 422.107(e)(1)(i), the data on enrollee experiences would come from the D-SNP's CAHPS results. States can require through the State Medicaid agency contract at § 422.107 that D-SNPs share CAHPS results with the State.

Allowing States to utilize existing annual experience surveys will reduce the risk of survey fatigue and enable the collection of annual experience surveys without placing an unreasonable demand on enrollees.

Comment: Some commenters encouraged CMS to also require States to survey providers as part of their annual surveying process to provide accurate information on root-cause analyses for issues with access. Commenters suggested the creation and administration of a family caregiver experience survey, the inclusion of questions directly related to mental health access or preferences for in-person services vs. telehealth services, and population specific surveys. A commenter recommended that CMS specify that the survey instrument must assess MCO performance for customer service, provider access, availability of benefits, any out-of-pocket cost burden,

and the availability of language services and disability accommodations.

Response: We thank commenters for these suggestions and encourage States to consider including these in their monitoring and oversight strategy. Provider surveys, while not required at this time, can be a rich source of information on managed care plan performance on topics that enrollees cannot provide. We encourage States to use robust provider surveys as a complement to enrollee surveys to capture a comprehensive view of the operations of their managed care programs. We believe the additional topic areas or surveys suggested by commenters would enable States to collect new types of information to better inform their monitoring and oversight activities.

Comment: Some commenters recommended that CMS mandate a specific survey instrument such as CAHPS® while some other commenters stated that CMS should not specify a survey instrument and give States the flexibility to use surveys that capture the topic areas most relevant to their programs. Others recommended requiring CAHPS to reduce burden and improve comparability, although some commenters noted increasing concerns with low response rates to CAHPS surveys. Some commenters noted that many States have been doing experience surveys for years and have refined their questions over time to gather the most valuable and needed data. A few commenters suggested that, at a minimum, CMS should define characteristics of an acceptable survey or develop evidence-based questions that States can use in their surveys. A few commenters stated that given the prevalent and successful adoption of National Core Indicators®—Intellectual and Developmental Disabilities (NCI-I/DD) and National Core Indicators—Aging and Disabilities (NCI-AD™), CMS should align expectations for the experience of care surveys for managed care with the approved HCBS measure set, including NCI. One commenter requested that CMS provide technical guidance on the sample methodology, targets for the consumer satisfaction index, and the baseline template for an enrollee experience survey.

Response: While we understand the concern about comparability among States, we believe that States capturing information that is specific to their programs and populations is critical for these surveys to inform the development and execution of effective monitoring and oversight activities. We expect that enrollee survey responses that are detailed and specific will be

more likely to be utilized by States to make program improvements as required in § 438.66(c). Standardized surveys such as CAHPS, NCI-I/DD, and NCI-AD may be sufficient for monitoring, oversight, and quality improvement activities of some programs, but not others, such as those with a narrow set of populations or benefits. As such, we believe we should allow States to select the enrollee experience survey that will best aid in their monitoring, oversight, and quality improvement activities. At this time, we do not believe we should define minimum survey characteristics or satisfaction index, develop evidence-based questions, or provide a template. Rather, we will monitor implementation of this requirement and may propose to revise § 438.66 to include this type of detail in future rulemaking.

Furthermore, the MAC QRS as specified in § 438.510, is requiring the full CAHPS Health Plan survey (both Adult and Child Surveys) in the initial mandatory measure set for the plans included in the MAC QRS. (See section I.B.6.e.) The CAHPS survey in the MAC QRS is a standardized instrument through which beneficiaries provide information about their experience with their managed care plan. The MAC QRS itself will, once it is implemented by all States that contract with an applicable managed care plan, provide standardized information and quality performance data to support users in comparing enrollee experience data for Medicaid (and/or CHIP) managed care plans available within a State and in making comparisons among plans with similar benefits across States.

Comment: One commenter recommended that States be required to collect enrollees' preferred languages during the Medicaid enrollment process and share it with plans so that enrollee surveys may be administered in the relevant language.

Response: We acknowledge that collecting preferred languages is ideally done at the time of eligibility determination or enrollment. However, applicants are not legally required to provide that information. As such, States and managed care plans should attempt to collect the information whenever they are in contact with an enrollee and store the information in their system so that any information provided to enrollees, including experience surveys, is in their preferred language.

Comment: One commenter requested that States with small percentages of enrollees in managed care be exempted from conducting an enrollee experience survey.

Response: We do not agree that States with small managed care programs should be exempted from conducting an enrollee experience survey. Regardless of the number of enrollees in a program, their direct input is valuable to States and managed care plans to ensure that they are meeting the needs of their covered populations.

Comment: One commenter suggested that States share information gathered from enrollee experience surveys with managed care plans to support continuous improvement in enrollee experiences across all plans.

Response: We agree and, although summary results will be provided by States in their annual MCPARs (which are published on their websites as required in 42 CFR 438.66(e)(3)(i)), we encourage States to share the detailed response data with their plans as soon as they are available. Improving managed care programs and enrollees' experience is a shared responsibility between CMS, the State, and its managed care plans and that is best fulfilled through collaboration and shared goals.

Comment: One commenter suggested that States be permitted to use surveys administered by their managed care plans while another recommended that States use independent survey vendors.

Response: States may elect to use an independent survey vendor; however, we decline to finalize that requirement in this rule to avoid additional burden on States. We will evaluate the results of the enrollee experience surveys and may use that information to inform future policy. We are finalizing § 438.66(c)(5) as a State obligation to facilitate consistency in administration within managed care programs. However, we will evaluate survey results and may revisit this policy in future rulemaking.

Comment: One commenter recommended that enhanced FFP be made available to cover the cost of administering the secret shopper surveys.

Response: We do not have the authority to provide enhanced FFP as the level of FFP available for Medicaid expenditures is specified in statute.

Comment: One commenter supported requiring States to include their most recent CHIP CAHPS survey results in their annual analysis of network adequacy and to post comparative summary results of CAHPS surveys by managed care plan annually on State websites to be applicable 60 days after the effective date of the final rule.

Response: We appreciate the support for our applicability date proposal.

Comment: Many commenters recommended that CMS delay the requirements to post CHIP CAHPS survey results and evaluate network adequacy requirements as described in §§ 457.1207 and 457.1230(b), respectively. The commenters stated concerns about State administrative burden (that is, staff training) and the additional time needed for States to disaggregate Medicaid and CHIP data. Commenters recommended a range of implementation timelines, from 1 to 2 years following the effective date of the final rule. Another commenter noted that they do not believe they will be able to meet the proposed deadline for posting CHIP CAHPS survey results without technical assistance from CMS.

Response: We appreciate the commenters' suggestion to extend the implementation deadline for these provisions and recognize the administrative burden these proposals may put on States. After consideration of the public comments we received, we are finalizing an implementation date of 2 years after the effective date of the final rule for the proposals at §§ 457.1230(b) and 457.1207. We believe extending the implementation date to 2 years following the effective date of the final rule will provide States with adequate time to conduct the network adequacy analysis. As always, we are available to provide technical assistance if needed.

Comment: Many commenters supported our proposal to post CHIP CAHPS survey data. Specifically, one commenter noted MCOs serving Medicaid populations already participate in the CHIP CAHPS survey to capture feedback from enrollees. The commenter noted that they believe that leveraging the CAHPS survey would improve comparability across plans while minimizing the administrative burden on plans to implement a new survey.

Response: We appreciate the robust number of comments in support of our proposal to require posting of comparative CHIP enrollee survey experience information by MCO. We agree that capturing information that is specific to each State's programs and populations is critical to inform the development and execution of effective monitoring and oversight activities.

Comment: One commenter had concerns about the administrative burden of collecting and reporting CHIP enrollee information in CHIP CAHPS surveys because low enrollment may make it challenging for States to collect statistically representative data at the subgroup level. The commenter recommended that States sample a

sufficient number of beneficiaries to ensure survey results are representative while weighing considerations related to cost-effectiveness.

Response: We understand the commenter's concern and acknowledge the administrative burden of collecting and reporting this information. We note that our minimum enrollment threshold policy at 438.515(a)(1)(i) for Medicaid, incorporated into separate CHIP regulations through a cross-reference at § 457.1240(d), requires States to collect data from contracted managed care plans that have 500 or more enrollees. We will provide guidance on when quality ratings should be suppressed due to lower enrollment in the technical resource manual. We believe CHIP CAHPS surveys are an important tool that States, and managed care plans can use to ensure they are meeting the needs of their covered populations regardless of program size.

After consideration of the public comments we received, we are finalizing §§ 438.66(b), and (f), and 457.1230(b) as proposed, except that we are finalizing an implementation date of 2 years after the effective date of the final rule for the proposals at §§ 457.1230(b) and 457.1207. We are also finalizing § 438.66(c)(5) to permit States to use a CAHPS survey as required for Medicare Advantage D-SNPs.

b. Appointment Wait Time Standards (§§ 438.68(e) and 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 noted 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)

Ensuring that it provides timely access to high-quality services in a manner that is equitable and consistent is central to an effective Medicaid and CHIP program. States and managed care plans have sometimes been challenged

to ensure that networks can provide all covered services in a timely manner.²³ During the PHE, managed care plans faced many new 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 have changed the delivery of health care services, requiring States and managed care plans 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 information²⁴ (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 study²⁵ 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 appointment and a 3.3-fold lower likelihood in successfully scheduling a specialty

appointment when compared with private insurance.²⁶

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 proposed a new quantitative network adequacy standard. Specifically, we proposed 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."

At § 438.68(e)(1)(i) through (iv), we proposed 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 included "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 fourth 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 services are likely not covered by a behavioral health PIHP; therefore, a State will not be required to set appointment wait time standards for primary care and OB/GYN providers for the behavioral health PIHP and will only have to set appointment wait time standards for mental health and SUD providers, 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 requested comment on whether behavioral health PIHPs and PAHPs include provider types other than mental health and SUD in their networks. Although we believe behavioral health PIHPs and PAHPs may include other provider types, we wanted to validate our understanding.

We proposed to adopt the proposed wait time standards for separate CHIP through an existing cross-reference at § 457.1218. We proposed primary care, OB/GYN, and mental health and SUD because they are indicators of core population health; therefore, we believe requiring States to set appointment wait time standards for them will have the most impact on access to care for Medicaid and CHIP managed care enrollees.

At § 438.68(e)(1)(iv), we proposed 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 did not propose to specify the type of evidence to be used; 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 will 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 will identify the provider type(s) they choose in existing reporting in MCPAR, per § 438.66(e), and the Network Adequacy and Access Assurances Report (NAAAR), 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 proposed to add ". . . , other than for appointment wait times . . ." in § 438.68(b)(1). We did not propose to define routine appointments in this rule; rather, we defer to States to define it as they deem appropriate. We encouraged States to work with their managed care plans and their network providers to develop a definition of "routine" that will reflect usual patterns of care and current clinical standards. We acknowledged 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 invited comments on defining these terms should we undertake additional rulemaking in the future. We clarified that setting appointment wait time standards for routine appointments as proposed at § 438.68(e)(1) will be a minimum; States are encouraged to set additional appointment wait time standards for other types of

²³ <https://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf>; <https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

²⁴ 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.medicare.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf>.

²⁵ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.01747>.

²⁶ 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>.

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 proposed 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 at § 438.68(e)(1)(i) and no longer than 15 business days for routine primary care at § 438.68(e)(1)(ii) and OB/GYN appointments at § 438.68(e)(1)(iii). We did not propose a maximum appointment wait time standard for the State-selected provider type. These proposed maximum timeframes were informed by standards for individual health insurance coverage offered through Federally-Facilitated Marketplaces (FFMs) established under the Affordable Care Act that will begin in 2025 of 10 business days for behavioral health and 15 business days for primary care services; we noted that we elected not to adopt the FFMs' 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 and CHIP managed care standards. These proposed timeframes were also informed by engagement with interested parties, including comments in response to the RFI. We proposed 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 will 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 SUD, primary care, and OB/GYN appointments. We invited comment on aligning with FFM standards at 10 and 15 business days, or whether wait time standards should differ, and if so, what standards will be the most appropriate.

To make the appointment wait time standards as effective as possible, we deferred 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, we proposed that wait time standards must, at a minimum, reflect the timing proposed in § 438.68(e)(1). We encouraged 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 sought to align across Medicaid managed care, CHIP managed care, the FFMs, and Medicare Advantage (MA) when reasonable to build consistency for individuals who may change coverage over time and to enable more effective and standardized comparison and monitoring across programs. Proposing 90 percent compliance with a 10- and 15-business day maximum appointment wait time standards will be consistent with standards set for qualified health plans (QHPs) on the FFMs for plan year 2025.²⁷ However, we note that for MA, CMS expects MA 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.²⁸

To ensure that managed care plans' contracts reflect their obligation to comply with the appointment wait time standards, we proposed 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 was necessary since our proposal at § 438.68(e)(1) to develop and enforce appointment wait time standards is a State responsibility; this revision to § 438.206(c)(1)(i) will specify the corresponding managed care plan responsibility.

We proposed 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 will 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 12 elements when developing their network adequacy standards. We reminded 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 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.²⁹ 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

²⁷ 45 CFR 156.230(a)(2)(i)(B); Draft 2025 Letter to Issuers in the Federally-facilitated Exchanges, chapter 2, section 3.iii.b, available at <https://www.cms.gov/files/document/2025-draft-letter-issuers-11-15-2023.pdf>.

²⁸ MCM Chapter 4 (www.cms.gov).

²⁹ <https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf>.

their appointment wait time standards. We also reminded States that they have broad flexibility for 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 reminded 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 reminded 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.³⁰

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 proposed 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 website required by § 438.10.” For additional clarity in redesignated § 438.68(g), we proposed 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 proposed that managed care plans will be deemed compliant with the standards established in paragraph (e)(1) when secret shopper results, described in section I.B.1.c. of this final 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 will 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 will 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 will be an effective measure of network adequacy, we believe we needed 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 proposed 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 recognized 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. Prior to this final rule, § 438.68(d) provided that, to the extent a State permitted an exception to any of the provider-specific network standards, the standard by which an exception will 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 proposed 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 proposed 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 will 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 reminded 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 final 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 believed 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 will aid managed care plans as they assess their networks, under § 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

³⁰ U.S. 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>.

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 proposed 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 proposed that States 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 proposed that States 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 proposed that States comply with § 438.68(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).

We summarize and respond to public comments received on appointment wait time standards (§§ 438.68(e) and 457.1218) below.

Comment: Many commenters supported our proposals related to appointment wait time standards in § 438.68(e) for Medicaid, and through cross-reference at § 457.1218 for separate CHIPs, and affirmed that development and enforcement of appointment wait times would contribute to improved access to enrollees.

Response: We appreciate the support for our proposals and believe that appointment wait time standards will complement the quantitative network

adequacy standards already implemented and enrich the data available to States for monitoring access to care.

Comment: Many commenters supported requiring appointment wait time standards but suggested that 10- and 15-business days may not be the appropriate standards. Most commenters that offered alternatives recommended either 30 business days—which is consistent with Medicare Advantage for routine appointments—or 30- and 45-days. A few recommended other maximum timeframes as high as 90 days. Some commenters stated that although aligning Medicaid managed care wait time standards with those of the FFMs seems a reasonable approach given the churn between the programs, the FFMs have not yet implemented the 10- and 15-business day standards so there is no data to verify whether they are realistic. A few commenters noted that they believe that Medicaid standards should not be significantly shorter than the average wait time for physician services in the United States generally. One commenter recommended that CMS collect data to calculate a baseline over a multi-year period and then use that to inform the development of a benchmark for improved access that is both feasible and meaningful.

Response: We appreciate the many comments on our 10- and 15-business day appointment wait time proposal. In developing this proposal, we considered other appointment wait time standards including 30 business days and 45 business days. However, we believe 30 business days and 45 business days as the maximum wait time may be too long as a standard; we understand it may be a realistic timeframe currently for other types of appointments but we were not convinced that they should be the standard for outpatient mental health and SUD, primary care, and OB/GYN appointments as these appointment types are the most commonly used, are indicators of core population health, and very often prevent the need for urgent or emergent care. We acknowledge that we do not yet have compliance data from the FFMs to substantiate that 10- and 15-business day appointment wait time standards are achievable or appropriate for Medicaid and CHIP managed care programs. However, we believe that any alignment with the FFMs strengthens managed care plan and provider performance due to the high overlap between the programs. Many issuers offering QHPs also offer Medicaid and CHIP managed care plans and may be able to find efficiencies in their policies

and practices. Similarly, payers that have QHPs and Medicaid and CHIP managed care plans often have many of the same providers in both networks, and having similar standards eases administrative burden on the providers. We agree that monitoring data over time is important and will help us assess whether the 10- and 15-business day standards need revision or if other systemic efforts are needed to improve appointment wait times, such as national initiatives to increase the provider supply. However, we believe we should finalize the new requirements and collect data concurrently to generate the most useful results.

Comment: Some commenters recommended that CMS define “routine” for appointment wait time standards for consistency in implementation and results while others supported letting States define it to be reflective of their local markets.

Response: We understand commenters’ concerns regarding consistency in implementation and interpreting the results of secret shopper surveys for compliance with appointment wait times. Currently, Medicaid, CHIP, Medicare, and the FFMs do not have a codified definition for a “routine” appointment. We believe that providers use many factors, including current specialty-specific clinical standards to assess appointment requests. We encourage States to work with their managed care plans and their network providers and even other States to develop a definition of “routine” appointment to ensure consistency within and across their managed care programs. At a minimum, we expect any definition of a “routine” appointment to include appointments for services such as well-child visits, annual gynecological exams, and medication management. We decline to adopt a definition of “routine” that States would be required to use in this final rule but will review data from the secret shopper surveys and may consider adding a definition in future guidance or rulemaking.

Comment: Some commenters recommended that CMS define “urgent” and “emergent” and include these types of appointments in the appointment wait time standards as well. A few commenters suggested that CMS refine the appointment wait time standards by specifying existing patient appointments separately from new patient appointments given that new patients often need an extended initial visit which is often not available within 10- or 15-business days.

Response: We decline to define “urgent” and “emergent” as we are not implementing appointment wait time standards in § 438.68(e) and through cross-reference at § 457.1218 for urgent or emergent appointments. We did not propose appointment wait time standards for urgent or emergent appointments given the potential for serious harm when there is a need for such care. We believe it is prudent to start with less time-sensitive appointments and use secret shopper data to inform any potential future rulemaking on urgent or emergent wait time standards. However, we remind States and managed care plans that “emergency medical condition” is defined in §§ 438.114(a) and 457.10 as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following: (i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; (ii) Serious impairment to bodily functions; or (iii) Serious dysfunction of any bodily organ or part. As noted in the prior response, we will review data from the secret shopper surveys to determine if adding additional definitions could improve appointment wait time compliance or measurement.

We appreciate commenters’ suggestion to add specificity to appointment availability by separately measuring for new and existing patients. However, we do not want to make developing and implementing appointment wait time standards unnecessarily complicated, particularly since this will be a new way of assessing access for some States. States are welcome to add this level of detail to their appointment wait time standards, but we decline to require it in this final rule. States that set appointment wait time standards separately for new and existing patients must ensure that both standards comply with the maximum wait times in § 438.68(e).

Comment: A few commenters recommended that States obtain input from interested parties to aide in choosing the fourth appointment type.

Response: We agree with commenters and encourage States to consult with a wide range of interested parties—including their Medicaid and CHIP managed care plans, other plan types, providers, enrollees, and local advocacy organizations—when determining which provider or specialty to select to

comply with §§ 438.68(e)(1)(iv) and 457.1218.

Comment: One commenter questioned how appointment wait time standards apply to dual eligible special needs plans (D-SNPs) and how they intersect with existing Medicare requirements. The commenter noted concern that, without clarification, there could be confusion on secret shopper surveys and enforcement of wait time standards.

Response: We appreciate the comment and the opportunity to clarify. The appointment wait time standards finalized in § 438.68(e) apply to routine appointments with certain types of Medicaid and CHIP managed care network providers. For Medicaid managed care plans that are also D-SNPs in Medicare Advantage, States are only required by § 438.68(e)(1)(i) through (iii) to apply appointment wait time standards if the MCO, PIHP or PAHP is the primary payer. Any requirements on D-SNPs for services under the D-SNP contract with CMS are addressed in Medicare Advantage regulations.

Comment: A few commenters suggested that instead of measuring compliance with appointment wait time standards linked to remedy plans, CMS should provide incentives to providers that meet certain wait time standards. These commenters noted this would be far more effective than approaching it from a punitive perspective. Commenters also recommended that managed care plans look at other policies and practices that impact provider contracting and appointment availability such as timely credentialing, accurate and timely claims payment, and inefficient and redundant prior authorization processes.

Response: We agree that managed care plans offering incentives to providers that meet appointment wait time standards is a very useful suggestion and encourage managed care plans to consider it as part of developing a more comprehensive approach to appointment availability. There are many processes used by managed care plans that influence a provider’s willingness to be part of a network and managed care plans should continually monitor processes that may jeopardize their networks’ stability and take action to address them. However, we do not agree that the results from secret shopper surveys should be used for incentives alone. We believe that remedy plans will help States and managed care plans address identified access concerns and secret shopper survey results will provide timely data to inform the development of robust and effective remedy plans. We

acknowledge that remedy plans should not be the only tool used by states and managed care plans and support the use of multifaceted approaches to improve access.

Comment: Some commenters recommended that CMS require managed care plans to include a hold harmless provision in their network provider contracts so that network providers cannot be held responsible for the managed care plan’s compliance with appointment wait time standards. Commenters stated concern that some managed care plans may impose some type of penalty on network providers that do not offer appointments that comply with the appointment wait time standards and that these actions could have the unintended consequence of worsening enrollees’ access to care as physician practices are forced to see fewer Medicaid patients or opt out of being network providers.

Response: We appreciate commenters raising this concern and while it is not immediately clear to us why managed care plans would believe punitive action on network providers would be an effective way to encourage providers to offer more timely appointments, we defer to States and managed care plans to determine the appropriateness of a hold harmless provision in network contracts. As we note in the prior comment, strengthening managed care plan networks through timely credentialing, accurate and timely claims payment, and efficient prior authorization processes would seem a far more productive way to support providers to improve or expand access. States and managed care plans should collaborate to bolster relationships with providers and focus on the shared goal of improving access.

Comment: One commenter suggested that we revise § 438.68(e) to use “services” instead of “provider types” to allow PCPs that do gynecological services to be counted towards compliance for primary care, as well as OB/GYN.

Response: We appreciate this comment and agree that “services” instead of “provider types” in § 438.68(e)(1) would be clearer and more consistent with §§ 438.68(a) and 438.206. Using “services” would also be more consistent with managed care plan contracts’ specification of “covered services.” Our intent in proposing and finalizing appointment wait time standards is assessing access to care, not to limit the types of providers that could offer the services in paragraphs (e)(1)(i) through (iii). Understanding the scope of services subject to appointment wait time standards can be useful when

incorporated into the secret shopper survey by producing more detailed results and a truer view of access as experienced by enrollees. We accordingly are adopting the commenter's suggestion to use "services" instead of "provider types" in the final version of § 438.68(e)(1) and, for consistency, (e)(3).

To ensure consistency in § 438.68(d) with the adoption of "services, we are finalizing minor wording revisions. In paragraph (d)(1), we are removing "provider-specific" to be more inclusive of all network standards in § 438.68; in (d)(1)(iii), we are adding "or for the service type;" and in paragraph (d)(2), we are adding "or service" after "provider type" for consistency with § 438.68(e)(1).

Comment: We received numerous suggestions for variations on our proposed wait time standards. One commenter recommended setting appointment wait time standards for obstetrical services based on trimesters, such as appointments within 14 calendar days in the first trimester, 7 calendar days in second trimester, and 3 calendar days in the third trimester. Another commenter recommended that CMS permit States to define an appointment wait time standard for additional behavioral health specialists, facility types, or service types, either inpatient or outpatient, as long as the specialist, facility, or service type identified in the State-defined standard is distinct from the broader group of outpatient mental health and SUD providers subject to the 10-business day standard.

Response: States have the flexibility to develop appointment wait time standards by using more detailed criteria as long as the additional level of detail does not create a standard that exceeds the maximum timeframes in § 438.68(e). For example, requiring obstetrical appointments within 14, 7, and 3 calendar days is acceptable as none of them exceed the 15-calendar day limit in § 438.68(e)(1)(iii). Additionally, States can also include additional wait time standards for other services beyond the requirement in (e)(1)(iv) for a State-selected type, but they cannot replace or supplant the services in § 438.68(e)(1)(i)–(iii).

Comment: A few commenters recommended that the appointment wait time standards in § 438.68(e)(1) use "calendar days" instead of "business days" for ease of application and monitoring. One commenter recommended adding appointment wait time standards for HCBS, which is rendered 24/7 thus making "calendar days" more appropriate.

Response: We decline to accept the commenters' suggestion as we believe that requiring appointment wait time standards only for routine appointments in this final rule makes "business days" appropriate. Additionally, using "business" days is consistent with standards for the FFMs and Medicare Advantage, which reduces burden on States, managed care plans, and providers. Should we consider revising § 438.68(e) in future rulemaking to address HCBS, we will consider the impact of using a calendar day standard.

Comment: Some commenters recommended that there be an exception process for rural areas or health professional shortage areas (HPSAs), as they will present some very large challenges for managed care plans to meet the appointment wait time standards due to provider shortages. One commenter recommended that CMS add more specificity to § 438.68(d) so that States use exceptions consistently.

Response: We understand that provider shortages, particularly prevalent in rural areas and HPSAs, present challenges to ensuring timely access. This is why we believe requiring the use of appointment wait time standards and measuring compliance with them is important and should produce valuable information that can help States and managed care plans develop effective solutions. However, we acknowledge that implementing standards, analyzing results, and developing solutions to access issues that need improvement will take time and in the interim, States may want a mechanism to identify known access challenges. Existing regulations at § 438.68(d) permit States to use an exception process for any of the provider-specific network standards required in § 438.68. The flexibility to permit States to decide if and/or when to use an exception process was codified in the 2016 final rule. States have been using exception processes that meet the needs of their programs and may find this provision useful as areas for improvement are identified and remedy plans are implemented.

Comment: Some commenters did not support requiring appointment wait time standards; they stated that one of the most common reasons for access issues is a shortage of providers in an area or a specialty and that appointment wait time standards cannot address provider supply. Commenters stated particular concerns for mental health and SUD, rural areas, and HPSAs. These commenters stated that appointment wait time standards will generate a significant amount of burden for States,

plans, and providers with little, if any, improvement in access. Some commenters raised concerns that appointment wait time standards will increase pressure on providers and lead to burn out, expand patient panels to unmanageable levels, and potentially drive providers out of Medicaid. One commenter stated that national standards without consideration for regional variances, market makeup, or workforce constraints, are overly rigid and, despite States' and plans' best efforts, may simply prove unachievable. Another stated that States must have the autonomy to design and implement their own standards to account for State-specific conditions. Commenters recommended that CMS partner with other agencies such as the Health Resources and Services Administration to promote growth of the provider supply nationally.

Response: We acknowledge that States developing and enforcing appointment wait time standards will not solve all access issues. However, we believe they can be effective for the majority of the routine appointments for services that we are finalizing. While some States already enforce appointment wait time standards, we know that it will be new and impose some new burden initially for other States. We believe the effort will have a positive impact on access once the standards are implemented and the State, managed care plans, and providers are taking a coordinated approach towards the same goal. We also believe that there are opportunities for managed care plans to ease provider burden to enable them to provide timely appointments such as by ensuring timely, efficient credentialing processes, ensuring that prior authorization is used effectively and meaningfully, and by ensuring timely and accurate claims payment. We believe we provide States the ability to account for regional variances, State-specific conditions, market makeup, or workforce constraints in two ways: by only providing the maximum appointment wait time with States setting the exact standard within that parameter for three types of services and by allowing States to set the wait time standard for an additional State-selected service. We reflect these in § 438.68(e) with "[. . .]State-established timeframes but no longer than[. . .]" and § 438.68(e)(1)(iv) with "[. . .]State-established timeframes." We intentionally drafted § 438.68(e) to provide parameters for appointment wait time standards while also giving States the ability to customize the

standards for their specific markets, populations, and programs. Lastly, broader efforts are underway to address access nationally. For example, on July 25, 2023, the Department of Agriculture announced USDA's Emergency Rural Health Care Grants³¹ to help strengthen rural America's health care infrastructure. Additionally, we released a proposed rule on September 1, 2023 proposing minimum staffing standards for long-term care facilities and Medicaid institutional payment transparency reporting.³²

Comment: Many commenters suggested revising the compliance date for appointment wait time standards from 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. We received comments suggesting an applicability date as soon as 1 year after the final rule's effective date and a few for applicability dates in excess of 5 years.

Response: We appreciate the comments on our proposed applicability date. We considered all of the access provisions in the final rule and have chosen applicability dates that balance the needs of enrollees with the level of effort necessary to effectively implement each provision. We believe finalizing the applicability date of 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 is appropriate for appointment wait time standards in § 438.68(e).

Comment: We received a few comments in response to our request in the preamble on whether behavioral health PIHPs and PAHPs include other services that would enable States to select another service to fulfill § 438.68(e)(1)(iv). Commenters clarified that most behavioral health PIHPs and PAHPs do not include other covered services, and therefore, States would be unable to comply with § 438.68(e)(1)(iv).

Response: We appreciate commenters clarifying this for us as we want to ensure that the regulation text is accurate. To reflect this, we will finalize a revision to § 438.68(e)(1)(iv) to add "and covered in the MCO's, PIHP's, or PAHP's contract" after "[. . .] other than those listed in paragraphs (e)(1)(i) through (iii) of this section." This will clarify that States do not need to develop appointment wait time

standards or perform secret shopper surveys for services other than mental health and SUD for PIHPs and PAHPs that cover mental health and SUD services only.

Comment: One commenter stated that CMS does not have the authority to set national appointment wait time standards because section 1932(c)(1)(A)(i) of the Act authorizes States to develop standards for access to care, not the Secretary.

Response: We clarify for the commenter that the text at § 438.68(e) requires States to develop appointment wait time standards and that § 438.68(e)(i) through (iii) only establish the maximum times within which States must set their standards.

Comment: We received several comments supportive of including appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts in § 438.206(c)(1)(i).

Response: We thank commenters for their support. We note a drafting error in the proposed rule for the applicability date for § 438.206(c)(1)(i) as specified in § 438.206(d). We proposed an applicability date in § 438.206(d) of the first rating period that begins on or after 4 years after July 9, 2024; however, to align with the requirement for States to develop and enforce appointment wait time standards at § 438.68(b), managed care plan contracts need to reflect the appointment wait time standards on the same timeframe. Because § 438.68(b) was proposed and is being finalized as the first rating period beginning on or after 3 years after July 9, 2024, so should § 438.206(c)(1)(i) as specified in § 438.206(d). Therefore, in this final rule, § 438.206(d) is being finalized as applicable on the first rating period beginning on or after 3 years after July 9, 2024.

Comment: One commenter suggested that CMS strengthen Federal requirements to ensure children enrolled in CHIP managed care plans have timely access to all covered services, when available, and encouraged CMS to further define specialists as being pediatric specialists. The commenter noted that they believe pediatric specialists are often not included in CHIP MCO networks if the State or Federal standard does not specifically require them. Therefore, CHIP MCOs may be able to satisfy network adequacy requirements by including adult specialists, despite their inability to adequately care for the specialized needs of pediatric patients.

Response: We appreciate the commenters' concern for strengthening requirements to ensure children

enrolled in managed care plans have timely access to all covered services, when available. We currently define pediatric specialist in Medicaid at § 438.68(b)(iv), which is incorporated into CHIP regulations through cross-reference at § 457.1218. We remind States that the standards described in Medicaid at § 438.68(b)(iv) and in CHIP through cross-reference at § 457.1218 are the minimum standards that a State must meet to comply with their annual quality review. If a State has identified deficiencies in pediatric specialist availability, States have the option to develop higher standards than the Federal minimum.

After reviewing the public comments, we are finalizing § 438.68(e) as proposed except for a revision to use "services" instead of "provider types" in § 438.68(e)(1) and (e)(3) and to add "and covered in the MCO's, PIHP's, or PAHP's contract" to § 438.68(e)(1)(iv). We are also finalizing minor conforming changes in § 438.68(d)(1) and (2). We are finalizing § 438.206(d), which is applicable for separate CHIPs through an existing cross-reference at § 457.1230(a) and a proposed cross-reference at § 457.1200(d), as ". . . the first rating period that begins on or after 3 years after July 9, 2024 . . ." We are finalizing §§ 438.68(h), 438.206(c) and 457.1218 as proposed.

c. Secret Shopper Surveys (§§ 438.68(f), 457.1207 and 457.1218)

We recognized that in some States and for some services, Medicaid beneficiaries face significant gaps in access to care. Evidence suggested 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.³³ 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

³¹ <https://www.usda.gov/media/press-releases/2023/07/25/biden-harris-administration-helps-expand-access-rural-health-care>.

³² <https://www.federalregister.gov/public-inspection/2023-18781/medicare-and-medicicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid>.

³³ 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>.

patients.³⁴ Relatedly, analyses have shown that the vast majority of 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.³⁵ 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 proposed 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 proposed a new § 438.68(f) 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 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 proposed 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 is critical to ensure unbiased results.

We also proposed 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 proposed 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 SUD providers, if they are included in the managed care plan’s provider directories. We proposed 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 proposed 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 acknowledged 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 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 noted 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 will limit comparability, we believe that the value of validating provider directory data outweighs this limitation and that having results for provider types that will be important to State-specific access issues will 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 proposed 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 proposed 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 proposed in § 438.68(f)(1)(iii) that

³⁴ 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 <https://pubmed.ncbi.nlm.nih.gov/35574863/>; A. Bauman and S. Haeder, “Potemkin Protections: Assessing Provider Directory Accuracy and Timely Access for Four Specialties in California,” *Journal of Health Politics, Policy and Law*, 2022, available at <https://pubmed.ncbi.nlm.nih.gov/34847230/>.

³⁵ 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>.

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 will 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 proposed 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 will not change a managed care plan’s compliance rate, it will improve provider directory accuracy more quickly and thus, improve access to care for enrollees.

To implement section 5123 of the Consolidated Appropriations Act, 2023,³⁶ which requires that managed care plans’ and PCCM entities’ (if applicable) provider directories be searchable and include specific information about providers, we proposed to revise § 438.10(h)(1) by adding “searchable” before “electronic form” to require that managed care plans’ and PCCM entities’ (if applicable) electronic provider directories be searchable. We also proposed to add paragraph (ix) to § 438.10(h)(1) to require that managed care plans’ and PCCM entities’ (if applicable) provider directories include information on whether each provider offers covered services via telehealth. These proposals will 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, 2023. Section 5123 of the Consolidated Appropriations Act, 2023 specifies that the amendments to section 1932(a)(5) of the Act will take effect on July 1, 2025; therefore, we proposed that States comply with the revisions to § 438.10(h)(1) and new (h)(1)(ix) by July 1, 2025.

³⁶ <https://www.congress.gov/117/bills/hr/2617/BILLS-117hr2617enr.pdf>.

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 proposed 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 will 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 will also be consistent with statutory intent to reflect accurate identity, locations, qualifications, and availability information. Secret shopper survey results will 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 proposed 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 proposed 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 final rule above, we noted 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 proposed 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 is 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 will help States determine if the type of appointments being offered by providers is consistent with expectations and enrollees’ needs. We note that this proposal differs from the draft requirement for QHPs in the FFMs beginning in 2025, which does not take telehealth appointments into account for purposes of satisfying the appointment wait time standards.³⁷ Managed care encounter data in Transformed Medicaid Statistical Information system (T-MSIS) reflect that most care is still provided in-person and that use of telehealth has quickly returned to near pre-pandemic levels. We believe 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 will produce a more accurate reflection of what enrollees’ experience when attempting to access care. We considered aligning appointment wait times and telehealth visits with the process used by MA for

³⁷ 45 CFR 156.230; 2025 Draft Letter to Issuers in the Federally facilitated Exchanges, available at <https://www.cms.gov/files/document/2025-draft-letter-issuers-11-15-2023.pdf>.

demonstrating overall network adequacy, which permits MA organizations to receive a 10-percent 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. See § 422.116. However, we believe our proposed methodology will provide States and CMS with more definitive data to assess the use of telehealth and enrollee preferences and will be the more appropriate method to use at this time. We requested comment on this proposal.

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 proposed 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 proposed 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 will not be an MCO, PIHP, or PAHP, will not be owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and will not own or control any of the MCOs, PIHPs, or PAHPs subject

to the surveys. We proposed 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 will make it easier for States to evaluate the suitability of potential survey entities. We reminded 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 wanted 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 will assist them in their program monitoring activities and help them achieve programmatic goals. To provide this flexibility, we proposed a limited number of methodological standards for the required secret shopper surveys. In § 438.68(f)(4), we proposed that secret shopper surveys use a random sample and include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract. We believe these are the most basic standards that all secret shopper surveys must meet to produce useful results that enable comparability between plans and among States. We proposed in § 438.68(f)(4)(iii) that secret shopper surveys to determine plan compliance with appointment wait time standards will 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 of 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 is 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 must provide additional data to enable completion of the survey for an entire statistically valid sample. We did not

believe this provision needed 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 proposed at § 438.68(f)(5), that the results of these surveys be reported to CMS and posted on the State's website. Specifically, at § 438.68(f)(5)(i), we proposed 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) must be reported to CMS annually using the content, form, and submission times proposed in § 438.207(d). At § 438.68(f)(5)(ii), we proposed 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) will lessen burden on States, particularly since we published the NAAAR template³⁸ in July 2022 and are also developing an electronic reporting portal to facilitate States' submissions. We anticipate revising the data fields in the NAAAR³⁹ 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 will be a significant undertaking, especially for States not already using them; but we believe that the data produced by successful implementation of them will be a valuable addition to States' and CMS's oversight efforts. As always, technical assistance will be available to help States effectively implement and utilize secret shopper surveys. We invited comment on the type of technical assistance that will be most useful for States, as well as States' best practices and lessons learned from using secret shopper surveys.

We also proposed in § 438.68(h) that States would have to comply with

³⁸ <https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx>.

³⁹ [https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-reporting/index.html#NETWORK--:text=Report.%20%20C2%A0The%20current-.excel%20template,-\(XLSX%2C%20218.99%20KB](https://www.medicaid.gov/medicaid/managed-care/guidance/medicaid-and-chip-managed-care-reporting/index.html#NETWORK--:text=Report.%20%20C2%A0The%20current-.excel%20template,-(XLSX%2C%20218.99%20KB).

§ 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 summarize and respond to public comments received on Secret shopper surveys (§§ 438.68(f), 457.1207, 457.1218) below.

Comment: Many commenters supported requiring States to use secret shopper surveys to validate compliance with appointment wait time standards and to verify the accuracy of certain provider directory data. Commenters stated that these surveys would provide valuable information on the access provided by plan networks and provide a mechanism to drive improvements in accuracy and specificity of provider directories. Another commenter stated that the results of secret shopper surveys would provide accurate and transparent plan information that is vital to ensuring Medicaid managed care populations have access to the care they need. A few commenters stated the proposed requirements would bring much-needed consistency to the way these surveys are conducted which should lead to uniform identification and quick correction of inaccurate information.

Response: We thank commenters for their support to require secret shopper surveys as proposed in § 438.68(f). We believe that all interested parties will benefit from an independent evaluation of the degree to which managed care plans' networks provide timely appointments and the accuracy of provider directory data. The results, particularly for provider directory data, will enable timely corrections that will improve access.

Comment: Many commenters supported the use of independent entities to perform the secret shopper surveys. Commenters stated that this would ensure that surveys were conducted in an impartial manner and would produce more reliable results. One commenter recommended that we also include "any direct or indirect relationship" to our definition of "independence," consistent with § 438.810(b)(2)(i).

Response: We appreciate the supportive comments; our intent in including an independence requirement for the surveyors was to improve the validity of the results and to assure interested parties that the results presented an objective assessment of routine appointment availability for their managed care plan and its network providers. We decline to modify the definition of "independence" in this final rule. We acknowledge a more robust definition is appropriate in

§ 438.810(b)(2) for enrollment brokers, but do not believe the same level is warranted for secret shopper surveys. Enrollment brokers are responsible for providing information to enrollees to assist them in making informed decisions when selecting a managed care plan. Because enrollees are often limited to changing their managed care plans annually and because managed care plans receive a capitation payment for each enrollee enrolled in their plan, ensuring that enrollment brokers are independent of the managed care plans from which enrollees can choose is critical to ensure that enrollees receive information and assistance in an unbiased manner and that the enrollees' best interest is prioritized. We do not believe the same level of risk exists with secret shopper surveys. Additionally, we have been made aware that States are sometimes challenged to find entities that meet the requirements in § 438.810 to fulfill the functions of an enrollment broker and we did not want to impose those same challenges on States when procuring secret shopper survey vendors. We believe the functions of an enrollment broker and a secret shopper survey vendor are sufficiently different to warrant a different level of requirements for independence.

Comment: One commenter recommended using revealed shopper surveys instead of secret shopper surveys. Another commenter recommended that CMS produce standardized definitions, methodologies, and templates for use in conducting secret shopper surveys.

Response: We appreciate the comments but decline to adopt them in this final rule. We believe that secret shopper surveys capture information that is unbiased, credible, and reflect what enrollees experience when trying to schedule an appointment. This is not possible with a revealed survey and, therefore, is less likely to fulfill our goal of assessing appointment availability or encountering incorrect provider directory data as enrollees do. To the suggestion that we publish definitions, methodologies, and templates, we do not believe that is necessary as we believe States have sufficient experience in using secret shopper surveys or can rely on the expertise of outside entities. Further, while we are finalizing a minimum set of methodological standards for secret shopper surveys in § 438.68(f)(4), we believe States should have some latitude to customize their surveys beyond the minimum requirements to capture information and details that impact their programs and populations. We believe that being

overly prescriptive may lessen the surveys' utility.

Comment: A few commenters recommended requiring implementation sooner than the rating period for contracts with MCOs, PIHPs, and PAHPs that begins on or after 4 years after the effective date, while other commenters recommended extending implementation beyond 4 years. A few commenters stated that a shorter timeframe was reasonable because some States already use secret shopper surveys for certain aspects of their program.

Response: We appreciate the range of comments on the applicability date. Because secret shopper surveys will be used to measure compliance with appointment wait time standards and provider directory accuracy, we intentionally proposed an applicability date that was 1 year after the applicability date for appointment wait time standards. We clarify that States can comply with § 438.68(f) sooner than the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after the effective date of the rule and we encourage them to do so, particularly for surveys of provider directory data accuracy. We considered all of the access provisions in the final rule and have chosen applicability dates for each provision that balance the needs of enrollees with the level of effort necessary to effectively implement each one. We believe finalizing the applicability date as the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after the effective date of the final rule is appropriate for § 438.68(f).

Comment: A few commenters stated that dually eligible individuals must navigate multiple provider networks and directories with Medicare serving as the primary payer of most services for which the secret shopper survey will evaluate appointment availability. These commenters recommended that secret shopper surveys for integrated D-SNPs should account for Medicare as a primary payer for many of the services evaluated in the survey and the challenges due to misalignment of provider networks.

Response: We clarify that network adequacy standards and any associated secret shopper surveys only apply for services for which the Medicaid managed care plan is the primary payer. Section 438.68(e) and (f) do not apply for services for which Traditional Medicare, a D-SNP, or another Medicare Advantage plan has primary responsibility for dually eligible Medicaid managed care plan enrollees.

Comment: A few commenters stated that many States already do some form of secret shopper surveys and requested CMS to clarify if existing secret shopper surveys will meet the requirements of § 438.68(f).

Response: It is possible that States' existing secret shopper surveys may satisfy the requirements of § 438.68(f); however, that is an assessment that each State would have to make by evaluating each existing survey's content and methodology to ensure that it complies with all requirements in § 438.68(f).

Comment: Some commenters recommended that CMS prohibit duplicative or multiple provider surveys. If CMS finalizes the requirement for States to utilize secret shopper surveys to determine timely access compliance, these commenters believe potential duplication must be addressed to prevent over burdening providers' staff and detracting from the time they have available to take actual patients' phone calls.

Response: We understand the commenters' concern and agree that States should make every effort to supply provider data to their survey entities that does not generate repeated calls to the same provider for multiple managed care plans. We acknowledge this may not always be possible in small geographic areas or areas with few providers. However, as § 438.68(f)(4)(iii) only requires a statistically valid sample of providers be included in each survey, we believe that the level of repeat calls to the same provider will be minimal.

Comment: We received many comments on our proposal that managed care plans must meet a 90 percent compliance threshold. Some commenters noted that they believe that 90 percent will likely prove exceedingly difficult to attain, particularly given the national shortages of providers of certain services and in certain geographic areas. These commenters recommended that CMS adopt a lower percentage in initial years and then adjust it as plans and providers acclimate to the new standards; suggestions included compliance rates from 50 percent to 75 percent. Other commenters supported a 90 percent compliance rate believing that it was appropriate for access to the services proposed. Some commenters also stated that aligning with FFM standards was effective and efficient given the high overlap of managed care plans between Medicaid and the FFMs.

Response: We acknowledge that achieving a 90 percent compliance rate is a high standard, but we believe that as we are finalizing appointment wait time standards for only four types of

services (primary care, OB/GYN, mental health and SUD, and a State chosen one), three of which are the most commonly used on a frequent and repetitive basis, we believe it is critically important that managed care plans have robust networks for these services with sufficient capacity to provide timely appointments to meet the needs of the plan's enrollees.

Additionally, as commenters noted, there is a high overlap of managed care plans between Medicaid and the FFMs, so efficiencies are likely achievable that will aid in meeting requirements for both products. Additionally, we intentionally proposed an applicability date for secret shopper surveys in § 438.68(f)(2) that was 1 year after the applicability date for appointment wait time standards in § 438.68(e)(1) to give managed care plans time to ensure that their networks are able to meet established standards. Given the importance for enrollees to be able to access routine appointments for the required services in a timely manner, we are finalizing a 90 percent compliance rate in § 438.68(e)(2).

Comment: A few commenters recommended a range of revisions to § 438.68(f) including adding additional services or all plan covered services to the secret shopper survey requirement. Other commenters suggested additional fields for surveys of provider directory data. One commenter recommended that CMS allow State-derived studies to continue which focus on key areas based on State needs instead of specifying provider types and directory fields.

Response: We believe that it is important to consistently focus the requirements for appointment wait time standards and secret shopper on the same provider and service types. This will enable coordinated and focused approaches and strategies. We believe it prudent to start with a core set of the most used services and let States and managed care plans evaluate and refine their network management activities to ensure appropriate access rather than be overly broad and dilute the impact of their efforts. After reviewing secret shopper survey data, we may include additional services in § 438.68(e)(1) in future rulemaking.

Comment: A few commenters stated that conducting annual studies of appointment availability for the same services does not allow initiatives based on the previous year's results to be implemented and assessed for effectiveness before the next study is done. A few commenters also stated that requiring an annual secret shopper survey does not consider seasonality.

Response: We acknowledge that not all areas for improvement identified in a secret shopper survey can be remedied within a year, as we reflected in § 438.207(f)(2). However, there are some that can be and conducting an annual secret shopper survey enables timely reporting of the results of managed care plans' successful efforts to improve access. To the comment on the impact of seasonality on secret shopper results, we acknowledge that some provider types are more impacted by seasonal fluctuations in appointment requests than others. We believe States can take that into consideration when they schedule their secret shopper surveys and, if done consistently from year to year, the impact should be consistent and not disproportionate.

Comment: A few commenters recommended that CMS make clear to States that the secret shopper surveys are to be used to collect the information proposed in this rule only and not use them to collect and make public any information about reproductive health care services.

Response: We confirm that the secret shopper surveys required at § 438.68(f) are to be used to collect information within the scope and intent of this final rule and not used to collect any other information or make public information beyond information on the performance of MCOs, PIHPs, and PAHPs in meeting wait time standards.

Comment: Some commenters recommended that CMS clarify whether the secret shopper survey requires that appointments be offered by a specific provider or by any provider in the practice that is in the managed care plan's network. For example, if a patient wants an appointment and a specific provider does not have availability but other comparable providers in the practice do, an appointment with another provider should be counted as meeting the appointment wait time standard. One commenter contended that secret shopper surveys are not the best tool to identify providers that do not see Medicaid enrollees (despite being in a plan's directory) or see only a minimal number. This commenter recommended using what the commenter believes were more productive approaches such as claims data analysis to identify providers in directories that do not bill Medicaid, analysis of hours authorized in a treatment plan versus hours of services delivered and analyzing direct feedback from members.

Response: We appreciate commenters raising this issue and giving us the opportunity to clarify our intent. We did not specify that the appointment wait

time standard had to be met by the specific provider in the directory, but rather that a routine appointment for primary care services, OB/GYN services, mental health and SUD services, and the State-chosen service type must be offered within established timeframes. We understand that while a specific provider may be listed in the directory, that provider may not have availability when an appointment is requested. Our goal with the initial implementation of the appointment wait time standards and secret shopper surveys is to determine if enrollees can access care when they request it. As such, we believe that being offered an appointment by any provider in a practice is sufficient for determining compliance with appointment wait time standards.

However, we want to clarify that when verifying the accuracy of provider directory data, secret shopper surveys must verify the published information. Meaning, if the provider directory lists Dr. X, then the active network status, address, phone number, and open panel status for Dr. X must be verified; a directory reflecting accurate information for other providers in the same practice is not sufficient for Dr. X's data to be considered "accurate" for compliance with § 438.68(f)(1)(ii). In the proposed rule preamble, we acknowledged the issue of providers being listed in managed care plan directories but delivering little or no care for Medicaid enrollees (88 FR 28101). This issue could be addressed in secret shopper surveys of appointment wait times and we encourage States to build their surveys to include this level of detail. However, we did not specifically require this in § 438.68(f) as we believe secret shopper surveys that verify provider directory data will capture this information. We believe there are efficiencies that can be utilized between the appointment wait time and provider directory data surveys, such as by requesting an appointment and verifying the information in 438.68(f)(ii) in the same call to a provider, that will reflect a more robust and accurate picture of access to providers listed in managed care plans' provider directories. We agree with the commenter's suggestions for other methods that can be used to validate network providers' availability and utilization to ensure that they are "active" network providers. However, we believe the commenters' suggestions should be used in addition to the secret shopper surveys to further refine and contextualize the secret shopper results.

Comment: Some commenters recommended that CMS require the

entity conducting the secret shopper surveys and States to send the applicable information on provider directory data errors on a schedule other than the proposed 3-business days. Suggestions ranged from 6 days to monthly. One commenter recommended that CMS consider an approach that allows States to receive and report managed care plan errors in an aggregate or summarized form on a quarterly basis in addition to an individual 6-day communication to managed care plans. One commenter recommended that States be permitted to select their own timeframe for when data would be sent to managed care plans. One commenter suggested that managed care plans should be given a seven-day grace period to correct directory data errors before it is counted against their final accuracy rate.

Response: We appreciate the range of comments on our proposals in § 438.68(f)(1)(iii) and (iv) on the timeframes for directory data identified in secret shopper surveys to be sent to States and managed care plans. As we stated in the proposed rule preamble, inaccuracies in the information subject to a secret shopper survey 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 that can provide care (88 FR 28102). We acknowledge that 3 business days is a fast turnaround time but we believe it's reasonable given that: (1) the information from the survey vendor will be transmitted electronically; (2) we explicitly stated 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; and (3) given that the applicability date for secret shopper surveys is the first rating period for MCOs, PIHPs, or PAHPs that begins on or after 4 years after the effective date of the rule, States and managed care plans have ample time to establish processes for this data exchange. We do not agree with the commenter that managed care plans should have a grace period in which to make corrections before the error is counted. The point of using secret shopper surveys is to assess enrollees' experience when they utilize a plan's provider directory; therefore, not

calculating an accurate error rate undermines the goal of the survey.

Comment: A few commenters stated that 3 business days was not sufficient time for managed care plans to make corrections to inaccurate directory data.

Response: We appreciate commenters raising this concern as it seems the preamble may have been unclear on this issue to some readers. Section 438.68(f)(1)(iii) specifies that States must receive information on errors in directory data identified in secret shopper surveys no later than 3 business days from the day the error is identified. Section 438.68(f)(1)(iv) requires States to send that information to the applicable managed care plan no later than 3 business days from receipt. As such, the 3 business day timeframes are for data transmission, not correction of the erroneous data. Section 438.10(h)(3)(iii) specifies that managed care plans must use the information received from the State to 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.

Comment: Some commenters opposed requiring secret shopper surveys and stated that utilizing secret shopper surveys requires significant State resources to contract with third party survey organizations, provide limited accuracy, and ultimately are not a meaningful way of advancing the goal of directory accuracy. A few commenters stated that secret shopper surveys are not effective for addressing the root causes of access issues and cause provider burden and dissatisfaction. One commenter believed that the burden would be particularly apparent for behavioral health providers, who often operate small businesses independently without staffing support. One commenter recommended just collecting attestations from plans, consistent with the approach in the 2024 Notice of Benefit and Payment Parameters final rule for QHPs on the FFMs.

Response: We understand commenters' concerns. However, despite existing regulations on network adequacy and access in §§ 438.68 and 438.206 and monitoring and reporting requirements in §§ 438.66 and 438.207, we continue to hear from enrollees and other interested parties that managed care plan networks do not provide access to covered services that meets the needs of covered populations. As we noted in the proposed rule preamble, external studies document findings that 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. Additionally, 34 audit studies demonstrated that Medicaid is associated with a 1.6-fold lower likelihood in successfully scheduling a primary care appointment (88 FR 28098). We believe that proactive steps are necessary to address areas that need improvement, and we believe provisions in this final rule, including requirements for secret shopper surveys to assess the accuracy of provider directory data and compliance with appointment wait time standards, are an important first step. The use of secret shopper surveys is consistent with the proposed requirements for QHPs on the FFMs as specified in the 2025 Draft Letter to Issuers in the Federally-facilitated Exchanges.⁴⁰

Comment: We received a wide range of comments and suggestions on the methodology for secret shopper surveys including: entities conducting secret shopper surveys need to be equipped with the same information that a Medicaid enrollee would have including Medicaid program name, plan name, member ID number, and date of birth; much of the value of a secret shopper survey depends on how a question is worded and requested; familiarity of office scheduling staff with secret shopper surveys—particularly when surveyors are unable to provide necessary information indicating they are real patients; and survey questions may need to account for factors such as providers that generally rely on electronic rather than telephone appointments.

Response: We appreciate the many comments that shared valuable input on secret shopper survey methodologies. We encourage States to consider these and collaborate with the survey entity when designing their surveys. We encourage States to consider providing sufficient details to their survey entity such as a verifiable Medicaid ID number to enable them to respond to requests for such information.

Comment: One commenter noted that given the mandatory nature of EQRO provider data validation activities § 438.358(b)(1)(iv), it is unclear how the proposed secret shopper survey will add any value to the existing policy framework or is not duplicative of existing processes. The commenter recommended that CMS require States to administer the CAHPS® survey which includes questions focused on appointment availability and access to care to prevent secret shopper surveys

outside of CAHPS® inadvertently negatively impacting CAHPS® results due to duplicative data collection, different survey methodologies, and inconsistent results across different surveys measuring appointment availability.

Response: We do not agree that secret shopper surveys would be duplicative of provider data validation activities in § 438.358(b)(1)(iv). As stated in the CMS EQR Protocols published in February 2023,⁴¹ the activities in protocol 4 include validating the data and methods used by managed care plans to assess network adequacy, validating the results and generating a validation rating, and reporting the validation findings in the annual EQR technical report. These activities are different than the secret shopper surveys finalized in § 438.68(f) which will verify appointment access and the accuracy of directory data directly with a provider's office. We are unclear why the commenter noted their belief that secret shopper surveys outside of CAHPS® could inadvertently negatively impact CAHPS® results due to duplicative data collection, different survey methodologies, and inconsistent results. We acknowledge that no single tool to measure access is perfect, which is why the managed care regulations in 42 CFR part 438 require multiple tools that will provide a more comprehensive and contextualized view of access for each program.

Comment: Many commenters supported posting the results of secret shopper surveys on States' websites and noted it will help individual patients and patient advocates better understand if there are individual or systemic issues. Some commenters appreciated our requiring that the results of secret shopper surveys be included in the NAAAR as that will make it easier to locate and provide context for the other network adequacy information in the report. A few commenters suggested that States' NAAARs also be posted on *Medicaid.gov*.

Response: We believe that reporting secret shopper survey results in the NAAAR is a logical and low burden option for States and will provide a consistent place for interested parties to locate them. We appreciate the suggestion to also include States' NAAARs on *Medicaid.gov*. Currently, there are challenges with producing the MCPAR and NAAAR as documents that are compliant with sections 504 and 508 of the Rehabilitation Act; thus, they cannot currently be posted on

Medicaid.gov. Efforts are underway to resolve these issues for MCPARs which are collected through the web-based portal, and we expect that when we are collecting NAAARs through a web-based portal, we will be able to resolve the current formatting challenges to produce compliant documents that can be posted.

Comment: A few commenters recommended that CMS not implement secret shopper surveys pending further decisions on development of a National Directory of Healthcare Providers and Services, the subject of a CMS request for information released in October 2022. These commenters stated that using a national directory to validate provider data would greatly reduce duplicative calls to providers that participate in multiple managed care plans and lessen burden on providers.

Response: We acknowledge that work on the National Directory of Healthcare Providers and Services is ongoing. We agree that if or when a national directory is available, there likely will be efficiencies that can be leveraged to lessen burden on providers and States. However, we believe that inaccurate directory data has been an issue for too long and has a great impact on access; as such, we do not agree that delaying the secret shopper requirement in § 438.68(f)(1) is appropriate.

Comment: One commenter requested clarification on how the proposed wait time standards interact with services that States "carve out" of managed care plan contracts (that is, services delivered in FFS) and requested that CMS issue guidance to ensure secret shopper surveys only assess compliance with appointment wait times for covered services.

Response: As specified in § 438.68(e)(1)(i) through (iii), appointment wait time standards must be established for routine appointments if the required services are covered by the managed care plan's contract. To make this clear, we explicitly include "If covered in the MCO's, PIHP's, or PAHP's contract, [. . .]" in paragraphs (e)(1)(i) through (iii). Therefore, secret shopper surveys must not include services that are not covered in a managed care plan's contract.

Comment: Some commenters supported our proposal to only count telehealth appointments toward wait time standards if the provider also offered in-person appointments. One commenter noted that telehealth should not replace in-person care, as there are some significant equity concerns and telehealth is not a one-size-fits-all solution. Many other commenters stated that all telehealth appointments should

⁴⁰ <https://www.cms.gov/files/document/2025-draft-letter-issuers-11-15-2023.pdf>.

⁴¹ <https://www.medicare.gov/medicaid/quality-of-care/medicaid-managed-care/quality-of-care-external-quality-review/index.html>.

be counted towards a plan's compliance rate and that this is especially important for mental health and SUD appointments. Other commenters recommended that CMS adopt the ten percent credit toward a plan's compliance rate as is used by Medicare Advantage. A few commenters recommended that States be permitted to determine how much telehealth appointments should be counted toward a plan's compliance score.

Response: We thank commenters for their comments on this important aspect of secret shopper surveys. As we stated in the preamble, we acknowledge the importance of telehealth, particularly for mental health and SUD services. However, we do not believe that managed care plans should be able to provide services via telehealth only. Managed care encounter data in 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 limiting the counting of telehealth visits to meet appointment wait time standards, as well as the segregation of telehealth and in-person appointment data, is the correct approach to use. While increased reliance on telehealth can and should be part of the solution to address access deficiencies and used to address a network adequacy or access issue for a limited time, it should be used in concert with other efforts and strategies to address the underlying access issue. We do not believe that relying solely on telehealth is an appropriate way to meet all enrollees' care needs in the long term. We will monitor information over time, such as encounter data, secret shopper survey results, MCPAR submissions, and NAAAR submissions to inform potential future revisions to § 438.68(f)(2)(ii). We do not believe adopting Medicare Advantage's ten-percent point credit methodology would be appropriate as it is designed to apply to time and distance standards—which are substantially different than appointment wait time standards.

Comment: One commenter recommended that CMS require that appointment wait time data evaluations be disaggregated by key social, demographic, and geographic variables to identify and address any access discrepancies for specific subpopulations.

Response: We decline to add these additional requirements on secret shopper survey results in this final rule; however, we believe data disaggregated as suggested by the commenter could provide States with valuable information about their programs. We

encourage States to consider these suggestions as they develop their surveys.

After reviewing the public comments, we are finalizing §§ 438.68(f), 457.1207, and 457.1218 as proposed.

d. Assurances of Adequate Capacity and Services—Provider Payment Analysis (§§ 438.207(b) and 457.1230(b))

We believe there needs to be greater transparency in Medicaid and CHIP provider payment rates 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 to assess Medicaid and CHIP payment rates across clinical specialties, managed care 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 multiple ways. Evidence suggests that low Medicaid physician fees limit physicians' participation in the program, particularly for behavioral health and primary care providers.^{42 43} 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.^{44 45} While

⁴² 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>.

⁴³ 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.

⁴⁴ 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>.

⁴⁵ Zuckerman S, Skopec L, and Aarons J. Medicaid Physician Fees Remained Substantially Below Fees Paid by Medicare in 2019. *Health Aff*

many factors affect provider participation, given the important role that payment 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.⁴⁶ 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 FFS Medicaid and CHIP programs, managed care plans generally have the ability to negotiate unique reimbursement rates for individual providers. Generally, unless imposed by States through a State-directed payment or mandated by statute (such as Federally qualified health center (FQHC) 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 will 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 us. 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 proposed a process through which managed care plans must report, and States must review and analyze, managed care payment rates to

(Millwood). 2021;40(2). doi:10.1377/hlthaff.2020.00611.

⁴⁶ Congressional Budget Office, "Baseline Projections—Medicaid," May 2022, available at <https://www.cbo.gov/system/files/2022-05/51301-2022-05-medicaid.pdf>.

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 CIB⁴⁷ 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, in our May 3, 2023 proposed rule, we proposed to require a payment analysis that managed care plans would submit to States per § 438.207(b)(3) and States would be required to review and include in the assurance and analysis to CMS per § 438.207(d). Specifically, we proposed to replace the periods at the end of § 438.207(b)(1) and (2) with semicolons and add "and" after § 438.207(b)(2) to make clear that (b)(1) through (3) will all be 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 proposed 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 proposed that the analysis 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 that using claims data ensures that utilization is considered to prevent extremely high or low payments from inappropriately skewing the results. We acknowledged that paid claims data will likely not be complete within 180 days of the end of a rating period, which is when this analysis is proposed to be reported by the State in § 438.207(d)(3)(ii). However, we believe that the data are 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 provides 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 proposed to require each MCO, PIHP, and PAHP to 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 FQHCs and rural health clinics (RHCs), we proposed in § 438.207(b)(3)(iv) to exclude these provider types from the analysis. We further proposed 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 will reflect the comparison of how much the managed care plan paid for the evaluation and management 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 proposed that the plans will 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 proposed that the percentages 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 will prevent the pediatric data from artificially inflating the adult totals and percentages. We believe this level of detail will be necessary to prevent misinterpretation of the data.

We proposed 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 amounts paid for homemaker services, home health aide services, and personal care services and the percentages 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 proposed two differences between this analysis and the analysis in § 438.207(b)(3)(i): first, this analysis will use all codes for the services as there are no evaluation and management CPT codes for these LTSS; and second, we proposed the comparison be to Medicaid or CHIP FFS payment rates, as applicable, due to the lack of comparable Medicare rates for these services. We proposed 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 will 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 requested comment on whether in-home habilitation services provided to enrollees with I/DD 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 will 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 § 438.207(b)(3) is appropriate and meaningful, we proposed at paragraph (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 paragraph (b)(3)(i) for which the managed care

⁴⁷ <https://www.medicaid.gov/federal-policy-guidance/downloads/cib08222022.pdf>.

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 will 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 will 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 authorize the proposals in this section of this final rule as enabling States to compare payment data among managed care plans in their program, which could provide useful data to fulfill their obligations for monitoring and evaluating quality and appropriateness of care.

We also proposed to revise § 438.207(g) to reflect that managed care plans will 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.

We summarize and respond to public comments received on Assurances of adequate capacity and services—Provider payment analysis (§§ 438.207(b) and 457.1230(b)) below.

Comment: Many commenters supported our proposal for a managed care plan payment analysis in § 438.207(b)(3). Commenters noted they believe it will provide greater insight into how Medicaid provider payment levels affect access to care. One commenter stated that it was abundantly clear that low provider payment rates harm Medicaid beneficiaries, as they limit provider participation. Some commenters stated the payment analysis can contribute to identifying and redressing gaps in access. One commenter stated that Medicaid FFS and Medicare rates are a matter of public knowledge and the rates paid by managed care plans should be as well.

Response: We agree that managed care programs should have comparable transparency on provider payment to

Medicaid and CHIP FFS programs and the analysis finalized at § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b) is an important step. We acknowledge an oversight in the wording of § 438.207(b)(3)(i) in the proposed regulation text. The preamble noted how the necessary calculations could be produced and included "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)." (88 FR 28105) Unfortunately, "amount paid by the" was erroneously omitted in (b)(3)(i) so that the sentence did not reflect the two components needed to produce a percentage. To correct this, we are finalizing § 438.207(b)(3)(i) to state that the payment analysis must provide the total amount paid for evaluation and management CPT 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 amount paid by the published Medicare payment rate for the same services.

Comment: Many commenters did not support our proposal for a managed care plan payment analysis in § 438.207(b)(3). A few commenters stated that CMS should rely on States to work with their contracted managed care plans in evaluating which factors they believe are most relevant to access in their specific areas, and in determining what types of comparative data (whether it is payment information or other metrics) would be most useful and cost effective for such evaluations. Some commenters were concerned that the comparison CMS is requesting will be misleading, statistically invalid, present an incomplete narrative on provider payment, and will dissuade participation by providers in the Medicaid program which is contrary to CMS's stated goals. Commenters believe that comparing payment on a per code level is likely to result in a volume of information that is overwhelming for a member of the general public and unlikely to yield information that is beneficial.

Response: We understand why States would prefer to be able to select which factors they believe are most relevant to access in their specific areas for evaluation and determine which types of comparative data would be most useful. However, we believe for these analyses to be useful, there must be consistency, and permitting each State to conduct a unique analysis would not

achieve that. We do not agree with commenters that state that the analysis will be misleading, statistically invalid, or produce too much information for most interested parties as we intentionally kept the scope of service types and results required to be produced very limited. For example, § 438.207(b)(3)(i)(A) and (B) requires a separate total and percentage for primary care, obstetrics and gynecology, mental health, and substance use disorder services, with a potential breakout of these percentages by adult and pediatric services. If a managed care plan's calculations do not produce a different percentage for pediatric services for a service type, then the managed care plan would only need to produce four totals and four percentages—one total and one percentage for primary care, obstetrics and gynecology, mental health, and substance use disorder services. If a managed care plan's calculations produce a different percentage for pediatric services, then the managed care plan would need to produce two percentages for each type of service. We do not believe that producing this few results will be misleading, invalid, or overwhelming for most interested parties. We also do not believe that the results of these analyses will dissuade providers from joining managed care plans' networks. We are confident that providers will be able to interpret the data appropriately and are familiar enough with managed care plan contracting practices to base their network participation decisions on specific information provided to them as part of network contract exploration and negotiation.

Comment: We received numerous comments on the proposed applicability date of the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after the effective date of the rule. Some commenters recommended that CMS finalize an applicability date at least 2 years following the release of any relevant subregulatory guidance. Other commenters recommended an applicability date sooner than 2 years after the effective date of the rule. Some commenters recommended that CMS pilot the payment analysis with a small subset of evaluation and management (E/M) codes, stating that this would allow CMS to address key implementation challenges before requiring national reporting on the broader subset of codes.

Response: We appreciate the input on our applicability date proposal. Given that almost all managed care plans evaluate their provider payment rates

annually when the Medicare payment rates are published, we do not believe that managed care plans will have an inordinate amount of burden performing the analysis finalized in § 438.207(b)(3). While we may publish guidance on performing the analysis in the future, it is not immediately planned and so we cannot predicate the applicability date on it. To the comments suggesting that we finalize a sooner applicability date, we do not believe that would be prudent given the other requirements being finalized in this rule that will impact managed care plans. We encourage managed care plans to use the time between the final rule and the first rating period that begins on or after 2 years after the effective date to develop the necessary calculations and data extracts. As always, we are available to provide technical assistance if needed.

Comment: Many commenters suggested ways to revise the payment analysis to produce different or more detailed results including: requiring the analysis for all payments to all provider types and for all services for which there is a network adequacy requirement; adding psychotherapy codes, psychological testing, and neuropsychological testing; showing the different payment rates between physicians and nurse practitioners; capturing average payment rates broken out by geographic and population areas; comparing Medicaid payment rates to commercial insurance rates; and publishing the average payment rate per service.

Response: We appreciate these suggestions and encourage States to include them in addition to the analysis required in § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b). Expanding the required analysis to include some or all of these layers of detail could prove very helpful to States and managed care plans in their network adequacy and access monitoring and improvement activities. To give managed care plans time to develop their analyses to comply with the final rule, we decline to add any of the suggested revisions to § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), at this time, but may consider them in future rulemaking.

Comment: Several commenters stated concern about proprietary and confidential data being released in the payment analysis and noted that CMS must ensure that data are protected from inappropriate disclosure. One commenter stated that any claims of the purported proprietary or confidential

nature of these provider payment rates should be summarily dismissed, particularly given that the contractors are using public funds. This commenter further contended that concerns that rate transparency is inflationary have not been seen with increasing transparency for commercial insurance provider payments; to the extent this does occur in Medicaid, it is needed. Another commenter stated concern that a requirement to publicly post the report of the results would make this information readily available to anyone in the State, including interested parties that are hostile to Medicaid and/or access to specific types of services and could expose some services and/or provider types to politically motivated attempts to decrease their payment rates.

Response: We appreciate commenters raising these issues. The provider payment analysis as finalized in this rule at § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), will produce only aggregate results without revealing specific payments or specific providers. As specified in § 438.207(b)(3)(i) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), the analysis would produce the total amount paid for E/M codes in the paid claims data from the prior rating period, as well as the percentage that results from dividing the total amount paid by the published Medicare payment rate for the same services. Although the resulting totals and percentages must be categorized as primary care, OB/GYN, mental health, or substance use disorder, no additional identifying data are required.

Comment: Many commenters questioned how non-FFS payments that often include non-E/M services should be accommodated in the analysis and recommended that CMS provide detailed guidance as to address capitated providers, value-based payment (VBP) arrangements, bundled payments, or alternative payment types. These commenters stated that excluding these types of payments would undermine and devalue the shift to alternative payment models and quality-based payment incentives and believe specific guidance is needed so that managed care plans can consistently and accurately reflect alternative payment models in their payment analyses. A few commenters recommended that such payments be excluded from the provider payment analysis to avoid results being skewed by Medicaid managed care plans' assumption-driven allocations of non-service specific payments to individual

services and to ensure comparability of analyses across multiple Medicaid managed care programs. Some commenters stated concern that this data collection effort will not factor in complex hospital, specialty hospital, and multi-functional inter-disciplinary health care delivery system arrangements which are negotiated in the context of the delivery of multiple services instead of on a one-off basis. One commenter recommended that the analysis allow managed care plans to incorporate a proportional allocation of incentive, bonus, or other payments made to a provider outside of the adjudication of claims to ensure that the analysis accurately reflects all payments, including those based on value or quality achievements.

Response: We agree that capitation (to providers), VBP arrangements, bundled payments, and other unique payment arrangements that reward and support quality over quantity are important, and it was not our intention to appear to discourage them or minimize their value. However, given the wide-ranging designs of such payments, we elected to not propose a specific way to address them in this iteration of the analyses. We believe that finding a consistent way to include these arrangements in these analyses is critical and want to use the analyses submitted to inform our determination of how best to do this. Further, as we are finalizing that only E/M codes be included in the analysis, we want to better understand the scope of services included in these types of arrangements. We decline to adopt the commenter's suggestion to permit a proportional allocation of incentive, bonus, or other payments to be incorporated into the totals or percentages required in § 438.207(b)(3)(i) and (ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b). However, to collect information on these arrangements and their impact on provider payment for primary care, OB/GYN, mental health, and SUD services, we will permit managed care plans to include data in their submissions required in § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b) that reflect the value of these non-FFS payment arrangements and their impact on the totals and percentages (to the degree possible given the inclusion of other services) required in § 438.207(b)(3)(i) and (ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b). As States are required to utilize the data submitted by their plans as required at

§ 438.207(b) to produce the analysis and assurance required at § 438.207(d), we will include fields in the NAAAR that will enable States to include this additional information. We encourage managed care plans and States to provide specific and detailed information on capitation (to providers), VBP arrangements, bundled payments, and other unique payment arrangements to enable us to determine the most appropriate way to collect this information in potential future revisions to § 438.207(b)(3).

Comment: One commenter contended that they believe the analysis will produce an inaccurate picture of the impact of Medicaid payments on access given the significant portion of Medicaid payments flowing through FQHCs and rural health clinics, which are excluded per § 438.207(b)(3)(iv).

Response: We intentionally excluded FQHCs and RHCs given their statutorily required payment structure. We acknowledge that FQHCs and RHCs provide a high volume of primary care, OB/GYN, mental health, and SUD services, but they are paid a bundled rate. As addressed in the prior response, bundled payments are challenging to disaggregate and we believe it best to not include them in the payment analysis at this time.

Comment: One commenter recommended that CMS require the data required in § 438.207(b)(3) to be submitted by plans to the State within 90 days of the end of the rating period for annual NAAAR submissions that must be submitted to CMS within 180 days of the end of a rating period.

Response: We decline to specify that managed care plans must submit the data required at § 438.207(b) to the State within 90 days of the end of the rating period. We defer to States to determine the timeframe for plan submission given that States must submit annual NAAARs within 180 days of the end of a rating period. We encourage States to specify the submission timeframe in their managed care plan contracts for clarity.

Comment: One commenter recommended that CMS require the payment analysis required at § 438.207(b)(3) to be certified by the managed care plan's CEO.

Response: Section 438.606(a) specifies that managed care plans' Chief Executive Officer; Chief Financial Officer; or an individual who has delegated authority to sign for the Chief Executive Officer or Chief Financial Officer must certify “. . . data, documentation, or information specified in § 438.604. . . .” As all information provided by managed care plans

consistent with § 438.207(b) must be posted on the State's website per § 438.604(a)(5), existing § 438.606(a) will apply the certification requirement to the data provided by the managed care plans for § 438.207(b)(3).

Comment: One commenter suggested that CMS publish a national report of these payment analyses to provide a nationwide picture of Medicaid payment.

Response: We appreciate the suggestion and may consider doing so in the future.

Comment: A few commenters recommended that the States should be required to make publicly available the results of the provider payment analyses.

Response: We point out the requirement in § 438.602(g)(2) that through cross reference to § 438.604(a)(5) requires documentation described in § 438.207(b), on which the State bases its certification that the managed care plan has complied with its requirements for availability and accessibility of services, be posted on the State's website as required at § 438.10(c)(3).

Comment: A few commenters contended that the payment analysis in § 438.207(b)(3) should not be required annually and suggested that triennially would be less burdensome on the State agencies.

Response: We appreciate commenters' suggestion but believe the payment analysis should be completed annually given that managed care plan contracts and capitation rates are developed and approved on an annual basis. We note a typographical error in § 438.207(b)(3) that we have corrected in this final rule.

In the preamble (88 FR 28104), we wrote “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.” Unfortunately, we failed to include “annual” in § 438.207(b)(3). We did not receive comments questioning this discrepancy and, as reflected in this and other comments, commenters understood our intent that the analyses be conducted and submitted annually. As such, we are finalizing § 438.207(b)(3) as “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 an annual payment analysis using paid

claims data from the immediate prior rating period. . . .”

Comment: A few commenters stated that the payment analysis at § 438.207(b)(3) would create a significant new burden for Medicaid agencies who would become responsible for conducting the complex analysis of payments for each managed care plan and across managed care plans for their market. One commenter stated that an actuarial services contractor would be needed to evaluate past encounter data to define which CPT or Healthcare Common Procedure Coding System (HCPCS) codes need to be included for each managed care plan.

Response: We appreciate the opportunity to provide clarity on managed care plan and State responsibilities as these comments are not consistent with the proposed requirements. The payment analysis is specified in § 438.207(b)(3) for Medicaid managed care, and through a cross-reference at § 457.1230(b) for separate CHIP and is required to be conducted by each managed care plan, not the State. The States' only calculation is specified in § 438.207(d)(2)(ii) for Medicaid, and through a cross-reference at § 457.1230(b) for separate CHIP and requires States to produce a State-level payment percentage for each service type by using the number of member months for the applicable rating period to weight each managed care plan's reported percentages. To the comment that an actuarial services contractor would need to define which CPT/HCPCS codes need to be included for each managed care plan, the analysis in § 438.207(b)(3) for Medicaid, and through a cross-reference at § 457.1230(b) for separate CHIP requires the use of paid claims data from the immediate prior rating period. Managed care plans have all of their claims data and can isolate the E/M codes and paid amounts. We are unclear why an actuary would be needed for that or why a State would assume this task for its managed care plans.

Comment: One commenter recommended that CMS reconsider the timelines for conducting and reporting provider rates due to the delayed approvals of State plans, waivers, and rate certifications of actuarially sound capitation rates that can impact the actual or planned managed care plan payments to providers. For example, if a State plan is approved within 90 days but the capitation rates the State will pay its managed care plans are not approved for several months after, States who are risk averse may postpone all reprocessing until all necessary CMS approvals have been received which

may extend beyond the deadline for reporting.

Response: We are unclear on the commenter's recommendation regarding the impact of State plans, waivers, and rate certification approvals on the payment analysis of provider payment. We are also unclear on the reference to "reprocessing." Regardless, we clarify that the timing of authority documents or managed care plan contracts and rates should not impact the provider payment analysis as it utilizes actual paid claims data for a single rating period; reprocessing of claims after the close of a rating period would be captured in the following year's analysis.

Comment: One commenter noted that in developing the statutory requirements for Medicaid managed care programs, Congress required States contracting with Medicaid managed care entities to "develop and implement a quality assessment and improvement strategy" that includes "[s]tandards 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." The commenter contended that the payment analysis and disclosure requirements being proposed by CMS are unsupported by this statutory language, which concerns itself with beneficiary access to care, not with comparative payment analyses.

Response: We disagree with the commenter as we believe there is a strong link between access to care and provider payment and the payment analysis finalized at § 438.207(b)(3) for Medicaid managed care, and through a cross-reference at § 457.1230(b) for separate CHIP, and the associated required review and analysis of the documentation submitted by its managed care plans at § 438.207(d) facilitates States' inclusion of payment information in a consistent way to enable States to develop effective "[s]tandards 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." As we noted in the preamble (88 FR 28104), evidence suggests that low Medicaid physician fees limit physicians' participation in the program, particularly for behavioral health and primary care providers.^{48 49}

⁴⁸ 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/>

Researchers also 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.^{50 51}

Comment: Some commenters stated that given the differences between the Medicaid population and the Medicare population, any payment analysis required to compare payment rates to providers in managed care should use Medicaid FFS as a benchmark as it is more appropriate and relevant than Medicare FFS. Some commenters question the validity of comparing Medicaid payment rates to Medicare, especially for OB/GYN, neonatal, and pediatric services given that Medicaid pays for far more of these services than Medicare. A few commenters recommended that CMS clarify that using Medicare is only a mechanism for evaluating payment adequacy in a standardized way and that CMS is not suggesting that Medicare payment rates are the appropriate benchmark to ensure Medicaid beneficiaries have access to care. One commenter stated that Medicare rates fall short of covering the cost to deliver care for most providers. A few commenters suggested that the payment analysis should use commercial plans' rates as the comparison.

Response: We appreciate the range of comments on our proposal to use Medicare FFS rates the payment analysis at § 438.207(b)(3) and through a cross-reference at § 457.1230(b) for separate CHIP. To the suggestion to use Medicaid or CHIP FFS rates, we do not believe that is appropriate given that each State sets their own rates and therefore, would provide no level of consistency or comparability among the analyses. We acknowledge that Medicare does not pay for a large volume of OB/GYN, neonatal, and pediatric services, but it still provides a consistent benchmark with rates

Physician-Acceptance-of-New-Medicaid-Patients.pdf.

⁴⁹ 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.

⁵⁰ 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>.

⁵¹ 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.

developed in a standardized and vetted manner. (88 FR 28104) However, we believe that limiting the analysis to E/M codes and requiring all managed care plans to conduct their analysis using published Medicare rates will mitigate the impact. Further, we clarify that our intent is not to make a statement on the appropriate benchmark to ensure Medicaid and CHIP beneficiaries have access to care. We selected Medicare FFS rates for the payment analysis for several reasons: they are consistently and rigorously developed and vetted, most managed care plans routinely evaluate their payment rates against Medicare FFS rates as a standard business practice, they are the only complete and reliable set of rates published annually, and they are easily accessible. We do not believe that using commercial rates would be feasible given that none of the reasons listed above are true for commercial rates.

Comment: We received several comments in support of including habilitation services in the payment analysis. These commenters stated that habilitation services are critical for enrollees, particularly those in the I/DD population, who commonly receive personal care services as part of their habilitation services. As such, since personal care services are included in the payment analysis, so too should habilitation services. These commenters also clarified that while habilitation services are most frequently covered for enrollees in the I/DD population and provided in their home, it could be covered for other enrollees in other settings. The commenters assert that limiting the payment analysis to habilitation services for just one population and setting adds unnecessary complexity and that using claims data for all habilitation services would reduce burden on managed care plans and make the results more comprehensive.

Response: We appreciate the comments and agree that adding habilitation services, irrespective of population or setting, to the payment analysis would provide States with valuable information for monitoring access to vital services for certain enrollees. This revision also makes the payment analysis for habilitation services consistent with the analysis for homemaker services, home health aide services, and personal care services—which has no limitations based on population or setting. We very much appreciate the information on reducing burden by eliminating an unnecessary limitation on the data based on population and setting and have revised § 438.207(b)(3)(ii) accordingly. To

reflect this, we are finalizing § 438.207(b)(3)(ii) by moving “personal care” before “and” and adding “habilitation services” after “and.”

Comment: A few commenters stated that some States do not maintain separate Medicaid FFS fee schedules for most I/DD services while others noted that some States that use managed long-term services and supports (MLTSS) exclusively do not maintain Medicaid FFS rates. These commenters pointed out that not having Medicaid FFS rates in these circumstances makes part of the payment analysis in § 438.207(b)(3)(ii) impossible. A few commenters suggested that CMS consider requiring States to report an average unit cost instead of a Medicaid FFS comparison as this would enable States that do not have a Medicaid FFS rate or have not made updates to Medicaid FFS rates to still produce a valuable analysis. One commenter suggested using other sources when a State’s Medicaid FFS fee schedule is unavailable such as comparison to regional payment data or other States’ rates.

Response: States can utilize a managed care delivery system for home health services, homemaker services, personal care services, and habilitation services but they must still identify payment methodologies in their State plans for all services authorized in their State plan. Thus, while a State may not be actively paying Medicaid FFS claims for the services identified in § 438.207(b)(3)(ii), they should be able to produce payment rates consistent with the methodology approved in their State plan. We also clarify that rates approved in 1915(c) waivers are considered CMS-approved FFS payment rates and can be used for the payment analysis in § 438.207(b)(3)(ii). We appreciate the suggestion of producing an average unit cost; however, that would be inconsistent with the rest of the analysis and would be overly impacted by outlier payment rates.

Comment: A few commenters stated that in the “Medicaid Program; Ensuring Access to Medicaid Services” proposed rule,⁵² CMS proposed to publish the E/M codes to be used for the payment rate analysis in subregulatory guidance along with the final rule and questioned if CMS would do that for the payment analysis in § 438.207(b)(3).

Response: We did not intend to publish a specific list of E/M codes for the managed care plan payment analysis in § 438.207(b)(3). We believe that using

paid claims data to derive the E/M codes is more appropriate as paid claims provide the codes used by managed care plan providers and limits the codes in plans’ analysis to those that are relevant. Further, we believe the varied scope of covered services among managed care plans makes using only E/M codes used by providers on their claims most appropriate and simplifies extracting the relevant data from a plan’s paid claims data. For example, a PIHP that covers only mental health and SUD will have far fewer E/M codes in their claims data than an MCO that covers primary care and OB/GYN services. In the interest of efficiency and relevance, we decline to publish a list of E/M codes for the managed care plan payment analysis in § 438.207(b)(3) in this rule.

Comment: A few commenters noted that final provider payments can include a variety of adjustments and that CMS should work with State Medicaid programs to develop an analysis method that accounts for these differences to ensure that comparisons accurately reflect differences in base provider payment rates. Another commenter stated concern that the results of this type of analysis could be biased by differences in the mix of services provided by different managed care plans and suggested that instead of each plan using its own utilization mix, States provide statewide utilization that would be used by all plans in their provider payment analysis.

Response: We understand that there are adjustments made to contractually negotiated provider rates when claims are adjudicated, and we believe it is appropriate to include these in the analysis to accurately reflect the amount paid to the provider types in the analysis as compared to the published Medicare payment rate. Regardless of the mix of services provided by different managed care plans, the analysis required at § 438.207(b)(3) only includes E/M codes for primary care, OB/GYN, mental health, and SUD; as such, we are unclear why the commenter believes that the results will be biased. Lastly, we do not agree with the commenter’s suggestion that each managed care plan should use statewide utilization instead of its own data that reflects the plan’s unique utilization mix. We believe this would render the analysis meaningless as the analysis is intended to produce customized results that reflect each plan’s expenditures.

Comment: One commenter requested clarification on whether States that report managed care plan payment rate analyses will report in the aggregate or by named managed care plan.

Response: The documentation provided by each managed care plan that will include the payment analysis finalized in § 438.207(b)(3) for Medicaid and, included in separate CHIP regulations through an existing cross-reference at § 457.1230(b), will be reviewed by States and reported in the NAAAR, per § 438.207(d). The fields in the NAAAR for reporting of the payment analysis will be by managed care plan consistent with § 438.207(d)(2)(i). States will report the data from its plans’ reported payment analysis percentages in the NAAAR as well as percentages weighted using the member months for the applicable rating period.

Comment: A few commenters requested clarification on the exact scope of LTSS included in the categories of homemaker, home health aide, and personal care services, and whether they should be included regardless of where they are provided or under what delivery model. One commenter suggested that CMS provide guidance clarifying whether payments for homemaker and home health aide services provided to dually eligible enrollees for intermittent skilled care or for other purposes would be excluded from the analysis.

Response: We thank commenters for raising these questions so that we can provide additional clarity. The payment analysis required at § 438.207(b)(3)(ii) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), includes all codes for homemaker services, home health aide services, personal care services, and habilitation services as these services do not generally utilize E/M CPT codes. (88 FR 28105) We did not specify limitations on where the services are provided and only services covered in a managed care delivery system can be included as the analysis must utilize managed care plan paid claims data. Regarding whether payments for homemaker and home health aide services provided to dually eligible enrollees are included in the analysis, § 438.207(b)(3)(iii) was proposed and finalized to specify that payments for which the managed care plan is not the primary payer are excluded from the analysis. Therefore, homemaker and home health aide services will be included in the managed care plan’s analysis if Medicaid was the primary payer for the claim.

Comment: One commenter stated that section 1932 of the Social Security Act does not address “comparability” of reimbursement rates or with transparency, leaving the proposed

⁵² Published in the May 3, 2023 *Federal Register* (88 FR 27960 through 28089); <https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-08959.pdf>.

payment analysis without any clear statutory basis.

Response: We believe that 1932(c)(1)(A)(ii) and (iii) of the Act provide CMS the authority for the payment analysis at § 438.207(b)(3). As we stated in the proposed rule, 1932(c)(1)(A)(ii) requires States' quality strategies to include an examination of other aspects of care and service directly related to the improvement of quality of care and procedures for monitoring and evaluating the quality and appropriateness of care and services. The payment analysis required at § 438.207(b)(3) will generate data on each managed care plan's payment levels for certain provider types which States should use in their examination of other aspects related to the improvement of quality of care, particularly access. Further, the data from the payment analysis will provide consistent, comparable data that can contribute an important perspective to States' activities to monitor and evaluate quality and appropriateness of care given the well-established link between payment levels and provider participation.

After reviewing the public comments, we are finalizing §§ 438.207(b)(3) and (g), and 457.1230(b) as proposed, except for a minor wording correction in § 438.207(b)(3)(i) and to add habilitation in § 438.207(b)(3)(ii).

e. Assurances of Adequate Capacity and Services Reporting (§§ 438.207(d) and 457.1230(b))

Section § 438.207(d) requires States 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 proposed 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 final rule) and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b). We also proposed to require States to include the payment analysis proposed in § 438.207(b)(3) (see section I.B.1.d. of this final rule) to their assurance and analyses reporting. Additionally, on July 6, 2022, we published a CIB⁵³ that provided a reporting template *Network Adequacy and Access Assurances Report*⁵⁴ for the reporting required at

§ 438.207(d). To be clear that States will have to use the published template, we proposed 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 will fulfill this requirement as will future versions including any potential electronic formats. We believe the revision proposed in § 438.207(d) is necessary to ensure consistent reporting to CMS and enable effective analysis and oversight. Lastly, because we proposed new requirements related to the inclusion of the payment analysis and the timing of the submission of this reporting to CMS, we proposed to redesignate the last sentence in paragraph (d) of § 438.207 as paragraph (d)(1) and create new paragraphs (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 proposed 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) proposed to require States to include the data submitted by each plan and § 438.207(d)(2)(ii) proposed 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 will provide valuable new data to support States' assurances of network adequacy and access and we will revise the NAAAR template published in July 2022 to add fields for States to easily report these data. We reminded 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 will be supplemented by the proposed 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 NAAAR 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 proposed 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 proposed that States submit their assurance and analysis at § 438.207(d)(3): (1) at the time they submit 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 proposed 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 will 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 proposed 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 proposed 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

⁵³ <https://www.medicaid.gov/federal-policy-guidance/downloads/cib07062022.pdf>.

⁵⁴ <https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx>.

§ 457.1230(b). We believe this was necessary as the text of § 438.207(e) only addressed 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 they have the capacity to serve the expected enrollment in its service area, including assurances that they offer 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 payment analysis proposed in § 438.207(b)(3) in 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 documentation from managed care plans in § 438.207(c)(3).

We also proposed to revise § 438.207(g) to reflect that States will 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 proposed that States will 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 proposed that States must

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.

We summarize and respond to public comments received on Assurances of adequate capacity and services reporting (§§ 438.207(d) and 457.1230(b)) below.

Comment: Many commenters supported our proposal to have States incorporate their review and analysis of their managed care plan provider payment analysis required in § 438.207(b)(3) into their NAAARs. These commenters stated this will provide much needed transparency in a consistent manner across all managed care programs.

Response: We thank commenters for their support for our proposal. We believe incorporating the payment analyses into a State's NAAAR is the least burdensome approach and will make the data easy to locate and understand.

Comment: One commenter suggested that in addition to requiring that the payment analysis in § 438.207(b) be included in States' NAAARs, which are posted on their website, that CMS also require States to submit their reports to their interested parties' advisory groups.

Response: We appreciate the suggestion that States share their NAAARs with their interested parties' advisory groups. We decline to adopt an additional requirement in this final rule but encourage States to consider incorporating distribution of their NAAARs into their advisory group processes.

Comment: A few commenters supported the specificity on the timing of submission of the NAAAR in § 438.207(d)(3), as it would improve consistency among States. One commenter pointed out that it seemed duplicative to submit the NAAAR for new managed care plans at the same time as the readiness review information (as proposed in § 438.207(d)(3)(i)) and suggested giving States more time to submit the NAAAR for newly contracted plans.

Response: We believe adding requirements for the submission times of the NAAAR will not only improve consistency but help States recognize some efficiencies as the submission times in § 438.207(d)(3) align with other existing report submissions. We appreciate commenters pointing out that our proposal in § 438.207(d)(3)(i) for States to submit the readiness review results and the NAAAR at the same time would not yield the most effective

information. To address this, we will finalize § 438.207(d)(3)(i) to require the submission of the NAAAR in advance of contract approval. This will provide managed care plans time to continue working to address any deficiencies identified in the readiness review and enable States to report the most current network adequacy and access information to inform our final determination regarding contract approval. We believe this revision in the submission timeframe will benefit the newly contracted managed care plan, the State, and CMS.

After reviewing the public comments, we are finalizing §§ 438.207(d) and 457.1230(b) as proposed except for a revision to § 438.207(d)(3)(i) to revise the submission time to enable contract approval.

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 will 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 proposed a process that will 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 will 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 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 will be needed to ensure that both CMS and States will adequately and appropriately address emerging access issues in Medicaid managed care programs.

Using § 447.203(b)(8) as a foundation, we proposed to redesignate existing § 438.207(f) as § 438.207(g) and

proposed 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 proposed that when the State, MCO, PIHP, PAHP, or CMS identifies an issue with a managed care plan's performance regarding any State standard for access to care under this part, including the standards at §§ 438.68 and 438.206, States will follow the steps set forth in paragraphs (i) through (iv). First, in paragraph (1)(i), States will 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 is 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 proposed that the State must 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 to 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 did not propose to specify that the remedy plan will be implemented by the managed care plans or the State; rather, we proposed that the remedy plan identify the responsible party required to make the access improvements at issue, which will often include actions by both States and their managed care plans. Additionally, we believe this proposal acknowledged 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 proposed some approaches that States could consider using 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 proposed in § 438.207(f)(1)(iii) to require States to ensure that improvements in access are measurable and sustainable. We believe it is critical that remedy plans produce measurable results to monitor progress and ultimately, bring about the desired improvements in access under the managed care plan. We also proposed that the improvements in access achieved by the actions be sustainable so that enrollees can continue receiving the improved access to care and managed care plans continue to ensure its provision. In paragraph (f)(1)(iv) of this section, we proposed that States submit quarterly progress updates to CMS on implementation of the remedy plan so that we will 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 proposed 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 will 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 will be an integral operational component of a State's quality assessment and improvement strategy.

We summarize and respond to public comments received on Remedy plans to improve access (§ 438.207(f)) below.

Comment: Many commenters stated support for requiring States to submit remedy plans to address access areas in need of improvement in § 438.207(f). Commenters noted that when combined with CMS's ability to disallow FFP for payments made under managed care contracts when the State fails to ensure access to care, requiring remedy plans would significantly advance the goal of ensuring that enrollees have access to the services they need. Many commenters supported requiring remedy plans to include specific steps and timelines and encouraged CMS to go further to include payment adequacy information. These commenters stated this requirement would impose much-needed transparency and accountability.

Response: We believe that the use of remedy plans will improve how States and managed care plans collaborate to develop robust, productive solutions to address access areas in need of improvement. We expect remedy plans to reflect how multiple factors were considered, including information on provider payment rates, State workforce initiatives, telehealth policies, and broad delivery system reforms. We decline to specifically require the inclusion of payment adequacy information in remedy plans in this final rule given the payment analysis requirement in § 438.207(b) and the associated reporting requirement in § 438.207(d); however, we encourage States to consider incorporating those analyses, as relevant, since they will be a readily available resource.

Comment: Some commenters recommended that remedy plans include input from a wide array of interested parties. These commenters stated that allowing community-

interested parties to understand how the State and its managed care plans intend to work together to correct the access issue(s) can not only help enrollees make informed enrollment choices, but also help ensure that all options for addressing the issues are considered and that steps in remedy plans are feasible for the assigned parties. A few commenters recommended requiring remedy plans to consider claim denial rates, prior authorization requests, and other sources of administrative burden which, in addition to payment rates, is another top reason physicians cite for not participating in managed care plans.

Response: We agree that remedy plans should include input from multiple sources to the extent feasible. We acknowledge that this may be challenging within the 90-calendar day timeframe for developing and submitting a plan. However, we believe States can gather input on ways to address access issues at any time and utilize it when a remedy plan is needed. We encourage States to consider how improvements in claim denial rates, timely and accurate prior authorization requests, and other sources of administrative burden can be used in remedy plans to encourage increased provider participation.

Comment: Many commenters stated concerns about the administrative burden of meeting the 90-day deadline for remedy plan submission and the diversion of limited State resources to comply with this mandate. Several commenters also stated that, depending on the number of potential remedies plans due at one time, 90 days may not be sufficient to collect data and complete the analysis needed to develop a useful remedy plan. These commenters recommended a longer timeframe between collecting reports from the plans and submission to CMS. Several commenters recommended revising the 90-day submission time to 180 days, given the anticipated volume of information reported.

Response: We understand commenters' concerns but do not believe extending the 90-calendar day development and submission timeframe for remedy plans is appropriate as States have experience using formal plans to address program areas in need of improvement. Further, States have been required to have a monitoring and oversight system that addresses all aspects of their managed care program and use the data collected from its monitoring activities to improve the performance of its managed care program since § 438.66(a) through (c) was issued in the 2016 final rule. We see the remedy plans finalized at

§ 438.207(f) to add structure (that is, specific steps, timelines, and responsible parties) to the requirement in § 438.66(c) to use data collected from a State's monitoring activities to improve the performance of its managed care program. As such, we do not believe that 90 calendar days is an unreasonable timeframe for submission.

Comment: Many commenters stated that 12 months to remediate many of the issues that will be included in remedy plans is not feasible particularly for those that include initiatives like changing State scope of practice laws. Some commenters noted that the most effective workforce recruitment and retention efforts may take more than 12 months to yield full results and result in sustainable improvements. Another commenter stated that it is unclear what meaningful change could be enacted and what systemic barriers could be solved within 12 months. However, other commenters stated that with as many issues of access to care as are already known, allowing for up to 2 years to remedy a specifically identified problem with multiple progress report opportunities would be too long for enrollees to wait to see the benefits. One commenter recommended that unless an extreme scenario occurs, CMS should employ a 12-month timeframe with no 12-month extension.

Response: We appreciate the wide range of comments on the duration of remedy plans.

We acknowledge that there are network adequacy and access issues that will be identified during secret shopper surveys that will require a range of effort, solutions, and time to produce improvement. Some issues will be able to be resolved with short, quickly implemented activities. While others, such as workforce expansion or changing scope of practice laws to permit enrollment of new provider types, will take more robust, multi-pronged, collaborative solutions over an extended period. Regardless, we believe that remedy plans serve a critical function in addressing identified deficiencies by focusing States', managed care plans', and other interested parties' efforts on the development and implementation of definitive steps to address areas for improvement, including both short-term and long-term strategies to address access to care issues. We also believe that including timeframes and responsible parties for each planned action provide structure and accountability, as well as facilitates effective implementation and monitoring.

As we state in § 438.207(f)(1)(ii), States' and managed care plans' actions may include a variety of approaches, including increasing payment rates to providers, improving outreach to and problem resolution with 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 encourage States to collaborate with their managed care plans as soon as feasible to evaluate plan performance for improvement opportunities and ensure that process improvements related to credentialing, accurate claims processing, and prior authorization processing are implemented effectively and timely. Given that § 438.207(f) will not be applicable until the first rating period that begins on or after 4 years after the effective date of the final rule, we believe States have ample time to use existing data from monitoring activities to identify existing access issues and begin formulating and implementing steps to remediate them in advance of a State's first remedy plan submission. We encourage States to proactively take steps to address identified access issues to minimize the number of issues that remain four years after the effective date of the final rule. We decline the suggestion to not finalize our ability to extend remedy plans for an additional 12 months. We believe that the ability to extend the remedy plans an additional 12 months is an important flexibility that will be necessary for issues that require a longer timeframe to produce measurable improvement. We also believe extending some remedy plans an additional 12 months enables ongoing monitoring and progress reporting to ensure adequate resolution and sustainability.

Comment: Many commenters requested that CMS provide additional detail on what access issues would rise to the level of needing a remedy plan. Commenters stated the text "could be improved" is vague and does not give clear criteria for States to know when remedy plans will be required. One commenter stated that the rule seems to give CMS a lot of discretion as to how heavy-handed it wants to be, on a case-by-case basis, without providing expectations that States can rely on. Several commenters stated that States need some level of assurance from CMS as to when they will need to produce remedy plans.

Response: We acknowledge that some commenters believe that the regulation text at § 438.207(f)(1) is vague. However,

we do not agree and believe that it is appropriate for us to have the ability to require remedy plans when an area in which a managed care plan's access to care under the access standards could be improved is identified and we should not be restricted to a finite list of criteria. Further, we clarify that § 438.207(f)(1) includes "under the access standards in this part" which provides many of the criteria upon which we will base our requests for remedy plans, such as the quantitative network adequacy and appointment wait time standards in § 438.68 and payment analysis reporting in § 438.207(d).

Comment: Some commenters were opposed to CMS requiring remedy plans. A few commenters stated that remedy plans were not needed as States already employ a variety of strategies, including corrective action plans, monetary damages, and other forms of intermediate sanctions, to ensure plan compliance with contractual standards regarding network adequacy and access to care. Some commenters stated concerns that this provision may not successfully address underlying challenges with access. A few commenters stated that it is inappropriate for CMS to insert itself into the contractor management process in the manner envisioned by the rule. A few commenters noted that withholding FFP in this case is a highly disproportionate and unreasonable consequence when States and managed care plans cannot make more providers exist in the State and can only have a limited impact on whether existing providers choose to enroll as Medicaid providers. A few commenters suggested that CMS give States the autonomy to create and enforce their own corrective action plans for access issues at State discretion. Some commenters recommended that CMS should first consider how it can play a role (perhaps by working closely with the Health Resources and Services Administration and the U.S. Department of Education), providing upside incentives to States to enact policies to help grow and retain the healthcare workforce and that the creation of remedy plans will be a distraction from what should be CMS's primary focus of growing the healthcare workforce.

Response: We understand that some commenters believe that remedy plans are not necessary. Prior to this final rule, the managed care regulations in 42 CFR, part 438 have not contained a specific provision for formal plans to address areas of program weakness. We have typically relied on technical assistance and periodic meetings to monitor States'

progress to strengthen program performance. Unfortunately, we find that these methods do not always yield consistent, documented results and we believe that access concerns in managed care programs warrant a more organized, traceable process. Additionally, we do not intend to use remedy plans to usurp authority from States or intervene inappropriately in their contractual relationships. To the contrary, we believe remedy plans will help CMS, States, and managed care plans work collaboratively and coalesce around blueprints for improvement of specific access issues that can be shared and enhanced over time. Lastly, as oversight bodies and interested parties continue to audit, submit Freedom of Information Act requests, and analyze performance of the Medicaid program, we believe establishing a consistent process for addressing access issues in managed care is necessary and CMS, States, and managed care plans will all benefit from having documentation to substantiate improvement efforts. To the comment that we also need to take steps to work with our Federal partners, HHS and the entire Biden-Harris Administration continues to undertake efforts to improve access. For example, funding was recently awarded to improve health care facilities in rural towns across the nation. See <https://www.usda.gov/media/press-releases/2023/07/25/biden-harris-administration-helps-expand-access-rural-health-care>. On August 10, 2023, the Health Resources and Services Administration announced awards of more than \$100 million to train more nurses and grow the nursing workforce. See <https://www.hhs.gov/about/news/2023/08/10/biden-harris-administration-announces-100-million-grow-nursing-workforce.html>.

Comment: One commenter requested that CMS consider permitting integrated plans for dually eligible individuals to substitute compliance with Medicare network requirements for participation in the proposed remedy plans.

Response: We appreciate that integrated plans must comply with Medicare and Medicaid requirements for network adequacy and access. However, we believe that when an access issue is identified that warrants a remedy plan, all the State's impacted Medicaid managed care plans need to contribute to the successful execution of it. This is particularly relevant given the vulnerable populations covered by plans that cover both Medicare and Medicaid services for dually eligible enrollees.

Comment: A few commenters recommended that the remedy plans,

once approved, be posted on the State's website and that the State agency be required to share them with interested parties' advisory groups.

Response: We appreciate the suggestion for States to post their approved remedy plans on their website; however, we decline to include that in this final rule. We encourage States to consider posting their approved remedy plans on their websites and sharing them with their interested parties' advisory groups so that interested parties can support States and plans as they work to execute their remedy plans.

Comment: Some commenters recommended delaying the applicability date until the first rating period for managed care plan contracts that begins on or after 6 years after the effective date of the final rule. Another commenter suggested an applicability date that is at least 1 year after the secret shopper survey is required.

Response: We believe it is important to align the use of remedy plans with States receiving secret shopper survey results. As such, we decline to extend the applicability date.

After reviewing the public comments, we are finalizing § 438.207(f) as proposed.

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. Regulations at § 438.10(c)(6)(ii) required certain information to be "prominent and readily accessible" and § 438.10(a) defined "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 determined that revisions were necessary to ensure that all States’ websites required by § 438.10(c)(3) provide a consistent and easy user experience. We acknowledged 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 noted that State and managed care plan websites must be compliant with all laws, including the Americans with Disabilities Act (ADA), section 504 and 508 of the Rehabilitation Act, Title VI of the Civil Rights Act of 1964, and section 1557 of the Affordable Care Act. In implementing this proposed rule, we believe there are several 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 was 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’ experience, we proposed in § 438.10(c)(3) to revise “websites” to “web pages” in the reference to managed care plans. We proposed 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 will have to be to the specific page that includes the requested information. We believe this prevents 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 proposed to add “States must:” to paragraph (c)(3) before the items specified in new paragraphs (c)(3)(i) through (iv). In § 438.10(c)(3)(i), we proposed 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 carefully chose 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 represented an important step toward eliminating common obstacles for States’ website users.

At § 438.10(c)(3)(ii), we proposed 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, will 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 will reduce the likelihood of users having to make unnecessary clicks as they search for specific information.

In § 438.10(c)(3)(iii), we proposed 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 proposed that a State’s website be checked for functionality and information timeliness no less than quarterly, we believe this to be 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 proposed 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 was consistent with existing information requirements in § 438.10(d) and section 1557 of the Affordable Care Act. Clear provision of this information will 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) will apply to separate CHIP through the existing cross-reference at § 457.1207.

To help States monitor their website for required content, we proposed to revise § 438.602(g) to contain a more complete list of information. While we believe the list proposed in § 438.602(g) will 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). Section 438.602(g) specified four types of information that States must post on their websites; we proposed to add nine more as (g)(5) through (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)(v)(A)(3); (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 proposed 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 proposed to make the list of website content more complete by removing references to paragraphs (g) through (i) only and including a reference to § 438.602(g) and "elsewhere in this part."

We proposed to revise § 438.10(j) to reflect that States will 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 will 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 proposed 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 dates provide reasonable time for compliance given the varying levels of State and managed care plan burden.

We proposed 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 proposed 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 proposed 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 did not propose 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 proposed 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) will apply to separate CHIP through an existing cross-reference at § 457.1230(b) (see section I.B.1.e. of this final rule). Since we did not adopt the managed care program annual reporting requirements at § 438.66(e) for separate CHIP, we proposed to exclude this reporting requirement at § 457.1230(b).

We proposed 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 proposed 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 final rule), though we proposed to exclude references to LTSS as not applicable to separate CHIP.

We proposed 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 final rule).

We did 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 proposed 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 proposed 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 proposed to exclude the reference to § 438.362(c) since MCO EQR exclusion is not applicable to separate CHIP.

We proposed 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 proposed 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 proposed 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 will 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 will directly help States fulfill their obligation to provide informational materials in a manner and form which may be easily understood.

We summarize and respond to public comments received on Transparency (§§ 438.10(c), 438.602(g), 457.1207, 457.1285) below.

Comment: Many commenters supported our proposal to require that States' managed care websites contain

all required information on one page that is clear and easy to understand, that is verified at least quarterly, and that helps users. Commenters confirmed that interested parties often face difficulty navigating State websites and the proposed requirements would greatly improve the usability of States' websites.

Response: We appreciate the support for our proposals. We believe State managed care websites are critical sources of information for interested parties and efforts to improve their utility is a fundamental responsibility for States.

Comment: We received a comment recommending that we require States to post direct links to the appropriate document or information on the managed care plan's site. Another commenter questioned whether the requirements in § 438.10(c)(3) will apply to the State website and/or the managed care plans' websites.

Response: We appreciate the commenter raising this question and welcome the opportunity to provide clarification. Existing regulation text at § 438.10(c)(3) requires "The State must operate a website that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, . . ." This means that the link to an MCO's, PIHP's, PAHP's or PCCM entity's website must be to the required content, not just to a random location on the MCO's, PIHP's, PAHP's, or PCCM entity's website. Our proposal to revise "websites" to "web pages" was intended to make that clearer, not alter this existing requirement. While the requirements of § 438.10(c)(3) are applicable to State websites, States can certainly apply them to their managed care plans through their managed care plan contract. Given that States must provide assistance to website users at § 438.10(c)(3)(iv) and through existing cross-reference at § 457.1207 for separate CHIP, we encourage States to ensure that their plans' websites meet at least the same minimum standards.

Comment: A few commenters urged CMS to require States to post other documents on the State website, such as the Annual Medical Loss Ratio reports and mental health parity compliance analyses that managed care plans must submit to the State. Conversely, other commenters stated concern that some required reports are inherently technical and difficult to understand and that it would be extremely hard or impossible to render at a grade 6 reading level.

Response: We appreciate the suggestion that managed care plans' MLR reports be posted on States' managed care web page. While we did

not propose that MLR reports be posted on States' managed care web page in this rule, we may consider it in future rulemaking. The posting of mental health parity analyses completed by MCOs is consistent with existing § 438.920 and we encourage States to ensure a clearly identifiable label on such analyses or links to them.

However, we want to be cognizant of the amount of information that we require States to present on their managed care web pages and balance that with interested parties' use and need. The website requirement in § 438.10(c)(3) was added in the 2016 final rule to acknowledge the increasing use of electronic media by enrollees and potential enrollees for critical program information. We believe these websites would be a valuable and welcome way to address problems that Medicaid and CHIP programs have struggled with for years; for example, missed mail, incorrect mailing addresses, and excessively long or too frequent mailings. While we understand that other interested parties also use the States' web page, we want to be thoughtful about the required content, particularly given that § 438.10(c)(3)(i) and § 457.1207 for separate CHIP will require that all information be accessible from one page.

To the concern that some reports that are required to be posted on States' managed care web page are complicated and technical, we acknowledge that not all of the information is as easy to present as others. We encourage States to include approaches that may assist readers, such as providing executive summaries that contain less detail and are easier to read but still capture the most important information. This type of an aid would enable readers to determine if they want to read the longer or more complicated document.

Comment: We received several comments regarding the administrative burden and cost associated with developing a chat feature. One commenter suggested that information should be able to be automatically heard read aloud by clicking on the material for the most common languages within each State.

Response: We clarify that including a chat feature on a website was a recommended practice, but it was not proposed in § 438.10(c)(3). As we stated, we believe a chat feature to be one of the minimal qualities that all websites should include but as we did not propose it, we did not include it in our burden estimates for this provision. We appreciate the suggestion that users should be able to click on the material and it be automatically read aloud and

encourage States and managed care plans to consider building this feature into their web pages.

Comment: A commenter supported our proposals at § 457.1207 to require States to operate a website that provides certain information, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites. The commenter suggested aligning transparency requirements for Medicaid MCOs proposed at § 438.602(g) with transparency requirements applicable to separate CHIP MCOs.

Response: We thank the commenter for their suggestion. We clarify that we did propose to align separate CHIP with most of the Medicaid transparency requirements at § 457.1207 through an amended cross-reference to § 438.602(g)(5) through (13), except in situations where the Medicaid requirement is not relevant for separate CHIP. We did not 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 believe finalizing the amendments at § 457.1285 will align the transparency requirements of Medicaid MCOs and separate CHIP MCOs when appropriate.

After reviewing the public comments, we are finalizing §§ 438.10(c), 438.602(g), 457.1207, and 457.1285 as proposed.

h. Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b) and 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 proposed 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 proposed 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 proposed to remove "behavioral health" and the parentheses; and for the provider types addressed in credentialing policies at § 438.214(b), we proposed to replace "behavioral" with "mental health." We also proposed 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 proposed 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 in an institution for mental disease (IMD).

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.

We summarize and respond to public comments received on Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b), 438.214(b)) below.

Comment: We received several comments supporting our proposal to revise “behavioral health” throughout part 438 regulations to “mental health” and “SUD” as appropriate.

Response: We appreciate commenters’ support and will finalize “mental health” and “SUD” in §§ 438.2, 438.3(e), 438.10(h), 438.68(b), 438.214(b) to ensure that these provisions are clear and unambiguous.

After reviewing the public comments, we are finalizing §§ 438.2, 438.3(e), 438.10(h), 438.68(b), and 438.214(b) as proposed.

2. State Directed Payments (SDPs) (§§ 438.6, 438.7 and 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 under which 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 access to 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. Balancing that this type of State direction reduces the plan’s ability to effectively manage costs but can be an important tool for states. 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 payment (VBP) models, that certain providers participate in multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives, or that the managed care plan use 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 are 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.⁵⁵ 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).⁵⁶ States must obtain written prior 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 laws. 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, we published the initial preprint form⁵⁷ along with guidance for States on the use of SDPs.⁵⁸ In May 2020, CMS published guidance on managed care flexibilities to respond to the PHE, including how States could use SDPs in support of their COVID-19 response efforts.⁵⁹ In January 2021, we 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, 2021.⁶⁰ 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

⁵⁶ <https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

⁵⁷ <https://www.medicaid.gov/sites/default/files/2020-02/438-preprint.pdf>.

⁵⁸ <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib11022017.pdf>.

⁵⁹ <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051420.pdf>.

⁶⁰ <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf>.

⁵⁵ 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).

of our review of SDPs to ensure compliance with the Federal regulatory requirements.⁶¹ 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 codified 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 CY 2017, we received 36 preprints from 15 States for our review and approval. In contrast, in CY 2021, we received 223 preprints from 39 States. For CY 2022, we received 298 preprints from States. In total, as of October 2023, we have reviewed nearly 1,400 SDP proposals and approved 1,244 proposals since the 2016 final rule was issued.⁶²

SDPs also represent a notable amount of spending. The Medicaid and CHIP Payment and Access Commission (MACPAC) reported that, in 2020, CMS approved SDP arrangements in 37 States, with spending exceeding more than \$25 billion.⁶³ The U.S. Government Accountability Office (GAO) also reported that at least \$20 billion in SDP expenditures has been approved by CMS for preprints with payments to be made on or after July 1, 2021, across 79 approved preprints⁶⁴ and in another report they estimated that SDPs totaled \$38.5 billion in 2022 according to their analysis of CMS approved SDP preprints approved through August 2022 while acknowledging the total estimated SDP spending was likely higher.⁶⁵ Our internal analysis of all SDPs approved

from the time that § 438.6(c) was issued in the 2016 final rule through the end of fiscal year 2022 estimates that the total spending for all SDPs approved for the most recent rating period for States is nearly \$52 billion annually⁶⁶ (Federal and State) and at least half of that amount is for provider payments States require plans to pay in addition to the rates negotiated between the plans and providers.

In its December 2023 report, the GAO acknowledged that CMS has taken steps to enhance its process for approving SDPs and recommended that CMS enhance fiscal guardrails for SDPs. Specifically, the GAO recommended that CMS improve these guardrails by establishing a definition of, and standards for, assessing whether SDPs result in payment rates that are reasonable and appropriate, and communicating those to States; determining whether additional fiscal limits are needed; and requiring States to submit data on actual spending amounts at the SDP preprint renewal.⁶⁷ The GAO also recommended that CMS consider interim evaluation results or other performance information from States at the SDP preprint renewal, and recommended increased transparency of SDP approvals. 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 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 rule are intended, individually and taken together, to ensure the following policy goals:

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

⁶⁶ This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through the end of fiscal year 2022, under CMS's standard review process. Rating periods differ by State; some States operate 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 the end of fiscal year 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).

⁶⁷ U.S. Government Accountability Office, "Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency." December 14, 2023, available at <https://www.gao.gov/assets/d24106202.pdf>.

(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.

We are issuing the requirements in this final rule 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, and is extended to PIHPs and PAHPs through regulations based on our authority under section 1902(a)(4) of the Act. As noted 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). 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 did not propose to adopt the new Medicaid managed care SDP requirements proposed at §§ 438.6 and 438.7 for separate CHIPs.

We proposed 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 proposed 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 paragraph (c) of § 438.6 to "*State Directed Payments under MCO, PIHP, or PAHP contracts*" to reflect this term.

In addition, we proposed several revisions to § 438.6 to further specify and add to the existing requirements

⁶¹ <https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

⁶² 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).

⁶³ 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.

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>.

⁶⁵ U.S. Government Accountability Office, "Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency." December 14, 2023, available at <https://www.gao.gov/assets/d24106202.pdf>.

and standards for SDPs. First, we proposed revisions, including: codifying administrative requirements included in recent guidance;⁶⁸ exempting SDPs that establish payment rate minimums at 100 percent of the total published Medicare payment rate from the written prior approval requirement; 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 proposed 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 proposed, some of which will require significant time for States to implement, we proposed a series of applicability dates over a roughly 5-year period for compliance. These applicability dates are discussed in section I.B.2.p. of this final rule.

We reiterate here our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Although the changes in this rule are intended to work harmoniously to achieve a set of goals and further specific policies, they are not so interdependent that they will not work as intended even if a provision is held invalid. The SDP provisions may operate independently of each other. For example, the financing provisions finalized as § 438.6(c)(2)(ii)(G) and (H) are separate, distinct, and severable from all the other standards enumerated in § 438.6(c). Most of the SDP parameters and conditions in the

regulation govern the development of the actual SDP arrangement, operational processes associated with documentation and CMS review and approval, as well as the SDP evaluation. If the financing provisions § 438.6(c)(2)(ii)(G) and/or (H) or even the payment limit established in § 438.6(c)(2)(iii) were to change, all the other standards around SDPs would continue to remain enforceable because the other provisions do not impact either of the financing provisions or the payment limit. Similarly, the operational and evaluation standards adopted in this rule could be implemented separately if necessary.

An outline of the remaining parts of this section of this final rule is provided below:

- b. Contract Requirements Considered to be SDPs (Grey Area Payments) (§ 438.6(c)(1))
- 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 438.6(c)(2)(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 (c)(2)(ii)(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)(C), (c)(2)(ii)(D), (c)(2)(ii)(F), (c)(2)(iv), (c)(2)(v) and (c)(7))
- k. Contract Term Requirements (§ 438.6(c)(5) and 438.7(c)(6))
- l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J) and (c)(6), and 438.7(f))
- m. SDPs included through Adjustments to Base Capitation Rates (§§ 438.6(c)(6), and § 438.7(c)(4) through (c)(6))
- n. Appeals (§ 430.3(e))
- o. Reporting Requirements to Support Oversight and Inclusion of SDPs in MLR Reporting (§§ 438.6(c)(4), and 438.8(e)(2)(iii)(C) and (f)(2)(vii))
- p. Applicability Dates (§§ 438.6(c)(4) and 438.6(c)(8), and 438.7(f))

We summarize and respond to public comments received on State Directed Payments (§§ 438.6, 438.7, 430.3) below.

We received comments related to the definitions of “academic medical center,” “qualified practitioner services at an academic medical center,” “inpatient hospital services,” “outpatient hospital services,” “performance measure” and “total published Medicare payment rate”; see sections

I.B.2.f., I.B.2.j., and I.B.2.c. respectively of this final rule for our responses.

We did not receive comments on the remaining proposed definitions.

We are finalizing the following definitions in § 438.6(a) as proposed: “Academic medical center,” “Average commercial rate,” “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,” “Total payment rate,” “Total published Medicare payment rate,” and “Uniform increase.” We are not finalizing a definition for the term “separate payment term” or the provisions regarding separate payment terms (see section I.B.2.l. of this final rule for discussion).

The definition for the term “State directed payment” is finalized as proposed but has been moved from § 438.6(a) to § 438.2 because it is used in multiple provisions in part 438. We are also finalizing revisions throughout §§ 438.6 and 438.7 to use the term “State directed payment” in place of “contract arrangement” or similar terms that are used in the current regulations to refer to State directed payments.

The definition for “Condition-based payment” is finalized with the phrase “covered under the contract” at the end to specify that such prospective payment must be for services delivered to Medicaid managed care enrollees covered under the managed care contract.

- b. Contract Requirements Considered to be SDPs (Grey Area Payments) (§ 438.6(c)(1))

Under § 438.6(c) (currently and as amended in this rule), 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 CIB entitled “Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts,” we noted instances

⁶⁸ <https://www.medicaid.gov/sites/default/files/2021-12/smd21001.pdf>.

where States may include general contract requirements for provider payments that will not be subject to approval under § 438.6(c) if the State was not mandating a specific payment methodology or amounts under the contract.⁶⁹ We also noted that these types of contract requirements will not be pass-through payments subject to the requirements under § 438.6(d), as we believe 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. However, 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 in the November 2017 CIB relates to instances where the State contractually implements 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 this type of vague contractual requirement for increased provider payment from 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).

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.⁷⁰ 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." (81 FR 27587) 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 require payments that are not directly associated with services delivered to enrollees covered under the contract." (81 FR 27589).

In January 2021, we published State Medicaid Director Letter (SMDL) #21–

001,⁷¹ 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 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; our proposal reflected this position. States 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 did not believe changes were needed to the regulation text in § 438.6(c) or (d) to reflect this reinterpretation and clarification because this preamble provided an opportunity to again bring this important information to States' attention. We noted in the proposed rule that CMS would continue this narrower interpretation of § 438.6(c) and (d) and we solicited comments on whether additional clarification about these grey area payments is necessary, or if revision to the regulation text would be helpful.

We summarize and respond to public comments received on Contract Requirements Considered to be SDPs (Grey Area Payments) below.

Comment: Some commenters supported CMS's restatement of our existing policy 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, and that "grey area payments" are prohibited. One

⁶⁹ <https://www.hhs.gov/guidance/document/delivery-system-and-provider-payment-initiatives-under-medicare-managed-care-contracts>.

⁷⁰ <https://www.federalregister.gov/documents/2017/01/18/2017-00916/medicaid-program-the-use-of-new-or-increased-pass-through-payments-in-medicare-managed-care-delivery>.

⁷¹ <https://www.medicare.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf>.

commenter noted that reiterating these existing requirements improves transparency.

Response: We appreciate the commenters' support and agree that restating our existing policy promotes greater transparency. We believe it aids States' planning and operational efforts for associated managed care activities. We note that guidance on this topic has been previously published at SMD #21–001 and restatement in this final rule provides consistent documentation of the policy and its scope. (see 88 FR 28113)

Comment: Some commenters opposed CMS's interpretation. These commenters encouraged CMS to revise the Federal regulatory requirements to instead indicate that broad contract requirements that direct managed care plans to move a set percent of provider payments into value-based arrangements do not trigger SDP provisions. One such commenter indicated that the continuation of "grey area payments" allows States necessary flexibility to support State initiatives to ensure access to medically necessary services, such as hospital services, while still operating within the financial realities of State budgets.

Response: We continue to believe that our current policy is reasonable and appropriate, and we decline to revise the regulation to allow flexibility for States to continue directing general increases to payments without using an SDP to ensure that payments are tied to utilization of service. We reject the recommendation to continue to permit "grey area payments" that are about general direction to increase payments. We believe the existing authorities available to States, including SDPs and incentive arrangements, can be useful tools in States' efforts to ensure access to care. After review of these comments, we recognize that our intent as outlined in the proposed rule preamble (88 FR 28113) would be clearer if we included a minor modification to § 438.6(c)(1). Therefore, we are amending § 438.6(c)(1) to add the phrase "in any way" after ". . . The State may not . . ." to make the regulation more explicit that any State direction of an MCO's, PIHP's or PAHP's expenditures is impermissible unless it meets the requirements set forth in § 438.6(c).

We are also finalizing the definition for "State directed payment" as proposed although we are moving it to § 438.2 in recognition of regulatory references to SDPs that are outside of § 438.6. We are making minor changes in the text of this definition to be consistent with how it is codified in § 438.2 instead of § 438.6. In addition,

the final definition cites § 438.6(c) instead of paragraphs (c)(1)(i) through (iii) to reflect how paragraph (c) includes additional requirements for SDPs.

Comment: Some commenters requested clarification on whether payments to FQHCs, RHCs and Certified Community Behavioral Health Clinics (CCBHCs) under a prospective payment system (PPS) are considered SDPs since they mandate the amount of payment.

Response: We appreciate this request for clarification as an opportunity to remind commenters of existing regulation that explicitly addresses this topic. As outlined in § 438.6(c)(1), the State may not direct the MCO's, PIHP's or PAHP's expenditures under the contract, except as specified in a provision of Title XIX or in another regulation implementing a Title XIX provision related to payments to providers. Therefore, the payment of statutorily-required PPS rates to FQHCs and RHCs under Title XIX or CCBHC demonstrations under section 223 of the Protecting Access to Medicare Act of 2014 are not considered SDPs and are not prohibited by § 438.6. If States elect to adopt payment methodologies similar to those under the CCBHC demonstration but the State or facilities are not part of an approved section 223 demonstration, those payment arrangements would need to comply with SDP requirements in § 438.6(c) as the Federal statutory requirements only extend to those States and facilities participating in an approved demonstration.

After reviewing public comments, and for the reasons outlined in the proposed rule and our responses to comments, we are amending § 438.6(c)(1) to clarify that States may not in any way direct MCO, PIHP or PAHP expenditures, unless such direction is permitted under § 438.6(c)(1) and we are finalizing the definition for "State directed payment" in § 438.2 instead of § 438.6(a) as originally proposed.

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

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.⁷² 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 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 contracts and rate certifications which include these SDPs, and TMSIS reporting requirements apply to SDPs that do not require prior approval. 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 reviewed and approved SDPs since the 2020 final rule, we

⁷² <https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicare-and-childrens-health-insurance-program-chip-managed-care>.

continue to believe this same rationale applies to SDPs that adopt a minimum fee schedule using Medicare established 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. Additionally, section 1852(a)(2) of the Act and 42 CFR 422.214 respectively provide, with some exceptions, that Medicare Advantage plans pay out-of-network providers, and those providers accept in full, 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.⁷³ These considerations mean that Medicare Part A and B payment rates are appropriate and do not require additional review by CMS in the context of a Medicaid managed care SDP. Therefore, prior written approval by CMS is not necessary to ensure that the standards for SDPs in current § 438.6(c)(2) are met when the total published Medicare payment rate is used in the same or a close period as a minimum fee schedule.

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

First, we proposed 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 proposed to redesignate the existing § 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 that is no older than from the 3 most recent

and complete years prior to the rating period as a permissible type of SDP.⁷⁴ We also proposed to revise redesignated 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 proposed to streamline the existing regulation text to eliminate the phrase “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 proposed 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 proposed to redesignate 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 included a conforming revision in § 438.6(c)(2)(i) to reflect the redesignation of § 438.6(c)(1)(iii)(B) through (D) as (c)(1)(iii)(C) through (E). This revision will ensure 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. As described in our proposed rule, 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. Under our proposal, 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 I.B.2.f. through I.B.2.l. of this final rule for proposed new requirements and revisions to existing requirements for all SDPs to be codified in paragraph (c)(2)(ii).)

Our proposal to exempt these Medicare payment rate SDPs from written prior approval from CMS was specific to SDPs that require the Medicaid managed care plan to use a

minimum fee schedule that is equal to 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 that 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. Accordingly, we believe SDPs that proposed provider payment rates that are incomplete or either above or below 100 percent of total published Medicare payment rates may not necessarily meet these criteria and thus, should remain subject to written prior approval by CMS. Our proposal was consistent with this belief.

We also did not propose 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 proposed the limit of 3 years to be consistent with how § 438.5(c)(2) requires use of base 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. 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 solicited 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 when 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 also proposed to add new § 438.6(c)(5) (with the paragraph

⁷³ 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/MedicareAdvgtgSpecRateStats/downloads/oonpayments.pdf>.

⁷⁴ Section 438.5 requires that States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates.

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) requires 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.

Under our proposal, the managed care contract must also 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 proposed § 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 like requirements in § 438.5 for rate setting, under which data that the actuary relies on 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 CY 2025, the Medicare fee schedule must have been in effect for purposes of Medicare payment at least at the beginning of CY 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 final rule.

We requested comment on other material or significant information about a Medicare fee schedule that will 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 final rule.

We summarize and respond to public comments received on our proposals related to the SDPs that use total published Medicare payment rates, including the proposed exemption from the written prior approval and contract

content requirements, § 438.6(c)(1)(iii)(B), (2), and (5)(iii)(A)(5) below.

Comment: Many commenters supported exempting minimum fee schedule SDPs at 100 percent of the total published Medicare payment rates specified in § 438.6(c)(1)(iii)(B) from written prior approval as Medicare payment rates have already been approved through the extensive Medicare notice-and-comment rulemaking process. As such, this exemption from written prior approval would reduce the administrative burden for State Medicaid programs and for CMS. Commenters also supported CMS's assertion that minimum fee schedules that are based on 100 percent of published Medicare payment rates pose comparatively little risk and satisfy the criteria of being reasonable, appropriate, and attainable. Further, commenters supported the proposal that the Medicare fee schedule should be in effect no more than 3 years prior to the start of the applicable rating period for the SDP.

Response: We appreciate commenters' support and agree that the exemption from written prior approval finalized in § 438.6(c)(2)(i) will eliminate an unnecessary and duplicative review process for SDPs and will facilitate more efficient and effective administration of the Medicaid program. We continue to believe that this exemption does not increase program integrity risk as Medicare payment rates are rigorously developed and vetted annually by CMS. Additionally, while the SDPs described in § 438.6(c)(1)(iii)(A) and (B) are not subject to prior approval, they are not automatically renewed, must comply with requirements and standards in part 438, and must be documented appropriately in the managed care contract and rate certification submission consistent with § 438.7. We take this opportunity to remind States that as specified in § 438.7(b)(6), rate certifications must include a description of any special contract provisions related to payment in § 438.6, including SDPs authorized under § 438.6(c)(1)(iii)(A) and (B). We also direct the commenter to section I.B.2.l. of this final rule for further details on the documentation of SDPs in rate certifications.

Comment: Several commenters supported the exemption from written prior approval for minimum fee schedule SDPs at 100 percent of the total published Medicare payment rate but suggested that we expand the scope of this exemption for additional SDPs that use Medicare fee schedules. Many of these commenters suggested a range,

such as 95 to 105 percent of Medicare payment rates, or a threshold as high as 125 percent of Medicare payment rates. One commenter suggested that any minimum fee schedule SDPs using payments in the range between the State Plan rate and the Medicare payment rate should qualify for the exemption from written prior approval.

Response: We continue to believe that minimum fee schedule SDPs using 100 percent of total published Medicare payment rates are reasonable and appropriate to remove from written prior approval requirements as they are developed by CMS and finalized through rulemaking. We have concerns about expanding this exemption to SDPs that use other percentages of total published Medicare payment rates. Only Medicare payment rates as published have undergone CMS development and oversight. Deviations from these payment rates introduce variations that have not been appropriately considered and vetted in a regulatory capacity to ensure the rate is reasonable, appropriate, and attainable. However, not using the published Medicare payment rate does not trigger a presumption on CMS's part that the proposed rates are not reasonable, appropriate, and attainable. Rather, we believe that minimum fee schedule SDPs which use Medicare payment rates that are incomplete or at a percentage other than 100 percent of the total published Medicare payment rate must continue to be reviewed by CMS and receive written prior approval via a preprint.

Comment: A few commenters recommended that CMS allow other SDPs to be exempt from prior approval requirements. Some of these commenters suggested CMS exempt from the prior written approval requirement any SDP that adopts minimum fee schedules, particularly those for behavioral health services and HCBS. Another commenter suggested extending this exemption to SDPs that provide uniform increases.

Response: We disagree that additional types of SDPs should be exempted from written prior approval of preprints. SDPs that use minimum fee schedules other than State plan approved rates or 100 percent of the total published Medicare payment rate, as well as uniform increases, must continue to be reviewed by CMS and receive written approval via a preprint, to ensure the payment rates are reasonable, appropriate, and attainable, in addition to ensuring compliance with § 438.6(c). The level of scrutiny and review that applies to the total Medicare payment rate and State plan approved rates does

not apply to other minimum or maximum fee schedules used in an SDP, so there are not sufficient assurances that the payment rates are reasonable, appropriate, and attainable to justify an exemption from CMS review and approval. Our exemption from written prior approval of certain SDPs is predicated on prior CMS involvement in the rates, such as our development of the total published Medicare payment rate and our approval of Medicaid State plan rates. As such, it would not be appropriate to exempt all minimum fee schedules or uniform increases regardless of service type and payment level.

Comment: One commenter suggested that any minimum fee schedule using Medicare as a benchmark should be exempt from all SDP requirements.

Response: We decline to expand the Medicare exemption from written prior approval to an exemption from all SDP regulatory requirements entirely. There are many critical components that every SDP must meet, including requirements that it be based on utilization and delivery of services, advance quality, not condition provider participation in the SDP on a provider entering or adhering to intergovernmental transfers (IGT) arrangements, and that it be documented in managed care plan contracts and accounted for in rate development. As discussed throughout this section of the final rule, there are important policy and legal considerations furthered by these requirements for SDPs. As always, CMS will continue to seek efficiencies in our operational review processes to facilitate timely action.

Comment: Some commenters who supported the Medicare exemption also requested that the exemption be expanded based on alternative benchmarks. One commenter requested alternatives for provider types not represented in Medicare. One commenter was concerned that States should be able to look to other Medicare payment methodologies than the Medicare Physician Fee Schedule, such as the Medicare partial hospitalization program for psychiatric care.

Response: We acknowledge that the exemption from written prior approval finalized in § 438.6(c)(2)(i) will not accommodate all service and provider types, such as those not addressed in the total published Medicare payment rates. Our goal in finalizing § 438.6(c)(2)(i) is to reduce State administrative burden by exempting SDPs that are a minimum fee schedule using a total published Medicare payment rate as this total payment rate is developed by CMS. States are still

able to pursue SDPs that are not tied to the State plan or Medicare payment rates, but those proposals require written prior approval. The term “total published Medicare payment rate” is defined in § 438.6(a) to include “amounts calculated for payment for specific services that have been developed under Title XVIII Part A and Part B.” Therefore, the exemption for SDPs specified in § 438.6(c)(1)(iii)(B) is not limited to the Medicare Physician Fee schedule and would encompass Medicare payment rates for other Medicare covered services under Parts A and B.

Comment: One commenter requested that CMS revise its definition of State plan approved rates to include payments that are estimated to be equivalent to what Medicare would have paid using a payment-to-charge ratio such as is permitted in the Medicaid FFS supplemental payment Upper Payment Limit demonstrations required by § 447.272.

Response: State plan approved rates are defined in § 438.6(a) as amounts calculated for services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the State plan, and this definition specifically indicates that “Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.” This is because Medicaid FFS supplemental payments are not calculated or paid based on the number of services rendered on behalf of an individual beneficiary, and therefore, are separate and distinct from State plan approved rates. We do not intend to revisit the definition for State plan approved rates or the associated exemption from written prior approval. Further detail on this policy is in the 2020 final rule (85 FR 72776 through 72779).

Comment: While commenters supported the administrative efficiency associated with this exemption, some commenters stated that Medicare rates are not sufficient compensation for certain services, for example for highly specialized services, and can yield extremely low payment rates for some services. One commenter urged CMS not to consider adopting a framework that suggests Medicare payment rates are the appropriate benchmark to ensure Medicaid beneficiaries have access to care and recommended clarifying that this approach is solely a mechanism for evaluating payment adequacy in a standardized way. Another commenter opposed this provision saying that exactly 100 percent of the published Medicare payment rates was an arbitrary

and strict benchmark. One commenter, while supportive of CMS’s goals, cautioned that CMS should not discourage States from using common service definitions, appropriate risk adjustment, and applicable payment groupings that are designed for the Medicaid population, rather than the Medicare population.

Response: The provision finalized as proposed at § 438.6(c)(2)(i)—to exempt certain SDPs described in § 438.6(c)(1)(iii)(B) from the prior written approval requirement—was intended solely to reduce administrative burden on States and CMS. As noted earlier, we are finalizing the exemption for minimum fee schedule SDPs at the total published Medicare payment rate because these rates, like Medicaid State plan rates, have already been approved by CMS. We disagree that 100 percent of total published Medicare rates is an arbitrary and overly rigid standard for the exemption from the prior written approval requirement. We also did not assert that Medicare rates were appropriate for all services, populations, and providers and do not intend this provision for certain SDPs to communicate such a position. States have the option to design SDPs based on the needs of their Medicaid population and the structure of their Medicaid managed care programs.

Comment: One commenter stated concerns that exempting these SDPs from prior approval would mean CMS would no longer receive evaluations for some minimum fee schedules that could substantially increase provider payment rates from Medicaid managed care plans.

Response: The exemption is limited to written prior approval of a preprint. As we discussed in the proposed rule, all SDPs, including those described in § 438.6(c)(1)(iii)(A) and (B), would still need to comply with the standards listed in the finalized § 438.6(c)(2)(ii) (see 88 FR 28114). As finalized, § 438.6(c)(2)(ii) reflects this policy. In addition, other requirements for SDPs adopted in the rule, such as the reporting requirements in paragraph (c)(4) and certain contract term requirements in paragraph (c)(5) will also apply to the SDPs specified in paragraph (c)(1)(iii)(A) and (B). (To the extent that certain SDP requirements are limited to specified SDPs, those are discussed in the relevant parts of section I.B.2. of this final rule.) For example, while it is true the SDP evaluation report would not need to be submitted to CMS for review at a specified time, the State is required to continue to evaluate the SDP and such evaluation must be made available to

CMS upon request. See section I.B.2.j. of this final rule for further details on SDP evaluations.

Comment: Some commenters were supportive of the proposed exemption but stated concern, urging CMS to consider requiring States and their actuaries to include detailed information describing the SDP within their rate certification documentation. These commenters stated that clear rate certification documentation that includes information about SDPs that are not subject to the CMS written prior approval process will help ensure the fiscal sustainability of the Medicaid program.

Response: We agree that SDPs being adequately described in rate certifications is an important program integrity safeguard. SDPs that are exempt from written prior approval must comply with requirements and standards in part 438 and be appropriately documented in the managed care contract and rate certification submission consistent with § 438.7. We take this opportunity to remind States that as specified in § 438.7(b)(6), rate certifications must include a description of any special contract provisions related to payment in § 438.6, including SDPs authorized under § 438.6(c)(1)(iii)(A) and (B). We also direct the commenter to section I.B.2.k. of this final rule for further details on the documentation of SDPs in rate certifications.

Comment: Another commenter recommended that CMS define “published Medicare rates” to be inclusive of additions and adjustments such as GME, indirect medical education, and Area Wage Index specific to each hospital to ensure the payment rates account for the acuity of the patient, the population served, and services provided in a particular geographic area of the country.

Response: The exemption from written prior approval in § 438.6(c)(2)(i) for SDPs specified in § 438.6(c)(1)(iii)(B) includes the “total published Medicare payment rate,” which aligns with the inpatient prospective payment system (IPPS) web pricer amount⁷⁵ and is fully inclusive of all components included in the rate developed by CMS for Medicare payment. States retain the ability to propose SDPs that use a fee schedule which is based on a Medicare payment rate but in some way revises or deviates from the underlying approved methodology or adds other types of variability. However, such SDPs are not within the scope of § 438.6(c)(1)(iii)(B) because they would not use 100 percent

of the total published Medicare payment rate. These would be SDPs described in § 438.6(c)(1)(iii)(C), which are not eligible for the exemption in § 438.6(c)(2)(i) and are subject to written approval from CMS. Additionally, any SDPs that use a payment in addition to the total published Medicare rate (as calculated by the IPPS web pricer) are not within the scope of § 438.6(c)(1)(iii)(B), are not eligible for the exemption in § 438.6(c)(2)(i) and are subject to written prior approval from CMS. Any SDP that in any way adjusts the total published Medicare payment rate must receive written prior approval by CMS.

Additionally, for clarity, we restate that for all SDPs that specify a Medicare-referenced fee schedule regardless of whether it is eligible for an exemption from written prior approval, the associated managed care contract must comply with § 438.6(c)(5)(iii)(A)(5) and include information about the Medicare fee schedule(s) that is necessary to implement the SDP, identify 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 are applied. We also direct the commenter to section I.B.2.k. of this final rule for further details on the documentation of SDPs in managed care contracts.

After consideration of the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to § 438.6(a), (c)(2)(i), and (c)(5)(iii)(A)(5) as proposed for the reasons outlined here and in the proposed rule. We are further finalizing the definition of “Total published Medicare payment rate” at § 438.6(a) as proposed and finalizing §§ 438.6(c)(1)(iii)(B), (c)(2), and (c)(5)(iii)(A)(5) as proposed.

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

We proposed 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’s 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.⁷⁶ 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 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 to (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 the 2016 final rule, 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.

⁷⁶ <https://www.federalregister.gov/d/2016-09581/p-1269>.

⁷⁵ <https://webpricer.cms.gov/#/>.

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 FFS 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 proposed these changes to provide States a tool to direct payment to non-network providers, as well as network providers.

Therefore, we proposed 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 § 438.6(c) and other regulations in part 438. We note that, as proposed, all standards and requirements under § 438.6(c) and related regulations (such as § 438.7(c)) will still be applicable to SDPs that direct payment arrangements for non-network providers.

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

We solicited public comments on our proposal. We sought comment on whether this change will 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 final rule.

We summarize and respond to public comments received on our proposal regarding SDPs for non-network providers (§ 438.6(c)(1)(iii)) below.

Comment: Many commenters supported our proposal to remove “network” from § 438.6(c)(1)(iii) noting that the revision would remove barriers to access to quality care for enrollees and provide more flexibility for States to direct managed care plan payment to a wider array of providers. Some commenters noted that this change would ensure alignment across all types of providers.

Response: We appreciate the support for the proposed changes to § 438.6(c)(1)(iii). We agree that these revisions will provide States with more flexibility, and could improve access to quality care, and establish parity for provider eligibility for all types of SDPs.

Comment: One commenter sought clarification as to whether CMS is proposing to require States to include non-network providers in SDPs or if States will have flexibility to elect whether an SDP is limited to network or non-network providers.

Response: We appreciate the request for clarification and clarify that the revision to § 438.6(c)(1)(iii) grants States the option to direct payment under § 438.6(c) to network and/or non-network providers. As part of the provider class definition for each SDP required in § 438.6(c)(2)(ii)(B), States should identify in the SDP preprint whether the provider class eligible for the SDP is inclusive of network and/or non-network providers. We are also finalizing § 438.6(c)(5)(ii) to require States to document both a description of the provider class eligible for the SDP and all eligibility requirements in the applicable managed care contract. We believe such description will need to include whether an SDP is applicable to network and/or non-network providers so that managed care plans can accurately implement the SDP.

Comment: One commenter noted that States should provide clear and timely guidance to managed care plans about SDP related adjustments to the capitation rates and sufficient details about the SDP for the managed care plan to be able to effectuate the SDP for non-network providers. The commenter stated that States should be required to issue a fee schedule for non-network

providers to managed care plans with sufficient time, preferably 90 days, to make programming and operational changes necessary to operationalize the SDP.

Response: We agree with the commenter that States should account for SDPs in applicable rate certifications and contracts in a clear and timely manner. To ensure that managed care plans receive necessary information on the State’s intent and direction for the SDP, we are finalizing provisions that establish minimum documentation requirements for all SDPs and timeframes for submission of managed care contracts and rate certifications that incorporate SDPs (see sections I.B.2.e., I.B.2.k., and I.B.2.l. of this final rule for further details). We believe these requirements will help ensure that plans have sufficient and timely information to effectuate SDPs with providers.

Comment: Several commenters stated support for removing “network” from § 438.6(c)(1)(iii) and requested that CMS permit SDPs that require network providers to be paid higher payment amounts than out-of-network providers. One commenter requested that CMS grant States flexibility to implement maximum fee schedules for non-network providers that are lower than the fee schedules for network providers to incentivize providers to join managed care plan networks while still allowing for flexibility in contracting.

Response: States are permitted to direct payment in any of the ways suggested by commenters, subject to all the requirements in § 438.6(c) and applicable law. Unless limited or circumscribed by a requirement for how a Medicaid managed care plan pays certain non-contracted providers, States could choose to utilize network status as the basis on which to define provider classes or subclasses for an SDP under § 438.6(c)(2)(i)(B). We encourage States to consider how best to design SDPs for network and non-network providers to achieve the goals and objectives of their managed care programs.

Comment: Several commenters opposed removing “network” from § 438.6(c)(1)(iii) and recommended that we continue to limit certain types of SDPs to network providers. Some of these commenters noted that this proposed change might disincentivize providers from contracting with managed care plans and undermine network adequacy or access to network providers. One commenter noted that this change would run counter to CMS’s goals to improve access to managed care network providers.

Response: We disagree that permitting States to direct fee schedule or uniform

increase type SDPs specified in § 438.6(c)(1)(iii) to non-network providers will erode access to network providers or undermine network adequacy. As discussed in the proposed rule, we believe that this change may improve access to care in certain situations. For example, States have stated interest in directing plans to pay at least the Medicaid State plan rate to non-network providers in neighboring States that furnish specialty services unavailable in the State or non-network providers that render services to enrollees during inpatient stays. (88 FR 28115) We believe these examples demonstrate that permitting SDPs for non-network providers could help States fulfill their obligation to ensure timely access to all covered services. To the extent that a State decides that concerns about disincentivizing network participation should limit SDPs that direct payment to non-network providers, our regulation similarly permits that policy choice.

Comment: One commenter urged CMS to delay the applicability date from the effective date of the final rule to the first rating period beginning on or after 2 years after the effective date of the rule to allow managed care plans to prepare for network adequacy fluctuations.

Response: We decline to delay the applicability date of § 438.6(c)(1)(iii). Since the inception of SDPs in the 2016 final rule, States have been permitted to direct plan expenditures to network and non-network providers consistent with § 438.6(c)(1)(i) and (ii). To our knowledge, these SDPs have not caused any network adequacy fluctuations. The revision to § 438.6(c)(1)(iii) simply extends the option for States to include non-network providers in other types of SDPs, including minimum fee schedules, maximum fee schedules and uniform increases. Therefore, we do not believe it necessary to extend the applicability date; this amendment to § 438.6(c)(1)(iii) is applicable upon the effective date of this final rule. States may seek prospective amendments to existing SDPs or develop new SDPs consistent with this amendment to § 438.6(c)(1)(iii) without additional delay.

Comment: One commenter noted that implementing certain payment arrangements with non-network providers could prove burdensome for managed care plans to implement and track as the managed care plans do not have a formal contractual relationship with non-network providers.

Response: Managed care plans have extensive experience paying claims for non-network providers for many purposes including for certain inpatient

care, emergency services, and statutorily permitted use of non-network family planning providers. Additionally, States have been permitted to adopt and CMS has approved SDPs described in existing § 438.6(c)(1)(i) and (ii) to direct managed care plans to pay non-network providers since the 2016 final rule. We encourage States and plans to utilize lessons learned to implement other types of SDPs that include non-network providers. Plans and States should work together to reduce administrative burden, including for the impacted non-network providers whenever possible, and develop SDP implementation processes to ensure timely and accurate payment.

Comment: One commenter opposed removing “network” from § 438.6(c)(1)(iii) stating that the provision cannot be adopted without CMS performing a regulatory impact analysis.

Response: We included a robust discussion of the most impactful SDP provisions for which we had sufficient data in the regulatory impact analysis in the proposed rule and the public had the opportunity to comment on it and provide additional information for our consideration. We acknowledge that we do not have sufficient quantitative data presently to assess the impact of all provisions, including removing “network” from § 438.6(c)(1)(iii). Nor did commenters provide such data.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revision to remove “network” from the descriptions of the SDPs in § 438.6(c)(1)(iii) as proposed.

e. SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (c)(2)(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 will likely necessitate contract and rate amendments,⁷⁷ 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 PHEs 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 repeated technical assistance to these States, and we published additional guidance in 2021⁷⁸ to reiterate our expectation that States submit SDP preprints before the start of a rating period. This guidance also made clear that CMS will 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 proposed a new § 438.6(c)(2)(viii)(A) through (C) to set the deadline for submission of SDP preprints that require written prior

⁷⁷ The term “rate amendment” is used to reference an amendment to the initial rate certification.

⁷⁸ <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf>.

approval from CMS under paragraph (c)(2)(i) (redesignated from § 438.6(c)(2)(ii)). In § 438.6(c)(2)(viii)(A), we proposed 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 proposed requirement would apply 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 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 can support the State in incorporating these payments into their Medicaid managed care contracts and rate development. We proposed to use a deadline of no later than 90 days prior to the end of the applicable rating period because we believed this minimum timeframe would balance 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 will not be eligible for written prior approval; therefore, the State will not be able to include the SDP in its Medicaid managed care contracts and rate certifications for that rating period.

In § 438.6(c)(2)(viii)(B), we proposed 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 will start less than 90 days before the end of the rating period. Although CMS is not finalizing this proposal, we note that it was intended to provide flexibility to allow States effectively to 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 currently be approved under § 438.6(c)(3) for up to three rating periods. For these, we proposed 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 in the proposed rule, we used the example of an SDP eligible for annual approval that

a State is seeking to include in their CY 2025 rating period. In the example, under the current regulations, CMS recommended 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 under our proposal. 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 described in the proposed rule 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. We noted in the proposed rule 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 described in the proposed rule 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 approach would provide additional flexibility for States establishing new SDPs but will limit the additional flexibility for that SDP to that initial rating period. If the State wanted to renew the SDP for 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 final rule on Applicability Dates, we proposed 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 solicited public comment on our proposals and these alternatives, as well as additional options that will 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 proposed 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 proposed 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). In that instance, 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 proposed in § 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 proposed 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 will be able to do the same for the CY 2027 rating period as well—amend the SDP before the end of 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 would be 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 will 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. If a State decides not to implement an approved SDP after it has been documented in the rate certification and contract the State would have to submit amendments for the rates and contract to remove the contractual obligation for the SDP and the impact of the SDP on the rates. We solicited comment on this aspect of our proposal.

We proposed 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) currently requires that any rate amendments⁷⁹ 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 reminded 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. of this final rule on Contract Term Requirements for SDPs; section I.B.2.l. of this final rule on Separate Payment Terms; and section I.B.2.m. of this final rule on SDPs included through Adjustments to Base Capitation Rates.

We proposed these regulatory changes to institute submission timeframes to ensure efficient and proper administration of the Medicaid program. We had also described an alternative of requiring that States submit all amendments to SDPs for written prior approval 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 will 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 will 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 SDP preprints. However, the timeframe 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 solicited public comment on our proposals and these alternatives, as well as additional options that will also meet our goals for adopting time limits on when SDP preprints are submitted to CMS for approval and 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 final rule.

We solicited public comments on these proposals.

We summarize and respond to public comments received on SDP Submission Timeframes (§ 438.6(c)(2)(viii) and (ix)) below.

Comment: We received a wide range of comments on the submission timeframes that we proposed for SDP preprints and amendments in § 438.6(c)(2)(viii) and (ix), as well as alternatives that we described in the proposed rule. Some commenters supported requiring States to submit preprints to CMS at least 90 days prior to end of the rating period as this proposal would provide States the most flexibility. One commenter contended that submission 90 days before the end of the rating period makes it difficult to ensure that there is time for CMS to review the SDP and for States to adequately and accurately update the contract(s) and capitation rate(s) to reflect the approved SDP. Commenters stated concern with States waiting so late into the rating period to submit an SDP preprint for CMS approval, and noted this would very often trigger retroactive contract and capitation rate adjustments, which creates more burden and uncertainty for States, managed care plans, providers, and CMS. One commenter noted that a submission timeframe not linked to the start of a rating period would help States implement SDPs when legislatures pass budgets after the start of a rating period or when they are designed to run less than a full rating period to address urgent access issues. Many of these commenters also supported our proposal in § 438.6(c)(2)(ix)(A) for SDP preprint amendments to be submitted prior to the end of the rating period, but some did not support our proposal in § 438.6(c)(2)(ix)(B) as they noted the differing timeframes by SDP approval duration disadvantaged States using

⁷⁹The term “rate amendment” is used to reference an amendment to the initial rate certification.

multi-year SDPs such as VBP arrangements. A few commenters also did not support having submission dates that varied from the initial year to subsequent years as those dates could be hard to track as SDPs changed over time. In contrast, other commenters suggested that SDP preprints be required to be submitted before the start of the rating period to ensure prospective implementation of SDPs. However, some of these commenters stated that 90 days before the rating period was too long and would often conflict with annual rate setting processes. Some commenters supported the alternative described in the proposed rule to use the start date of the payment arrangement instead of the start of the rating period because this enabled States to respond to events during a rating period such as changes to State budgets, other legislative actions, identified access issues, or natural disasters and emergencies most efficiently and in the least burdensome way. Some commenters had overall concerns with the complexity of our proposals on submission timeframes for SDP preprints and preprint amendments and stated that this could lead to States inadvertently missing submission deadlines, particularly during certain situations such as natural disasters.

Response: We appreciate the comments on our proposals in § 438.6(c)(2)(viii) and (ix), as well as on the other SDP preprint submission timeframes alternatives described in the proposed rule (88 FR 28116 and 28117). Since § 438.6(c) was codified in the 2016 final rule, we have encouraged States to submit SDP preprints at least 90 days in advance of the start of the applicable rating period for consistency with the prospective nature of managed care plan contracts and capitation rates, and because it facilitates timely contract and rate certification review and approval by CMS. However, some States have consistently struggled to submit preprints 90 days in advance of the rating period for a multitude of reasons, including State budget processes and unexpected program issues that arose during the rating period. To make our processes more responsive to States' needs while ensuring that contract and rate certification reviews dependent on SDP approvals are not unnecessarily delayed, we proposed a new § 438.6(c)(2)(viii) and (ix) that specified multiple submission timeframes based on the duration of an SDP. While we received comments in support of and in opposition to our proposals in § 438.6(c)(2)(viii) and (ix), the comments persuaded us that our proposal could

inadvertently make submission timeframes overly complicated which could exacerbate rather than alleviate submission compliance and hinder States' efforts to respond to unexpected issues. We recognize the need for flexibility for States to propose or revise SDPs to address changes that occur during the rating period that are unexpected or expected but that will not be in effect until after the start of the rating period. However, we also continue to believe that it is important for States to be timely with submissions of SDPs as much as possible to align with contract and rate certification reviews, as well as to facilitate efficient implementation of SDPs by managed care plans. While we appreciate the support provided by commenters for requiring States to submit preprints 90 days before the end of the rating period, we share commenters' concern about the number of retroactive contract and rate adjustments that may be necessitated by approval of an SDP preprint after the end of a rating period. This would create more burden and uncertainty for States, plans, providers, and CMS.

After review of the comments, we reconsidered how to balance timely and accurate SDP preprint submissions with enabling States to be nimble enough to administer efficient and responsive programs. In the discussion in the proposed rule about the alternative of requiring that States submit all SDPs in advance of the start of the payment arrangement, we stated "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 . . . , it would have to resubmit the preprint before the start of that rating period." After reviewing the comments that emphasized the need for State flexibility, we have determined that there is no substantial risk to requiring all SDP preprints to be submitted before the start of payment arrangement and that a single submission timeframe is the most efficient and, least burdensome, and strikes the right balance between the extremes of the start and end of the rating period. As such, we are finalizing the submission timeframe for all SDPs as before the implementation of the payment arrangement as indicated by the start date for the SDP identified in the preprint. The start date specified in the preprint is the date when the managed care plans must implement the payment arrangement, and therefore, we believe

a more relevant date upon which to base preprint submission than the start or end of the rating period. We encourage States to submit their preprints as far in advance of an SDP's start date as possible to facilitate approval before the start date. We also remind States that they remain at risk for a disallowance of FFP until and unless we have approved the SDP preprint, when required, as well as the managed care contracts and capitation rates that include the payment arrangement, and all other conditions and requirements for FFP have been satisfied (for example, the prior approval requirement for managed care contracts and the claims timely filing deadline).

To further simplify our regulation text and help States understand their obligations relative to SDP preprint submissions, we are also finalizing that all amendments to SDP preprints must be submitted before the start date of the SDP amendment. We believe these changes will reduce burden for States, managed care plans, and providers, facilitate efficient implementation of SDPs by managed care plans, and promote more timely and accurate processing of SDP amendments.

To reflect these changes, several revisions to the text that was proposed in § 438.6(c)(2)(viii) and (ix) are being finalized in this rule. First, § 438.6(c)(2)(viii) will be revised to specify that States must complete and submit all required documentation for each SDP for which written approval is required before the specified start date of the SDP. Required documentation includes at least the completed preprint and as applicable, the total payment rate analysis and the ACR demonstration as described in § 438.6(c)(2)(iii) and the evaluation plan as required in § 438.6(c)(2)(iv). The deadline we are finalizing means before the first payment to a provider under the SDP (not merely prior to the State's request for FFP for the State's payments to its managed care plans that incorporate the SDPs). Second, proposed § 438.6(c)(2)(viii)(A) through (C) are not being finalized. Third, proposed § 438.6(c)(2)(ix) is not being finalized.

Under § 438.6(c)(2)(viii) as finalized, if the required documentation—meaning a complete SDP preprint or complete amendment to the preprint (inclusive of at least the completed preprint and, as applicable, the total payment rate analysis, the ACR demonstration and the evaluation plan)—is not submitted before the start date specified in the preprint, the SDP or SDP amendment will not be eligible for approval. States must be diligent and ensure that an SDP preprint or

amendment is accurate and complete, as further described in CMCS Informational Bulletin “Medicaid and CHIP Managed Care Monitoring and Oversight Tools” published on November 7, 2023.⁸⁰ Please note that the required documentation to satisfy § 438.6(c)(2)(viii) does not include the Medicaid managed care contract amendment or rate amendment that accounts for the SDP; the timeframes for submission of contracts and rates that account for SDPs are addressed in section I.B.2.k. and section I.B.2.m. of this final rule.

Comment: A few commenters either opposed instituting a “hard” deadline for submission or recommended a provision be added to provide CMS and States additional flexibility to adjust timeframes if determined necessary for the benefit of the Medicaid program and its recipients at CMS’s discretion.

Response: We respectfully disagree with commenters. As stated in the preamble of the proposed rule and in our responses to other comments, we believe it is critical to ensure timely processing of contracts and rates, provide transparency for plans and interested parties, align more with the prospective nature of managed care and ensure more timely payment for providers. In addition, this new requirement for when SDP preprints or amendments to preprints must be submitted to CMS for approval before the SDP starts will provide an opportunity to protect program integrity by assuring that the scope and terms of SDPs are described and documented for evaluation against the regulatory requirements before payments under the SDP begin. As noted in the earlier response, if the required documentation—meaning a complete SDP preprint or complete amendment to the preprint (inclusive of at least the completed preprint, the total payment rate analysis, the ACR demonstration and the evaluation plan as applicable) is not submitted before the start date specified in the preprint, the SDP or SDP amendment will not be eligible for approval. We also believe that the submission deadline we are finalizing will provide flexibility to allow States to respond to quickly changing conditions for the benefit of their Medicaid enrollees and programs by tying the submission of the required documentation to before the SDP begins, rather than the beginning or end of the relevant rating period.

Comment: One commenter encouraged CMS to consider an

equivalent 90-day timeframe for CMS’s review and approval of preprint submissions.

Response: We are committed to working with States to review SDP preprints as expeditiously as possible and encourage States to request technical assistance, particularly for new or complicated proposals, as early as possible before formally submitting preprints. We reiterate that we encourage States to submit preprints as far as possible in advance of the SDP start date to facilitate timely processing of preprints, contracts, and rate certifications.

Comment: One commenter suggested that CMS encourage States to work with their managed care plan partners and share SDP preprints after they are submitted to CMS to facilitate managed care plans’ timely and accurate implementation of the SDP.

Response: We agree that while CMS is not requiring States to share SDP preprints with their managed care plans after submission, close collaboration between States and their plans and actuaries facilitates timely and accurate implementation of SDPs. In February 2023, we started publicly posting SDP approvals on Medicaid.gov to facilitate transparency. We encourage States to consider collaborating with both their managed care plans and other partners early in the SDP process.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(viii) to specify that States must complete and submit all required documentation for all SDPs and associated amendments for which written approval is required before the specified start date and are not finalizing paragraphs § 438.6(c)(2)(viii)(A) through (C) and paragraph (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), 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. Under CMS regulations and interpretations of section 1903(m)(2)(A)(iii) of the Act, 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 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 or regulatory 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 issued in the 2016 final rule. MACPAC reported that CMS approved SDP arrangements in 37 States, with spending exceeding more than \$25 billion in 2020.⁸¹ Our internal analysis of all SDPs approved from when § 438.6(c) was issued in the 2016 final rule through the end of fiscal year 2022, provides that the total spending approved for each SDP for the most recent rating period for States is nearly \$52 billion annually⁸² with at least half of that spending representing payments that States are requiring be paid in

⁸¹ 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.

⁸² This data point is an estimate and reflective of the most recent approval for all unique payment arrangements that have been approved through the end of fiscal year 2022, under CMS’s standard review process. Rating periods differ by State; some States operate 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 the end of fiscal year 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).

⁸⁰ <https://www.medicaid.gov/sites/default/files/2023-11/cib11072023.pdf>.

addition to negotiated rates.⁸³ This \$52 billion figure is an estimate of annual spending. As SDP spending continues to increase, we believed it is appropriate to apply additional regulatory requirements for the totality of provider payment rates under SDPs to ensure proper fiscal and programmatic oversight in Medicaid managed care programs, and we proposed 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.

Federal requirements at § 438.6(c)(2) specify 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 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 proposed 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 proposed 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

⁸³ As part of the revised preprint form, States are requested to identify if the payment arrangement requires plans to pay an amount in addition to negotiated rates versus 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.

request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class. We proposed 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 noted 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 noted that § 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 finalized in section I.B.2.c. of this final rule, § 438.6(c)(1)(iii)(B) describes 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 proposed in § 438.6(c)(2)(i) to not require written 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 will 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 included 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 did not propose 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 section I.B.2.f. 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 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 form⁸⁴ published in January 2021, and described it in the accompanying SMDL. We noted in the proposed rule that 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 to providers under SDPs 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 solicited comments on our proposed changes.

Establishment of Payment Rate Limitations for Certain SDPs. Some entities, including MACPAC⁸⁵ and GAO,⁸⁶ have released reports focused on SDPs. Both noted concerns about the growth of SDPs and lack of a regulatory payment ceiling on the amounts paid to providers under an SDP. Our proposed standard at § 438.6(c)(2)(ii)(I) will codify our current practice of determining whether the total payment rate is

⁸⁴ <https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

⁸⁵ <https://www.macpac.gov/publication/june-2022-report-to-congress-on-medicare-and-chip/june-2022-report-to-congress-on-medicare-and-chip-chapter-2>.

⁸⁶ 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>.

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 proposed several regulatory standards to establish when the total payment rates for certain SDPs are reasonable, appropriate, and attainable. We proposed 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 discussed 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 types of services) and some alternatives considered, 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 is reasonable, appropriate, and attainable.

Medicare is a significant payer in the health insurance market and Medicare payment is a standardized benchmark used in the industry. Medicare payment is also a benchmark used in Medicaid FFS, including the Upper Payment Limits (UPLs) that apply to classes of institutional providers, such as inpatient and outpatient hospitals, clinics, nursing facilities, and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID), that are based on a reasonable estimate of the amount that Medicare would pay for the Medicaid services. The UPLs apply an aggregate payment ceiling based on an estimate of how much Medicare would have paid in total for the Medicaid services as a mechanism for determining economy and efficiency of payment for State plan services while allowing for facility-specific payments.⁸⁷ 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 to those providers for those services. 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.

Currently, § 438.6(c)(2)(ii)(B) (which requires SDPs to direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the managed care contract) 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

⁸⁷ 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).

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 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.⁸⁸ CMS had previously approved SDPs that resulted in total 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 proposed 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, or PAHPs to make payments higher than the UPL does not violate any current 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

⁸⁸ 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.medicare.gov/medicaid/financial-management/payment-limit-demonstrations/index.html>. Instructions specific to qualified practitioner services ACR are further described in the following instructions: <https://www.medicare.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.

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 believe using the ACR presented the least disruption for States as they were transitioning existing, and often long-standing, pass-through payments⁸⁹ into SDPs, while at the same time providing a ceiling for 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.⁹⁰

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 provided a uniform increase for inpatient and outpatient hospital services with two provider

⁸⁹ 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."

⁹⁰ 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. Instructions specific to qualified practitioner services ACR are further described in the following instructions: <https://www.medicare.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.

classes (rural hospitals and non-rural hospitals), the State is 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 is 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 form⁹¹ 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 historically requested the impact not only of the SDP under review, but any other payments required by the State to be 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 and provider class 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 all of the 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 included payment rates that are projected to exceed the ACR, States are increasingly submitting preprints that will push total payment rates up to the ACR. Therefore, we

⁹¹ <https://www.medicare.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

proposed to move away from the use of an internal benchmark to a regulatory limit on the 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 also considered other potential options for this limit on total payment rate for these four services.

CMS believes that using the ACR as a limit is 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 paid 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).⁹² For these three services, commercial payers typically pay the highest rates, followed by Medicare, followed by Medicaid.^{93 94 95 96}

Based on both CMS's 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 Medicaid, Medicare and the commercial markets, we believe that for these three services, the ACR payment rate limit will 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 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.⁹⁷ Therefore, we proposed 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 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 will not be approvable under our proposal. Such arrangements will 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) codifying specific payment level limits for certain types of SDPs. We noted that while the total payment rate 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. The proposed total payment limit will apply across all SDPs in a managed care program; States will 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, we rely 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,⁹⁸ mental health services,⁹⁹ substance use disorder services,¹⁰⁰ and

⁹² <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData>.

⁹³ 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>.

⁹⁴ 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/>.

⁹⁵ 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>.

⁹⁶ 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-medicare-medicare-and-commercial-health-insurance-payment-rates-impact>.

⁹⁷ 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>.

⁹⁸ 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>.

⁹⁹ <https://www.medicare.gov/medicaid/benefits/behavioral-health-services/index.html>.

¹⁰⁰ <https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/>.

obstetrics and gynecology services^{101 102}), interested parties have raised concerns about a number of issues surrounding these services, including quality and access to care. For some of these services States have found it difficult to determine the appropriate payment rate to allow them to further their overall Medicaid program goals and objectives. For example, one State 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 study¹⁰³ authorized through Oregon's Legislature outlined several disparities in behavioral health 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.

We acknowledged that some States have had difficulty with providing payment rate analyses that compare a particular payment rate to the 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 stated 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 did not propose 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, we noted that we believe further research is needed before codifying a specific payment rate limit for these services. 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 proposed to define several terms in § 438.6(a), including a definition for "inpatient hospital services" that will be the same as specified at 42 CFR 440.10, "outpatient hospital services" that will be the same as specified in § 440.20(a) and "nursing facility services" that will 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 proposed 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 will be limited based on the proposed payment rate. We proposed to define "academic medical center" as a facility that includes a health professional school with an affiliated teaching hospital. We proposed 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.

We did not propose 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 will likely be burdensome on States and could inhibit States from pursuing SDPs for providers such as primary care physicians and mental health providers; we sought 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.

In the proposed rule, we noted our position 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, as we monitor implementation of this SDP policy, in future rulemaking we may consider establishing additional criteria for approval of SDPs at the ACR, such as meeting minimum thresholds for payment rates for primary care and behavioral health, to ensure the State and its managed care plans are providing quality care to Medicaid and CHIP enrollees and to support State efforts to further their overall program goals and objectives, such as improving access to care. These additional criteria could incorporate a transition period to mitigate any disruption to provider payment levels.

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. Most 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

¹⁰¹ <https://www.acog.org/advocacy/policy-priorities/medicaid>.

¹⁰² <https://www.kff.org/womens-health-policy/issue-brief/medicaid-coverage-for-women/>.

¹⁰³ 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>.

not only by CMS but oversight bodies and interested parties such as MACPAC,¹⁰⁴ we proposed additional regulatory changes related to financing the non-Federal share; see section I.B.2.g. of the proposed rule and section I.B.2.g. of this final rule for further information.

In light of these concerns, the proposed rule described several 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. One alternative discussed was 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 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. A total payment rate limit at the Medicare rate may limit the growth in payment rates more than limiting the total payment rate to the ACR. We also considered, and solicited 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 invited public comments on these alternatives.

We also noted our 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 in section I.B.2.f. of the 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 sought public comment to further evaluate if Medicare will be a reasonable limit for the total provider rate for the four types of services delivered through managed care that we proposed, all services, and/or additional types of services. Beneficiaries enrolled in a Medicaid managed care plan are often more aligned with individuals in commercial health insurance (such as, adults and kids), whereas the Medicaid 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 solicited 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 invited public comments on these alternatives.

In considering these potential alternatives, we solicited comment on 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 described including 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, one of the benefits of establishing a total payment rate limit of the ACR for these four services is State 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. One alternative we considered in the proposed rule was 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 would account for 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 while limiting higher payment rates used when quality outcomes or quality driven payment models are not being used. We invited public comments on whether this potential alternative should be included in the final rule.

We acknowledged that some States currently have SDPs that have total payment rates up to the ACR and that these alternative proposals could be more restrictive. Under the alternative proposals, 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 sought public comment on whether 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 sought 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 solicited public comment on the alternatives we considered for 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 solicited 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

To ensure compliance with the proposed provision 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 proposed in

¹⁰⁴MACPAC'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>.

§ 438.6(c)(2)(iii) that States provide two pieces of documentation: (1) an ACR demonstration (which will document the average commercial rate using data in alignment with the requirements we are finalizing at § 438.6(c)(2)(iii)(A)); and (2) a total payment rate comparison to the ACR at § 438.6(c)(2)(iii)(B). We proposed the timing for these submissions in § 438.6(c)(2)(iii)(C). Under our proposal, 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 proposed 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 considered QHPs operating in the Marketplaces to be commercial payers for purposes of this proposed provision, and therefore, payment data from QHPs should be included when available.

At § 438.6(c)(2)(iii)(A)(1), States would be required 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 will be important and appropriate to continue to do so.

At § 438.6(c)(2)(iii)(A)(2), we proposed to 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 will ensure that the data are 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 proposed 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, which 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—will 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 payment rates, 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 proposed 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.¹⁰⁵ 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 will 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) required that the providers in a provider class be treated the same—meaning they get the same uniform increase. In some cases, this has resulted in States not being able to use Medicaid funds to target hospitals that provide critical services to the Medicaid population, but instead using 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 will provide different increases for different classes of hospitals (for example, rural and urban public hospitals will receive a higher percentage increase than teaching hospitals and short-term acute care hospitals). The SDP preprint could

¹⁰⁵ MACPAC Issue Brief, "Medicaid and Rural Health." Published April 2021 <https://www.macpac.gov/wp-content/uploads/2021/04/Medicaid-and-Rural-Health.pdf>.

provide for separate additional 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 will 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 will 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 proposed to require an ACR demonstration using payment data specific to the service type (that is, by the specific type of service). This will 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 will 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 will 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 will be considered a separate provider class), but rather at the broader service level will 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. Under this proposal, 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 reminded 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 (FFS or managed care).

At § 438.6(c)(2)(iii)(B), we proposed 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 of the SDP 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 proposed to codify that the total payment rate comparison will be specific to each Medicaid managed care program to which the SDP under review will apply. Evaluating payment at the managed care program level will

be consistent with the payment analysis described in section I.B.1.d. of this final rule. The total payment rate comparison proposed at § 438.6(c)(iii)(B) will 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 proposed 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 would be required to follow in conducting their ACR analysis. However, we did not propose to require that States use a specific source of data for the ACR analysis. Further, at this time, we did not propose 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.¹⁰⁶ 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.

Data for inpatient and outpatient hospital service payment rates tend to be more readily available in both Medicare and the 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,

¹⁰⁶ <https://www.medicare.gov/medicaid/financial-management/payment-limit-demonstrations/index.html>.

provided the data used for the analyses meet the proposed requirements in § 438.6(c)(2)(iii), will be acceptable to meet our proposed requirements.

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

We proposed 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 proposed 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 final rule.

Expenditure Limit for SDPs. The increasing use of SDPs by States has been cited as a key area of oversight risk for CMS. Several oversight bodies and interested parties, including MACPAC, Office of Inspector General (OIG), and GAO, have authored reports focused on CMS oversight of SDPs.^{107 108 109} 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 their 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 accounted 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 were 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.

In the proposed rule, CMS considered and invited comment on potentially imposing a limit on the amount of SDP expenditures in the final rule based on comments received. Specifically, we sought public comment on whether we should adopt a limit on SDP expenditures in the final rule.

We summarize and respond to public comments received on our proposals regarding the standard for total payment rates for each SDP, the establishment of payment rate limitations for certain SDPs, and the expenditure limit for all SDPs (§ 438.6(c)(2)(ii)(I), 438.6(c)(2)(iii)) below.

Standard for Total Payment Rates for Each SDP (§§ 438.6(a), 438.6(c)(2)(ii)(I))

Comment: Some commenters supported the proposal at § 438.6(c)(2)(ii)(I) that each SDP must ensure that the total payment rate for each service and provider class included in the SDP must be reasonable,

appropriate, and attainable but recommended that the standards of "reasonable, appropriate, and attainable" be further defined to avoid confusion between States, managed care plans and CMS. One commenter noted that the use of "reasonable, appropriate, and attainable" is understood as it relates to capitation rate development, but not in assessing provider rates, providers' costs, or the level of rates that will incentivize providers to accept a Medicaid contract in a given region. We did not receive any comments on the definition of "total payment rate" proposed in § 438.6(a).

Response: We appreciate commenters support for our proposal at § 438.6(c)(2)(ii)(I) to require that all SDPs must ensure that the total payment rate for each service and provider class included in the SDP must be reasonable, appropriate, and attainable; and upon CMS request, the State must provide documentation demonstrating the total payment rate for each service and provider class (or, depending on the timing, a projection of the total payment rate for the SDP). We believe that monitoring the total payment rate for all SDPs is important for proper monitoring and oversight, and finalizing this provision codifies an existing standard in the SMDL published on January 8, 2021. We are finalizing the proposed definition of the term "total payment rate." When the total payment rate analysis and documentation are to be submitted with the SDP preprint, it will largely be a projected amount, based on projections of the payments and effects of those payments under the SDP. Therefore, when we are referring specifically to projected amounts, we occasionally use the term "projected total payment rate" or something similar. We use the term consistent with the definition throughout this discussion.

In reviewing all SDPs, CMS may request that States provide additional information to assess whether payments to providers are reasonable, appropriate, and attainable. Information specific to each SDP and State Medicaid delivery system may be used and taken into account to assess whether and when that standard is not met for SDPs that are not subject to the more specific standards that we discuss in the section below entitled "Establishment of Total Payment Rate Limitation for Certain SDPs" in section I.B.2.f. of this final rule (§§ 438.6(a), 438.6(c)(2)(iii)). To demonstrate whether total payment rates for such services are reasonable, appropriate, and attainable, States could provide an actuarial analysis, use similar Medicaid FFS State plan

¹⁰⁷ 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>.

¹⁰⁸ 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>.

¹⁰⁹ 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>.

services as a comparative benchmark for provider payment analysis or, provide another methodologically sound analysis deemed acceptable by CMS. As finalized in this rule, § 438.6(c)(2)(ii)(I) requires States to provide documentation demonstrating compliance with this requirement upon CMS request for all SDPs. We will continue to review and monitor all projected payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that SDP total payment rates are reasonable, appropriate, and attainable. Further, we clarify here that although we are only finalizing the total payment rate limit at ACR for four provider types and services at § 438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark by which we will evaluate whether all SDP total payment rates are reasonable, appropriate, and attainable.

We are finalizing the definition of “Total payment rate” at § 438.6(a) as proposed. We are also finalizing § 438.6(c)(2)(ii)(I) with minor revisions. First, we are replacing “must be” with “is” so that subparagraph (I) is consistent with the introductory paragraph in § 438.6(c)(2)(ii) to require that each SDP must ensure the total payment rate standard. Second, we are adding a comma after “appropriate” and before the “and” for consistency with the requirement at § 438.4(a), and to acknowledge that “reasonable, appropriate, and attainable” are distinct components for the assessment of the total payment rate. Finally, we are adding a semicolon after “attainable” and removing “and,” to ensure a consistent format throughout § 438.6(c)(2)(ii).

Comment: One commenter suggested that CMS revise § 438.6(c)(2)(ii)(I) to require that the total payment rate by provider type rather than for each service and provider class (for example, all hospitals together rather than by provider class) be reasonable, appropriate, and attainable in recognition that some provider classes may be disadvantaged in negotiating higher rates with commercial payers (88 FR 28125–28124).

Response: We appreciate the commenter’s suggestion to revise § 438.6(c)(2)(ii)(I) in the final rule. However, given that States have significant flexibility in designing the provider classes eligible for SDPs and that providers can furnish more than one type of service (that is, clinics can provide primary care services and mental health services), we believe it is

appropriate to finalize the provision as proposed with minor grammatical and punctuation edits described in the prior response. We reiterate here that we will continue to review and monitor all total payment rates information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that total payment rates are reasonable, appropriate, and attainable.

Comment: Some commenters requested clarification on the State documentation requirement demonstrating the total payment rate by service and provider class specified in § 438.6(c)(2)(ii)(I). One commenter requested that CMS allow a comparison by service category rather than per specific CPT code to avoid administrative burden and provide appropriate transparency and flexibility to balance the interest of all provider classes. One commenter also suggested that this documentation could be a comparison to contiguous or regional State’s Medicaid rates when services do not have a Medicaid State plan rate or a Medicare rate, and this commenter noted that this was frequently relied upon by States as they utilize providers that are located on a State’s borders or region. Another commentor requested that CMS clarify if States could use an empirical analysis, such as a provider rate study, as sufficient documentation demonstrating the total payment rate for each service and provider class.

Response: In the proposed rule (88 FR 28126), we did not propose 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 using a standardized measure. We do not believe or anticipate that we would request a State to conduct and provide a total payment rate analysis at the CPT code level when exercising our authority under § 438.6(c)(2)(ii)(I) to request documentation demonstrating the total payment rate for each service and provider class. Frequently, States complete total payment rate analyses at the service category level as part of our current SDP review process and it is not our intention for § 438.6(c)(2)(ii)(I) to prohibit this practice. States could choose to conduct this analysis at the CPT code level. For example, some States conduct the total payment rate analysis at the CPT code level if they design their SDPs to focus only on specific CPT codes.

We appreciate the suggestion by commenters that we consider a comparison to contiguous or regional

State’s Medicaid rates when services do not have a Medicaid State plan rate or a Medicare rate. This issue has not come up very often in SDP reviews, but when it has, it is usually in reference to HCBS delivered in a MLTSS program. In these cases, the States did not provide the services in an FFS delivery system so there was not a comparison point available for the analysis in Medicaid FFS. While we would encourage States to use data that is State specific, § 438.6(c)(2)(ii)(I) (unlike § 428.6(c)(2)(iii)) does not require use of State-specific data. If a State does not utilize State specific data, we recommend that the State provide a rationale in its analysis to reduce questions from CMS during our review.

While we provided examples of standardized measures that have commonly been used in total payment rate analyses such as the Medicaid State plan approved rates or the total published Medicare payment rate, we did not specify that States must use a specific standardized measure. We may issue additional guidance further detailing documentation requirements and a specified format based on our ongoing monitoring and oversight.

Comment: One commenter supported the standards proposed at § 438.6(c)(2)(ii)(I) but recommended CMS go further and revise the proposal to require all States provide documentation demonstrating the total payment rate for each service and provider class under § 438.6(c)(2)(ii)(I), not just at CMS’s request, and require that this documentation be available publicly to increase transparency.

Response: We appreciate the commenter’s suggestion to expand the documentation requirements included in § 438.6(c)(2)(ii)(I), as finalized. We support increased transparency in States’ use of SDPs and with this same aim in mind, we began publishing approved SDP packages starting in February 2023. These approval packages include the final SDP preprint form which includes the analysis of the total payment rate. We additionally noted in the proposed rule (88 FR 28126) that 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 final 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 form¹¹⁰ published in January 2021, and described it in the accompanying SMDL. We reiterate here that we will continue to review and monitor all projected payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class in an SDP be reasonable, appropriate, and attainable.

After reviewing public comments, we are finalizing the definition of “Total payment rate” at § 438.6(a) and the standard for the provider payment rate applicable to all SDPs at § 438.6(c)(2)(ii)(I) with revisions as described in the above section.

Establishment of Total Payment Rate Limitation for Certain SDPs (§§ 438.6(a), 438.6(c)(2)(iii))

Comment: Many commenters supported finalizing a total payment rate limit that may not exceed the ACR as proposed at § 438.6(c)(2)(iii) for inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center. These commenters believe ACR is a reasonable threshold that allows managed care plans to compete with commercial plans for providers to participate in their networks to furnish comparable access to services. Other commenters provided support for this proposal as they believe it is consistent with the goal of equity in payment across delivery systems. Some of the commenters that supported this proposal stated that if accurately calculated, ACR would generally represent an approximation of fair market value for the services provided and would function as an appropriate fiscal guardrail to ensure that individual program spending is reasonable, appropriate, and attainable.

Some commenters stated significant concerns with finalizing a total payment rate limit lower than ACR on any SDP, not just the four services proposed in § 438.6(c)(2)(iii), as they believe a total payment rate limit lower than ACR would be financially destabilizing, would have damaging ramifications on healthcare providers that would affect their ability to provide services to Medicaid patients, potentially threatening the viability of some providers, and this in turn would have

devastating consequences on access to and quality of healthcare services for Medicaid patients.

Some of these commenters opposed codifying a total payment rate limit for certain SDPs (that is, SDPs for the four services proposed in § 438.6(c)(2)(iii)) at the Medicare rate as the commenters believe that such a limit would not actually cover the cost of treatment due to many unallowed charges under Medicare payment principles. Many of these commenters noted that implementing Medicare rates as the total payment rate limit for SDPs for these four service types would result in significantly lower payment arrangements for providers that rely on the SDP payments to fill Medicaid payment gaps. Many of these commenters noted that finalizing a total payment rate limit below ACR or at the Medicare rates for these SDPs would reduce the ability of managed care plans to compete with commercial plans for providers to participate in their networks and could result in a reduction of access, particularly for States that already have SDPs at ACR.

Response: We acknowledge the concerns raised by commenters about finalizing a total payment rate limit lower than ACR. One of the primary goals of this rulemaking is to improve beneficiary access to and quality of care. We believe payment policy is a critical component in not only ensuring but improving access to and quality of care for Medicaid beneficiaries. SDPs are an optional tool for States to use to direct how managed care plans pay providers to further the State’s overall Medicaid program goals and objectives, including those related to access and health equity. In establishing a total payment rate limit, it was not our intent to restrict States’ ability to effectively use SDPs to further the State’s overall Medicaid program goals and objectives. Our goal was to balance the need for increased transparency and fiscal integrity with the need for State flexibility to accomplish State policy objectives, such as increasing access to care.

Our internal analysis indicates that establishing a total payment rate limit less than the ACR could result in reductions in total payment rates from existing total payment rate levels for some SDPs, particularly given the number of States with approved SDPs that exceed the Medicare rate. It is difficult to specify the impact such policies would have for each State. States are not required to utilize SDPs and there are separate regulatory requirements that require States that contract with an MCO, PIHP or PAHP to

deliver Medicaid services to address network adequacy and access to care, regardless of the use of SDPs. We reiterate that although we are only finalizing the total payment rate limit at ACR for four service types at § 438.6(c)(2)(iii), we will continue to use ACR as the fiscal benchmark, to evaluate whether total payment rates for all SDPs are reasonable, appropriate, and attainable.

As we monitor implementation of this SDP policy, in future rulemaking we may consider establishing additional criteria for approval of SDPs at the ACR, such as meeting minimum thresholds for payment rates for primary care and behavioral health care, to ensure the State and its managed care plans are providing quality care to Medicaid and CHIP enrollees and to support State efforts to further their overall program goals and objectives, such as improving access to care. These additional criteria could incorporate a transition period to mitigate any disruption to provider payment levels.

Comment: Some commenters recommended that CMS finalize a total payment rate limit at the Medicare rate rather than ACR for the four service types. These commenters noted that Medicare rates are published yearly and available to the public, which would increase transparency and predictability of costs and the commenters believe that using Medicare as the threshold for a total payment rate limit is more in alignment with the UPL for Medicaid FFS supplemental payments to hospitals and other institutional providers. A few commenters also supported utilizing the Medicare rate as the total payment rate limit for SDPs for these four services for fiscal integrity reasons as they noted concerns that SDPs increasing payments to the ACR will accelerate hospital consolidation and create strong inflationary pressure on both commercial hospital prices and Federal Medicaid spending.

Response: While we recognize that setting a total payment rate limit at the Medicare rate would provide a strong fiscal guardrail for SDPs, we also recognize that this limit could impact States’ efforts to further their overall Medicaid program goals and objectives. Under risk-based managed care arrangements with the State, Medicaid managed care plans have the responsibility to negotiate payment rates with providers at levels that will ensure network adequacy. 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

¹¹⁰ <https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

for services covered under the contract between the State and the plan (§§ 438.6 and 438.60, respectively). SDPs allow States to direct how managed care plans pay providers to further the State's overall Medicaid program goals and objectives.

Our internal analysis indicates that instituting a total payment rate limit at the Medicare rate may result in total payment rate reductions compared to existing total payment rates for some SDPs, particularly given the number of States with approved SDPs that exceed Medicare. We reiterate that although we are only finalizing the total payment rate limit at ACR for four service types at § 438.6(c)(2)(iii), we will continue to use ACR as the fiscal benchmark to evaluate whether total payment rates are reasonable, appropriate, and attainable.

As finalized, § 438.6(c)(2)(iii) establishes a total payment rate limit when States choose to implement SDPs for one of the four service types at the ACR (inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center); it does not require States to implement SDPs that are projected to increase the total payment rate to the ACR. We agree with the concerns raised by commenters about hospital consolidation and inflationary pressures that SDPs can have on hospital prices in other markets and on State and Federal spending. We encourage States to take such factors into account when considering the implementation and design of an SDP. States have significant flexibility in designing the SDP, including the provider class(es) and the type of payment arrangement. States are required to monitor the impact of SDPs after implementation and adjust SDPs appropriately to address any unintended consequences.

Comment: Some commenters stated concerns with our proposal at § 438.6(c)(2)(iii) to require that the total payment rate projected for each SDP for four specific services (inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center) not exceed the ACR. They suggested that CMS consider using the ACR as a guideline for measuring the reasonableness of SDP rates when considering whether the managed care plans' capitation rates are reasonable, appropriate, and attainable, which is the key standard for actuarial soundness described at § 438.4(a), rather than applying this standard as a limit on SDP payment rates. These commenters believe this alternative would maximize

flexibility for States to address concerns with access to care. A number of these commenters also noted that in other contexts, Medicaid payment limits have led to retrospective audits and unanticipated recoupments, often years after the fact; these commenters stated that using a guideline instead of a limit would lessen the burden on providers. Some commenters suggested that CMS not institute a total payment rate limit for SDPs for these four service types as proposed, but instead use the detailed data gathered as required in other provisions in § 438.6(c) of the final rule to inform policies and address a total payment rate limit for SDPs in future rulemaking, if warranted.

Response: As noted in the proposed rule, we have been using the ACR as an internal benchmark in assessing SDPs since 2018. However, States and interested parties over time as part of SDP reviews have often stated confusion about what that internal ACR benchmark means and have requested significant technical assistance on how to demonstrate that the total payment rate for SDPs is reasonable, appropriate, and attainable. Finalizing a total payment rate limit for these four service types will provide clarity and transparency in what CMS considers reasonable, appropriate, and attainable. We reiterate that although we are only finalizing the total payment rate limit at ACR for four service types at § 438.6(c)(2)(iii), we will continue to use ACR as the fiscal benchmark for all provider types and services by which we'll evaluate whether total payment rates are reasonable, appropriate, and attainable for all SDPs.

Further, SDPs are contractual obligations between the State and managed care plan; as noted in proposed rule (88 FR 28144), 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). 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). This includes the requirement in § 438.4(b)(1) that the capitation rates must be developed with generally accepted actuarial principles and practices and the requirement in § 438.4(b)(7) that the capitation rates account for any applicable special contract provisions as specified in

§ 438.6, including SDPs, to ensure that all contractual arrangements are considered as the actuary develops the actuarially sound capitation rates.

We continue to believe that it is appropriate to implement additional regulatory requirements to ensure fiscal guardrails and oversight of SDPs while also balancing the need to ensure States have the flexibility to utilize SDPs as a mechanism to improve access to care and advance health equity. As SDP spending continues to grow, we believe there must be appropriate fiscal protections in place to ensure that SDPs further the objectives of the Medicaid programs and that the total payment rate under SDPs for each service and provider class do not grow unfettered beyond what is reasonable, appropriate, and attainable.

We reiterate that the total payment rate limit at § 438.6(c)(2)(iii)—meaning the ACR limit—would apply to the total payment rate(s) for these four service types only when a State chooses to implement an SDP for one of these four service types. States are not required to implement SDPs. The proposed total payment rate limit would not apply to rates negotiated between plans and their providers in the absence of an SDP and we note it may not be appropriate for States to implement SDPs in instances when their plans negotiate provider payment rates that support recruitment of robust provider networks. Further, the regulatory text proposed by CMS at § 438.6(c)(2)(iii) limits the total payment rate for each SDP and provides an important fiscal guardrail for these contractual obligations that would have to be accounted for in development of capitation rates paid to managed care plans. As part of CMS' monitoring and oversight of SDPs and review of preprint submissions, CMS plans to use T-MSIS data (see section I.B.2.o. of this final rule for further discussion) to assess historical total payment rates for SDPs and could, for example, request corrective modifications to future SDP submissions to address discrepancies between projections of the total payment rate under the SDP and the actual payments made to eligible providers. Future approval of SDPs may be at risk if we identify these discrepancies.

We are finalizing § 438.6(c)(2)(iii) as proposed.

Comment: A few commenters noted concerns with applying a total payment rate limit for these four service types to VBP models, and multi-payor or Medicaid-specific delivery system reform, or performance improvement initiatives. These commenters noted a numeric limit was not necessary and

inconsistent for these types of SDPs and that a total payment rate limit would disincentivize the development of VBP SDPs. The commenters noted that there does not appear to be a problem with payment levels in these VBP SDPs identified by CMS.

Response: We appreciate commenters' concerns. We support States increasing the use of VBP initiatives, including through SDPs in Medicaid managed care risk-based contracts. We are finalizing in this rule several regulatory changes to address challenges States have identified in current regulations governing SDPs to provide easier pathways to reasonably and appropriately adopt VBP SDPs (see section I.B.2.i. of this final rule). However, we continue to believe that implementing a total payment rate limit at the ACR for SDPs for these four service types provides a necessary fiscal guardrail and a prudent oversight mechanism to ensure program integrity of these SDPs as States pursue new payment models. While many of the VBP SDPs that we have reviewed to-date do not increase provider payment rates to ACR, we believe that it is important to establish an ACR limit for the four service types across all types of SDPs to ensure alignment and, so that States have a clear standard for what is approvable by CMS in the future as opposed to a changeable standard that would require repeated rulemaking. Further, we clarify here that although we are only finalizing the total payment rate limit at ACR for four provider types and services at § 438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark through which we will evaluate whether SDP total payment rates are reasonable, appropriate, and attainable.

Comment: Some commenters questioned applying the total payment rate limit to only SDPs for the four service types outlined in the proposed rule (for example, inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center). These commenters suggested that instituting a total payment rate limit at the ACR for just four service types was inequitable treatment that does not have a basis in statute nor in the best interest of Medicaid clients. The commenters noted that hospitals, nursing facilities and academic medical centers often serve a disproportionate number of Medicaid clients as part of their total client care and subjecting such provider types or services to an arbitrary payment limit is contrary to CMS's goal of ensuring access to quality care because

it indicates that CMS is willing to authorize higher payment amounts for other service providers because they are unaffiliated with training medical professionals for the future.

Response: We appreciate commenters' concerns. However, we disagree with commenters' characterization. There is currently enough evidence to support that the ACR is an appropriate total payment rate limit for Medicaid managed care coverage of inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services. As noted in the proposed rule, private insurers are the primary payer for hospital expenditures as well as physician and clinical expenditures. For these three service types, commercial payers typically pay the highest rates followed by Medicare, followed by Medicaid (88 FR 28122). This is generally reflected in our internal review of total payment rate analyses collected from States for inpatient hospital services, outpatient hospital services, and professional services provided at academic medical centers. As noted in the proposed rule (88 FR 28122), we have also approved a few SDPs for nursing facility services that were projected to increase total payment rates to the ACR. There have also been some concerns raised as part of published audit findings about a particular nursing facility SDP.¹¹¹

As noted in the proposed rule, further research is needed before codifying a specific payment rate limit for other services beyond these four service types, particularly where there is a lack of data due to Medicaid being the primary payer in the market.

We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable. Based on our continued review of SDPs and monitoring of payment rates, we may revisit codifying a specific payment rate limit for other services depending on future experience.

SDPs are a tool that States have the option to use to direct how managed care plans pay providers to further the

State's overall Medicaid program goals and objectives. States are not required to use SDPs; in fact, 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). The total payment rate limit we are finalizing at § 438.6(c)(2)(iii) applies to SDPs; it is a limit on the State's ability to direct the managed care plan's expenditures. However, as noted earlier, although we are finalizing the total payment rate limit at ACR for four provider types and services at § 438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark by which we will evaluate whether SDP total payment rates are reasonable, appropriate, and attainable. The total payment rate limit does not apply outside of the context of approved SDPs and therefore, does not apply to rates independently negotiated between managed care plans and providers; managed care plans will still be allowed to negotiate payment rates with network providers to furnish covered services.

Comment: Some commenters supported applying the ACR limit to all service types, not just those four service types proposed. Other commenters noted that specifying an ACR limit beyond the four service types (inpatient hospital services, outpatient hospital services, nursing facility services and qualified practitioner services at an academic medical center) was not necessary and that they supported limiting the total payment rate limit to the four service types proposed given the administrative work necessary to comply with the documentation requirements.

Response: We appreciate commenters' feedback. As noted in an earlier response, there is currently enough evidence to support that the ACR is an appropriate limit for the total payment rate for SDPs for inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services.

Further research is needed before codifying a specific total payment rate limit for other services beyond these four service types. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring

¹¹¹ 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>.

compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP is reasonable, appropriate, and attainable. Based on our continued review of SDPs and monitoring of payment rates, we may revisit codifying a specific total payment rate limit for other services.

Comment: Some commenters requested clarification on how CMS intends to enforce the SDP total payment rate limit for the four service types (inpatient hospital services, outpatient hospital services, qualified practitioner services at academic medical centers and nursing facility services) if actual payments made by the plans to eligible providers exceeds the total payment rate limit.

Response: We appreciate the request for clarification. As discussed in section I.B.2.o. of this final rule, we are requiring States to submit to CMS no later than 1 year after each rating period, data to the T-MSIS specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs, including amounts paid to individual providers (§ 438.6(c)(4)). States are required to regularly monitor payments made by plans to providers as part of standard monitoring and oversight, including ensuring plans comply with the contractual requirements for SDPs in alignment with the requirements in § 438.6(c). CMS will use the data collected from States on the actual final payment rate through T-MSIS (discussed in section I.B.2.o. of this final rule) as part of our monitoring and oversight; if the actual final payment rates differ from what was projected, at minimum, we will use this information to inform future reviews of SDPs.

Comment: Some commenters agreed with CMS's decision to not codify a specific total payment rate limit for some services such as HCBS or behavioral health. Commenters also supported not implementing a total payment rate limit for physician services.

Response: We appreciate commenters' support for the proposal. As noted in response to an earlier comment, we agree that limiting SDP approval based on the total payment rate not exceeding the ACR is appropriate. However, we will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class

included in an SDP must be reasonable, appropriate, and attainable.

We continue to believe that additional experience is needed before codifying a specific limit for the total payment rate for SDPs directing plan expenditures for services beyond the four service types enumerated in § 438.6(c)(2)(iii).

We did not propose to establish a specific, set limit for the total payment rate for practitioners that are not affiliated with or employed by an academic medical center; this would include physician services. As noted in the proposed rule, we have not seen a comparable volume or size of SDP preprints for provider types not affiliated with hospitals or academic medical centers, and do not believe there is currently enough evidence to support ACR as an appropriate limit on the total payment rates for physician services. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable. Depending on our future experience, we may revisit this issue as necessary.

Comment: We received a wide range of comments on establishing a total payment rate limit at the ACR for nursing facilities. Many commenters broadly supported establishing a total payment rate limit at the ACR for all four service types. However, some commenters encouraged CMS to not finalize a total payment rate limit for nursing facilities. They noted that Medicaid, not commercial insurance, is the primary payer for nursing facilities. These commenters also noted that Medicare is not a reasonable benchmark for nursing facilities services since Medicare adopted the Patient-Driven Payment Model reimbursement methodology. Some commenters suggested that CMS consider a total payment rate limit for nursing facilities that would be the greater of the ACR or what Medicare would have paid to accommodate circumstances in which a provider may serve a low volume of commercial clients and therefore have insufficient negotiation ability. Other commenters suggested CMS consider a benchmark, but not a total payment rate limit, for nursing facilities based on cost as this would be State-specific and market-based.

Response: We appreciate commenters' concerns. We acknowledge the change in Medicare payment policy from the

resource utilization groups system to the Patient-Driven Payment Model and the implications it has for States in determining Medicaid payment policies for SNFs.¹¹² As noted in the proposed rule, we have received SDP proposals that increase total payment rates up to the ACR for nursing facilities. We have also received a growing number of SDP proposals for nursing facilities that are projected to increase the total payment rate above the Medicare rate. There have also been concerns raised as part of published audit findings about a particular nursing facility SDP unlike other service category types.¹¹³ We believe it is important to have oversight and monitor fiscal integrity risks for nursing facility services and other services where Medicaid is a payer. We will continue to review and monitor all payment rate information submitted by States for all SDPs as part of our oversight activities, including but not limited to ensuring compliance with the requirement (finalized in this rule at § 438.6(c)(2)(ii)(I)) that the total payment rate for each service and provider class included in an SDP must be reasonable, appropriate, and attainable. Depending on our future experience, we may revisit this issue as necessary.

Comment: We received many comments that supported establishing a total payment rate limit at the ACR for qualified practitioner services provided at an academic medical center. Some commenters stated that a total payment rate limit at the ACR is critical because commercial plans typically pay the highest rates for these services and academic medical centers furnish a significant volume of services to Medicaid beneficiaries ensuring access to care. These commenters noted that academic medical centers are often the only source for certain specialty and sub-specialty care.

Response: We appreciate the support for finalizing a total payment rate limit at the ACR for qualified practitioner services provided at an academic medical center. This will align with the long-standing Medicaid FFS payment policy¹¹⁴ and we believe it is critical to

¹¹² <https://www.medicaid.gov/sites/default/files/2023-02/smd22005.pdf>.

¹¹³ 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>.

¹¹⁴ 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

ensure continued access to services that are often not available elsewhere.

Comment: We received mixed comments on our proposed definition of “qualified practitioner services at an academic medical center” and “academic medical center.” Some commenters supported these definitions as proposed. Other commenters raised concerns that the proposed definitions were unclear on which types of services or practitioners would be included and would exclude many academic medical centers that are “affiliated with” but do not “include” a health professional school. The commenters noted that many academic medical centers include clinical facilities (for example, hospitals and clinics) that have affiliations with health professional schools, and they are concerned that the proposed definition does not sufficiently define “facility.” Another commenter suggested that CMS streamline the definition of an academic medical center to include “any facility that both provides patient care and educates healthcare providers in connection with at least one health professional school.”

Response: We appreciate commenters support on our proposed definition of “qualified practitioner services at an academic medical center.” To the comments that the definition of “academic medical center” should be more inclusive and use “affiliated with,” we acknowledge that the use of “includes” may result in some facilities being excluded but we believe that the definition aligns with common practices and understanding. Therefore, we are finalizing the definition as proposed. We will continue to monitor and may revisit this definition in future rulemaking.

Comment: One comment supported our proposed definitions of inpatient hospital services and outpatient hospital services as proposed in § 438.6(a) and recommended that all definitions of Part 440 Subpart A be codified as applicable

information on this and other payment demonstrations is published on [Medicaid.gov](https://www.medicaid.gov). 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.

to Medicaid managed care more generally to align with Medicare Advantage.

Response: We appreciate the commenter’s support for our proposed definitions of inpatient hospital services and outpatient hospital services. As the commenter notes, the definitions proposed and finalized in § 438.6(a) for inpatient hospital services and outpatient hospital services are specific to SDPs and are intended to help determine which SDPs are subject to the requirements in § 438.6(c)(2)(iii). We appreciate the suggestion to apply these definitions and others more broadly than proposed; however, we did not propose to expand the applicability of these terms in the proposed rule and have not considered, or received public comment on, broader use of part 440 definitions for all regulations in part 438; there may be unintended consequences for such a wholesale approach to importing the defined terms used in the FFS context to the managed care context given how certain flexibilities in coverage are limited to the managed care context (see for example, § 438.3(e)). We also note that § 438.206 already provides that “all services covered under the State plan [must be] available and accessible to enrollees of MCOs, PIHPs, and PAHPs in a timely manner” and that § 438.210 provides that the amount, duration and scope of coverage benefits through the managed care plan must be no less than in the Medicaid state plan.

Comment: Some commenters suggested establishing national floors for payment levels at the Medicare rate.

Response: States have the option to implement minimum fee schedule requirements through SDPs provided they comply with the regulatory requirements in § 438.6(c). While we recognize the importance of adequate payment rates to ensure access to care, we did not propose, nor was it our intent to propose, a national minimum payment level at the Medicare payment rate for Medicaid managed care plans.

Comment: A few commenters requested confirmation that the proposed total payment rate limit for SDPs did not impact existing Federal requirements related to payment for Indian Health Care Providers at the IHS All-Inclusive Encounter Rate.

Response: In § 438.6(c), it explicitly provides an exception to the prohibition on State direction of a managed care plan’s expenditures for certain payments by stating: “Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title

XIX provision related to payments to providers . . .” Because payment of Indian health care providers by MCOs is specified in Title XIX, including section 1932(h) and section 1902(bb) for those that are FQHCs, and associated implementing regulations also generally extend those payment provisions to PIHPs and PAHPs in § 438.14, the SDP provisions in § 438.6(c) do not apply to State direction of managed care plan expenditures necessary to ensure compliance with the applicable statutory and regulatory requirements. States are required to ensure that Indian health care providers receive the minimum payment rates set forth under the aforementioned statutes and implementing regulations (such as § 438.14).

Comment: Some commenters supported our proposals in § 438.6(c)(2)(iii)(A) and (B) for data standards for the ACR demonstration and the total payment rate comparison. These commenters believe these proposals would improve fiscal integrity and ensure that SDPs advance the objectives of the Medicaid program. Commenters also supported the proposals outlined in § 438.6(c)(2)(iii)(C) regarding the submission process for the ACR demonstration and the total payment rate comparison, including the requirement for these to be provided with the initial SDP preprint and then updated at least once every 3 years thereafter. These commenters believe these proposals would allow for State flexibility and lessen the administrative burden to implement and report on ACR demonstrations since § 438.6(c)(2)(iii) does not require specific data sources or templates.

Response: We appreciate commenters’ support for the proposed data standards at § 438.6(c)(2)(iii)(A) and (B), and the submission process for the ACR demonstration and the total payment rate comparison in § 438.6(c)(2)(iii)(C). The total payment rate comparison required at § 438.6(c)(2)(iii)(B) must be updated and submitted with each initial preprint, amendment, and renewal and that it must be specific to both the service and the provider class, which differs from the ACR demonstration requirements (specific to the service type only and updated at least once every three years). We may publish additional guidance on best practices for ACR demonstrations and total payment rate demonstrations as well as a template to help facilitate CMS’s review.

Comment: Several commenters requested clarification on the data sources that should be utilized for ACR demonstrations and total payment rate

comparisons proposed in § 438.6(c)(iii)(A) and (B). Some commenters noted that commercial rate data are difficult for States to provide absent an all-payer claims database. Other commenters noted it was unclear if the data in the ACR demonstration and total payment rate comparison will be collected in a way to clearly identify non-Medicaid covered services in commercial payments or third-party liability amounts. Commenters requested that CMS provide guidance and technical assistance about the data sources that would be appropriate for States to utilize for the ACR demonstrations and total payment rate comparisons. A few commenters questioned if States should utilize Medicare cost reports or whether CMS will make all-payer claims databases publicly accessible to States. Other commenters requested that CMS identify appropriate ACR sources (including any national data sources) and methods for developing total payment rate comparisons.

Response: We appreciate the request for clarification and additional guidance on data sources to utilize for ACR demonstrations and total payment rate comparisons. We reiterate that we are not requiring States to use specific data sources at this time (88 FR 28126) for the SDP submissions of the information required by § 438.6(c)(2)(iii). We agree that all-payer claims databases are good sources of data, though not all State Medicaid agencies have access to such data. Additionally, commercial data are often proprietary and to our knowledge, there are no publicly available data sources for commercial data. Some States conduct a code-level analysis of the ACR as is currently used for the qualified practitioner services at academic medical centers supplemental payments for Medicaid FFS while others have provided analyses using hospital cost reports. Actuaries and consultants may have access to private commercial databases to aid States to produce an ACR analysis or some States have purchased access to private commercial databases to inform these analyses. Finally, other States have required providers to provide commercial payment data as a condition of eligibility for the SDP. We expect to publish additional guidance in the future that highlights best practices from States consistent with the regulatory requirements finalized in § 438.6(c)(2)(iii)(A) and (B). Whatever data source the State uses will need to comply with the standards set in § 438.6(c)(2)(iii)(A) and (B), including that data must exclude non-Medicaid

covered services and third-party liability amounts.

Comment: Many commenters supported our proposal at § 438.6(c)(2)(iii)(A)(3) to allow ACR demonstrations that are specific to the service included in the SDP and appreciated that the ACR demonstrations are not required to be specific to both each service type and each provider class. Commenters noted that this flexibility would allow States to better target funding for financially vulnerable providers, such as rural and safety net hospitals than current practice allows for today. A few commenters disagreed with our proposal and recommended that CMS revise the regulatory text in § 438.6(c)(2)(iii)(A)(3) about what States must use to demonstrate the ACR to “is specific to the service(s) and provider class(es) addressed by the State directed payment,” to align with current practice. These commenters noted that if a State chooses to create separate classes of providers, then each class should be limited to the ACR for that service and that provider class, and States should be prohibited from relying on a cumulative ACR calculation to increase payment to some provider classes at the expense of other provider classes. These commenters stated that this practice undermines the equal access to services that SDPs are intended to advance. Other commenters suggested that CMS allow States maximum flexibility to calculate the ACR demonstration by service, by provider class, or by geography or market at the State’s option.

Response: We appreciate the support for the proposal to allow ACR demonstrations that are specific to the service addressed by the SDP at § 438.6(c)(iii)(A)(3). We agree that requiring the ACR demonstration to be specific to the service addressed by the SDP but not specific to both the service and provider class provides additional flexibility to States to target resources to accomplish Medicaid program goals and objectives. In the proposed rule (88 FR 28125), we provided a lengthy discussion of our experience working with States and how requiring an ACR analysis that is specific to both to the service and provider class for SDPs can have deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries through SDPs. 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, tend to be less profitable than urban hospitals which

often have a wider mix of payers, and are at a greater risk of closure. 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 managed care plan payments for hospital services to rural hospitals through SDPs, limiting the total payment rate limit for such payments to the ACR for rural hospitals only would result in a lower total payment rate limit for such SDPs than if the State were to broaden the provider class in the SDP 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 regulatory requirement for SDPs at § 438.6(c)(2)(ii)(B) requires that SDPs direct expenditures equally using the same terms of performance for a class of providers—meaning the rural hospitals and the specialty cardiac hospitals in our examples would get the same uniform increase, even though the State may not have the same access to care concerns for Medicaid beneficiaries receiving specialty care at cardiac hospitals.

The focus on the ACR for the service at the provider class level has the potential to disadvantage providers with less market power to negotiate rates with commercial payers on par with providers with more market power. Therefore, we proposed and are finalizing the more flexible approach.

While we understand commenters’ concerns about our proposal at § 438.6(c)(2)(iii)(A)(3) to allow ACR demonstrations that are specific to the service addressed by the SDP and not to the provider classes, we believe that the commenter may have misunderstood the proposal. The commenter asserts that allowing the ACR demonstrations to be specific to the broad service type and not the individual provider class will result in unequal treatment among provider classes. In fact, the final rule would provide States the option to use the same ACR analysis as the comparison point for the total payment rate comparison (which is required to be conducted at the service and provider level) for all classes providing the same service affected by the SDP. Further, there is nothing in the final rule that permits SDP payments above ACR or to favor one class of providers at the expense of another. We remind commenters that there is no requirement that States implement SDPs. In addition, States have broad discretion in defining

provider classes for SDPs. This provision (at § 438.6(c)(2)(iii)(A)(3)) would also not change the existing regulatory requirement § 438.6(c)(2)(ii)(B) that SDPs direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract. We are finalizing § 438.6(c)(2)(iii)(A)(3) as proposed.

Finally, we appreciate the recommendations to allow States maximum flexibility to use ACR and to calculate ACR by service, by provider class, or by geography or market. States retain the discretion to use payment data that is specific to the service(s) and provider classes in the SDP and can also consider further specifics such as market and geography so long as the payment data are still specific to the State. We proposed at § 438.6(c)(2)(iii)(A)(1) that States would be required to use payment data specific to the State for the analysis as opposed to regional or national data to provide more accurate information for assessment. We noted that there is wide variation in payment for the same service from State to State and that regional or national analyses that cut across multiple States can be misleading, particularly when determining the impact on capitation rates that are State specific (88 FR 28125). For these reasons, we believe that finalizing § 438.6(c)(2)(iii)(A)(1) as proposed is appropriate.

We received no other comments on the remaining portions of § 438.6(c)(2)(iii)(A) and are finalizing as proposed.

Comment: One commenter suggested that CMS allow Medicaid agencies to increase the ACR level used to set the payment amounts in an SDP between ACR demonstrations submitted to CMS, so that the State could direct increased payments to account for inflation. While the commenter supports only requiring States to submit an ACR demonstration every three years in § 438.6(c)(2)(iii)(C) to reduce State burden, they noted that medical inflation trends are not static over three-year periods (meaning, between ACR demonstration submissions). The commenter recommended that CMS allow States to account for medical inflation within their jurisdiction in their ACR during the three-year period without requiring States to revise the ACR demonstration.

Response: We recognize that medical inflation may continue to increase over the three-year period between ACR demonstrations. If medical inflation has a notable impact during the three-year period between demonstrations, States have the option to update the ACR

demonstration any time a preprint is submitted, and that updated ACR demonstration is subject to CMS review as part of review of the SDP preprint. We believe this is a reasonable approach that provides us the ability to review such updates.

Comment: One commenter requested that CMS delay implementation of § 438.6(c)(2)(iii) for 1 year after the effective date of this final rule. The commenter believes States will need more time than the proposed applicability date, the first rating period after the effective date of the final rule, provides.

Response: We appreciate the concern raised by commenters. This requirement is largely in alignment with existing practices and should not cause significant burden for States to implement. Therefore, we are finalizing at § 438.6(c)(8)(ii) the applicability date of the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as proposed.

Expenditure Limit for All SDPs

Comment: Many commenters did not support the alternative options we outlined in the proposed rule for an expenditure limit on SDPs. Some commenters stated that any limit on SDP expenditures as a proportion of managed care spending could be an arbitrary limit that could have deleterious effects on enrollee access to care and impede State flexibility to meet the goals and objectives of their managed care program. A few commenters raised concerns that any SDP expenditure limits could penalize States with lower base managed care expenditures due to the relative size of the State or managed care program. Other commenters believed that the proposed total payment rate limit at ACR for inpatient and outpatient hospital services, nursing facilities and professional services at academic medical centers provided a reasonable limit on SDPs and that an additional limit on total expenditures for SDPs was unnecessary. A few commenters recommended that CMS complete additional studies including using future SDP evaluations to better understand the impact of an SDP expenditure limit and assess whether an SDP expenditure limit, either in totality or for specific provider classes, was truly needed.

Response: We carefully considered alternative options for the SDP expenditure limit outlined in the proposed rule. We recognize that the alternative options for the SDP expenditure limit outlined in the

proposed rule could have unintended consequences to States' efforts to further their overall Medicaid program goals and objectives, such as improving access to care for Medicaid beneficiaries and reduce health disparities through SDPs. We agree with commenters that the total payment limit at the ACR that we are finalizing for the four specific categories of services listed in § 438.6(c)(2)(iii) is the reasonable and appropriate policy to ensure the fiscal integrity of SDP arrangements.

Comment: Several commenters recommended that if CMS finalizes an expenditure limit for SDPs, existing SDPs be either exempted from the expenditure limit or provided a transition period for States to develop alternative frameworks.

Response: As we explain in the prior response, we are not finalizing an overall SDP expenditure limit in this final rule.

We did not receive any comments on our proposed definitions of "average commercial rate" or "nursing facility services" in § 438.6(a). After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed definitions in § 438.6(a). We are also finalizing § 438.6(c)(2)(ii)(I) with minor revisions also discussed earlier. Finally, we are finalizing 438.6(c)(2)(iii) as proposed, with one modification in paragraph (c)(2)(iii)(B)(3) to clarify that the prior approval referenced is "prior approval of the State directed payment . . .".

g. Financing (§ 438.6(c)(2)(ii)(G) and (c)(2)(ii)(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, waivers, 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;¹¹⁵ and (4) 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.¹¹⁶ 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.

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.¹¹⁷ 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

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).

¹¹⁶ 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.

¹¹⁷ 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>.

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; § 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 matched with Federal funds. In 1991, Congress passed the Medicaid Voluntary Contribution and Provider-Specific Tax Amendments (Pub. L. 102-234, 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) of the Act requires that health care-related taxes be broad-based as defined in section 1903(w)(3)(B) of the Act, which specifies that the tax must be imposed for a permissible class of health care items or services (as described in section 1903(w)(7)(A) of the Act) or for providers of such items or services and generally imposed at least for all items or services in the class furnished by all non-Federal, nonpublic providers or for 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

¹¹⁵ “Bona fide” provider-related donations are truly voluntary and not part of a hold harmless arrangement that effectively repays the donation to

1903(w)(4) of the Act for 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 for 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 by 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 will

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 and 9687). Accordingly, in discussing revisions to the hold harmless guarantee test in § 433.68(f)(3), the February 2008 final rule preamble noted 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 will 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 the 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 (FFS 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 FFS 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 final rule, noting "certain financing requirements in statute and regulation are applicable across the Medicaid program irrespective of the delivery system (for example, FFS, managed care, and demonstration authorities), and are similarly applicable whether a State elects to direct payments under § 438.6(c)" (85 FR 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.¹¹⁸ Concerns around the funding of the non-Federal share for SDPs have been raised by oversight bodies.^{119 120}

¹¹⁸ <https://www.medicare.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

¹¹⁹ 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>.

¹²⁰ See Medicaid and CHIP Payment and Access Commission, "Oversight of Managed Care Directed Payments," June 2022, available at <https://>

Through our review of SDP preprint proposals over the past few years, we have identified various non-Federal share sources that appeared unallowable. Primarily, the potentially unallowable non-Federal share arrangements have involved health care-related taxes. Specifically, we have identified multiple 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 one particular form of a hold harmless arrangement, with 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 will 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 FFP 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 will otherwise be matchable as medical assistance if the State share being matched does not comply with the conditions in section 1903(w) of the Act, 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 another 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 will 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 believed 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. Therefore, these redistribution arrangements help ensure that State or local governments are successful in enacting or continuing provider tax programs.

The Medicaid statute at section 1903(w) of the Act 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 noted our belief 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 will 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 noted 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 will ultimately have to be disallowed, when it would be more efficient to not allow such expenditures to be made in the first place. Therefore, we 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 to support the authority to make explicit in § 438.6 that CMS may disapprove an SDP when we are aware the State share of 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 stated 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 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. The policies in the rule will help 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 paragraph (c)(2)(ii)(H). The new attestation requirement will 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, subpart B of part 433, 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 believe updating the 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 will strengthen 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 are finalizing § 438.6(c)(2)(ii) to add a new paragraph (c)(2)(ii)(G) that will explicitly require that an SDP comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, subpart B of part 433, as part of the CMS review process.

We are also finalizing our proposed revision to § 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 regulation, States will be required to ensure that participating providers in an SDP arrangement attest that they do not participate in any hold harmless arrangement for 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 will be held harmless for all or a portion of their cost of a health care-related tax. States will 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 will comply with this proposed requirement by obtaining each provider's attestation or requiring the Medicaid managed care plan to obtain each provider's attestation.

After reviewing comments, we have determined that we should make explicit that the failure of one or a small number of providers to submit an attestation would not necessarily lead to disapproval of the State's proposed SDP preprint. CMS may disapprove the SDP preprint proposal because some attestations are not obtained or are not made available by the State. However, CMS will still perform our standard, comprehensive review of whether a health care-related tax is allowable, and through this review may approve the proposed SDP preprint if the available information establishes that there is not likely to be a prohibited hold harmless arrangement in place. This policy recognizes that the presence or absence of provider attestations does not conclusively establish whether a hold harmless arrangement exists or not, but merely provides information that is relevant in determining whether there is or may be a hold harmless arrangement. It further recognizes that the actions of one or a small number of providers should not automatically invalidate the efforts of the State (and other providers in the State who would receive the SDP) to comply with financing requirements.

For example, the fact that a few providers (who would be eligible for an SDP) expect to pay more in taxes than they will receive in payments might lead these providers not to complete an attestation, even if no hold harmless arrangement is in place, because they find it to be in their interest not to make the attestation in order to interfere with implementation of the tax and/or the SDP. If that is the reason the State is unable to obtain attestations from all providers who would receive the SDP and there are no other indicia that a prohibited hold harmless arrangement is in place, we intend to leave flexibility to approve the SDP under this final rule. On the other hand, even if all providers who are eligible for an SDP attest that they do not participate in a hold harmless arrangement, we may disapprove the SDP or initiate actions to defer or disallow FFP under a previously approved SDP if we learn that a prohibited hold harmless arrangement is or appears to be in place despite the attestations.

We proposed, at § 438.6(c)(2)(ii)(H), to require that the State ensure that such attestations are available upon CMS request. To better reflect our standard

review process for SDPs, we are finalizing the proposal to require States to, upon request, submit to CMS the provider attestations, with the modification that States may, as applicable, provide an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations. For an explanation to be satisfactory, it must demonstrate to CMS why the missing attestation(s) does not indicate that a hold harmless arrangement is or is likely to be in place and why the absence of the attestation(s) therefore should not impact our evaluation of the permissibility of the health care-related tax. We discuss this modification further in response to comments.

Under this rule, we note that 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 where 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 providers receiving a payment based on the SDP that they do not participate in any hold harmless arrangement. As part of our restructuring of § 438.6(c)(2), these provisions will apply to all SDPs, regardless of whether written prior approval is required. We relied 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 finalize 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, subpart B of part 433, apply regardless of delivery system, we also solicited public comment on whether the proposed changes in § 438.6(c)(2)(ii)(G) and (H) should be incorporated more broadly into part 438.

For discussion on the proposed applicability dates for the provisions outlined in this section, see section I.B.2.p. of this final rule. Please note that we are updating the effective date for § 438.6(c)(2)(ii)(H) to no later than

the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, as discussed in the responses to comments on that provision.

We solicited public comments on these proposals.

We summarize and respond to public comments received on Financing (§ 438.6(c)(2)(ii)(G) and (H)) below.

Comments on § 438.6(c)(2)(ii)(G)

Please note that some commenters cited paragraph (G) in their comments; however, upon review we determined the comments were referencing the attestation policies contained in paragraph (H), and those comments are discussed separately after the paragraph (G) comments.

Comment: Some commenters stated that the proposed rule will restrict States' ability to raise funds to finance the non-Federal share of the Medicaid programs in the same manner as States have in the past. The commenters indicated that such a change would reduce the payment rates to providers, which may harm access to care for Medicaid beneficiaries.

Response: We recognize that any changes to States' financing can be challenging, given limited budgets. However, CMS disagrees that the regulation would restrict non-Federal share financing sources. Rather, this regulation emphasizes States' responsibilities to adhere to existing Federal financing requirements. If a State believes this regulation will require them to end a particular financing arrangement, then such an arrangement is already impermissible even absent the rule. When a State finds that it needs to transition to another financing source or modify an existing one, CMS works with that State to ensure such a transition can be executed as seamlessly as possible under Federal law.

CMS has worked with many States to modify financing arrangements over the years. To the extent that States find that they must change the source of their financing to comply with Federal law, States have several types of permissible means for financing the non-Federal share of Medicaid expenditures. As discussed earlier in this section, those include, but are 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; and (4) 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.

The final rule is not designed to limit the amount of funds that States spend on qualifying services by reducing provider payment rates or otherwise. Rather, the rule is intended to ensure compliance with existing Federal requirements for financing the non-Federal share of program expenditures. CMS understands the critical role that health care-related taxes have in financing the non-Federal share of Medicaid expenditures in many States. According to MACPAC, for State fiscal year 2018, 17 percent of the non-Federal share of nationwide Medicaid expenditures was derived from health care-related taxes, totaling \$36.9 billion.¹²¹ The scale at which health care-related taxes have come to be used as the non-Federal share of Medicaid expenditures throughout the country underscores the importance of ensuring that these funds meet Federal requirements when used to pay for Medicaid expenditures.

Comment: One commenter stated that they understood that States are already required to follow all rules related to financing the non-Federal share of Medicaid payments, but did not provide any additional information.

Response: The commenter is correct that all Federal legal requirements for the financing of the non-Federal share, including those stated in section 1903(w) of the Act and implementing regulations in 42 CFR part 433, subpart B, apply to all non-Federal share financing arrangements. We assume the commenter meant to indicate that the need for this provision of the proposed rule was unclear, since the commenter understood that the existing requirements apply regardless of delivery system. However, before this final rule, § 438.6(c) did 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. We are concerned that the failure of the current regulations to explicitly condition written prior approval of an SDP on compliance with the non-Federal share financing requirements may create some ambiguity with regard to our ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Although this commenter is correct about the funding requirements already existing, the proposed rule and this final rule were written to remove any possibility of confusion and codify that SDPs may be disapproved on the basis of impermissible financing.

Comment: One commenter indicated that the broad language in paragraph (G) requiring compliance "with all Federal legal requirements for the financing of the non-Federal share," coupled with the use of "including but not limited to," would cause uncertainty regarding CMS' interpretation of Federal requirements, does not provide enough information for providers to know what they are attesting to, and that sub-regulatory guidance would be an inappropriate means to provide clarifications because such guidance would in effect be requirements.

Similarly, another commenter objected to the way that they anticipated CMS would implement a final regulation through the issuance of sub-regulatory guidance that goes beyond the regulatory requirements. The commenter stated concerns that CMS would impose further requirements on States using sub-regulatory guidance, rather than through the rulemaking process.

Response: The provision at § 438.6(c)(ii)(G) explicitly requires that an SDP comply with all Federal statutory and regulatory 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. The regulatory citation following "including but not limited to" is an illustrative example, and one we wanted to state explicitly, but it does not change the requirement to comply with all financing requirements. For example, the provision also requires compliance with section 1903(w) of the Act. This requirement will help ensure that States are compliant with all Federal requirements regarding non-Federal share financing. Paragraph § 438.6(c)(ii)(H) requires States to ensure that providers receiving an SDP attest that they do not participate in any hold harmless arrangement for any health care-related tax. Providers will not be required to attest to a State's compliance

¹²¹ See <https://www.macpac.gov/wp-content/uploads/2020/01/Health-Care-Related-Taxes-in-Medicaid.pdf>.

with financing rules; rather, States will be required to ensure that providers attest to their own conduct.

Any guidance CMS would release to clarify the requirement in § 438.6(c)(ii)(G) would not change requirements, because the regulation already encompasses all Federal statutory and regulatory requirements. CMS uses sub-regulatory guidance to, among other things, explain how we interpret a statute or regulation, or provide additional clarifications. One of the main purposes of guidance is to explain and help States comply with agency regulations, particularly for circumstances that were not necessarily anticipated when issuing a regulation and when additional clarifications are needed. CMS cannot anticipate every scenario that States will encounter as they implement requirements, but the inability to anticipate every possible future scenario does not mean that such scenarios will not already be subject to the requirements finalized in regulation, which underscores the potential need for and role of sub-regulatory guidance. As such, CMS will continue to issue interpretive subregulatory guidance, as appropriate, to help ensure that requirements for States are clear and transparent.

Comment: One commenter objected to CMS imposing new financing requirements on SDPs and indicated that the proposed rule would create inconsistency between requirements for FFS payments and payments under managed care arrangements.

Response: As we noted in the preamble to the proposed rule¹²² and in this final rule, 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, already apply to all Medicaid expenditures regardless of delivery system (FFS or managed care). We are not imposing new financing requirements on SDPs. Rather, we reiterate that 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. CMS views these finalized regulations as improving financing consistency.

Comment: One commenter supported CMS' proposals related to SDPs on the basis that these requirements would

help ensure that provider payments are consistent with Federal requirements.

Response: We are finalizing the changes to the financing regulations at § 438.6(c)(2)(ii)(G) as proposed.

Comments on § 438.6(c)(2)(ii)(H)

Comment: Some commenters were concerned that the proposed rule requiring States to ensure that providers receiving an SDP attest to their compliance with certain financing requirements would add burden to States, providers, or managed care plans. Two commenters noted that, under the proposed rule, States could delegate to managed care plans the responsibility for gathering the attestations and suggested that doing so would be burdensome to providers, which may be under contract with a number of different managed care plans. Commenters suggested limiting the number of attestations to one per provider, or requiring States to collect the attestations, rather than allowing States to delegate to managed care plans.

Response: We understand that some States may have to take on new responsibilities to implement the requirements of § 438.6(c)(2)(ii)(H). To assist in these efforts, we will work with States to provide technical assistance, and we are also available to assist States with questions about matching funds for qualifying State Medicaid administrative activities to implement the regulation.

After consideration of the public comments, as further discussed in this section, we are finalizing § 438.6(c)(2)(ii)(H) with modifications discussed in other responses in this section of the final rule. To help ease the transition to the collection of required provider attestations, we are establishing an applicability date at § 438.6(c)(8)(vii) of no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, for the attestation provisions located at § 438.6(c)(ii)(H), to allow States sufficient time to establish the attestation collection process that works best for their individual circumstances. This will also provide time for States to restructure SDPs that may involve arrangements that prevent providers from truthfully attesting that they do not engage in hold harmless arrangements. We will utilize this time to collect additional information about the prevalence of hold harmless arrangements and work with States to come into compliance.

We acknowledge that, if States delegate to Medicaid managed care plans the responsibility for collecting

attestations, providers may need to submit multiple attestations if they participate in multiple managed care networks. Furthermore, providers may need to submit multiple attestations if they are subject to multiple State taxes and/or receive multiple SDPs, in particular if the provider participates in multiple tax and payment programs that operate on different timelines. To minimize burden on providers, Medicaid managed care plans, and States, we recommend States that delegate the collection of provider attestations to Medicaid managed care plans furnish standardized attestation language or forms that reflect which tax or taxes it concerns and what time period it covers, and that, in general, are as comprehensive as reasonably possible under the circumstances in the State. Ultimately, States will be responsible for implementing the attestation requirement under this final rule, and CMS encourages States to consider the complexities that may arise from delegating the responsibility to plans. States may find it is ultimately more efficient to gather the attestations, one per provider, to limit complexity or variations in process with the multiple managed care plans with which a provider may participate.

Our goal of ensuring compliance with the law warrants the additional State and Federal resources required to implement these provisions, as we are increasingly encountering issues with States financing the non-Federal share of SDPs using potentially impermissible hold harmless arrangements. CMS has a duty to ensure that Federal financial participation is paid only in accordance with Federal law. In addition, the applicability date of no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, will allow sufficient time for States to develop systems to collect attestations in the most efficient, least burdensome way for each.

Comment: Some commenters noted that the requirement for providers to sign attestations was "overly broad," which could lead to confusion among States, managed care plans, and providers. One commenter stated that CMS needs to clarify the scope of the attestation requirement to specify exactly what parties are attesting to generally and particularly for hold harmless relationships.

Response: We understand that States will be taking on increased responsibility for ensuring that providers receiving SDPs attest that they do not participate in hold harmless arrangements under § 433.68(f)(3). We

¹²² 88 FR 28092 at 28129.

also understand that providers may be confused by the requirement to attest to matters concerning laws they may not have considered previously. The regulation at paragraph

§ 438.6(c)(2)(ii)(H) makes clear that providers would need to attest to their compliance with § 433.68(f)(3), and we would expect States to guide providers on this provision and the types of arrangements prohibited under that regulation before they are expected to sign. We also note that States have flexibility in how they frame their attestations and in the specific instructions they make to providers, so long as the requirements of the regulation are met. As always, CMS will work diligently with States to provide technical assistance as necessary to guide a State through any unique circumstances. We will also release sub-regulatory guidance if needed to highlight use cases and best practices.

Comment: One commenter recommended that CMS collect the attestations from providers rather than requiring States to do so, to avoid imposing additional burdens on State governments.

Response: We recognize that States have responsibility for managing Medicaid programs, and the new attestation requirement may increase some States' responsibilities further when States use SDPs. However, we generally do not have the direct relationship that each State has with its Medicaid providers and managed care plans, as providers enroll through States and are paid by States or State-contracted plans and generally do not interact with us. Conversely, we have an extensive partnership with States. As such, we determined the most appropriate mechanism to ensure compliance with financing requirements is for States (or plans, at the direction of States) to collect these attestations. The rule is clear that States are not required to submit these attestations to us en masse, but rather to retain and make them available to us upon request. As always, we will work diligently with States to provide technical assistance and sub-regulatory guidance as necessary, and when possible, to reduce burden on States. In addition, the effective date of no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028, for § 438.6(c)(ii)(H) will allow States sufficient time to develop processes to minimize State administrative burden.

Comment: One commenter sought clarification on how the proposed regulation would be applied if a provider declined to sign the attestation

or if a provider did sign the attestation and was later found to be in violation of § 433.68(f)(3). Another commenter requested clarity about how CMS would treat States when a provider fails to comply with the signed attestation.

Response: As noted in the preamble to the proposed rule¹²³ and in this final rule, States would be required to note in the preprint their compliance with this requirement prior to our written approval of SDPs. As a result, if a State sought approval of an SDP preprint for which not every provider that would receive an SDP had submitted an attestation under § 438.6(c)(ii)(H), then the SDP preprint would be at risk of disapproval.

However, as discussed earlier in this section, CMS will still be performing a comprehensive review of the permissibility of the SDP and the source(s) of non-Federal share that support the SDP, including any applicable health care-related taxes. In the case of a health care-related tax, the presence or absence of one or more attestations will be a component of our review. We do not believe that it would represent sound Medicaid policy to allow one or a small number of providers, for reasons unrelated to participation in impermissible arrangements, to obstruct approval of an entire SDP that could apply to hundreds of providers. Similarly, it would not represent sound Medicaid policy to automatically approve SDPs when 100 percent of relevant attestations are provided by the State, if CMS has specific information indicating that a hold harmless arrangement is, or is likely to be, in place.

There are several possible scenarios where a State might be unable to collect one or more attestations, yet CMS would determine that the absence of those attestations does not indicate that an impermissible hold harmless arrangement is likely to exist. For example, a provider might expect to pay more under a health care-related tax than it will receive in Medicaid payments supported by the tax, and therefore might refuse to provide an attestation in an attempt to interfere with implementation of the tax and the SDP even if no hold harmless arrangement exists. In instances where not all providers sign the required attestations, CMS will expect the State to provide sufficient information to determine the reason(s) behind the failure to obtain attestations from all providers eligible for an SDP, which is a component of CMS's overall review of approvability. The requirement for

States to collect all attestations nevertheless remains a necessary component of this process, as it will allow CMS to still consider available attestations in our review of whether the non-Federal share meets Federal requirements. Additionally, through the process of collecting provider attestations, we expect the State will gain information about why certain providers may fail to submit them, which the State will need to share with us under the requirement in this final rule that the State provide an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make required attestations. CMS will view the lack of an attestation or attestations as evidence that there are impermissible hold harmless arrangements, unless the State satisfactorily explains how the absence of the attestation(s) does not suggest that a hold harmless arrangement is in place or is otherwise unrelated to the permissibility of the health care-related tax.

When a provider signs an attestation, they affirm the attested information to be true. States should treat these attestations in the same manner as they treat other attestations supplied by providers that affirm that the provider complies with various requirements to receive payment. As with all Federal requirements, States must oversee their programs to ensure that the State can identify noncompliant providers. As described earlier in the preamble to this section, if a provider submits an inaccurate attestation or refuses to submit a signed attestation, FFP could be at risk, because the State may be claiming Medicaid expenditures with an impermissible source of non-Federal share (due to the existence of a hold harmless arrangement). In such a situation (for example, where a provider fails to provide a required attestation), the State could make signing an attestation a condition of eligibility for the SDP, according to the terms of the contract that conditions receipt of SDP funds on compliance with provision of an attestation, as a risk mitigation strategy, to avoid making a payment that guarantees to hold the taxpayer harmless. Some States have already undertaken this approach. If the State chooses this risk mitigation strategy, the State should include the requirement that a provider sign an attestation to qualify for the SDP in its contracts with the managed care plans making the payments to providers.

After consideration of the public comments, we are modifying the regulatory text at § 438.6(c)(ii)(H) to include language saying States must

¹²³ 88 FR 28092 at 28132.

“ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations.” This change will help protect States, and other providers submitting attestations, in cases of uncooperative and/or unresponsive providers. We emphasize that, while providers refusing to sign the attestations may result in an SDP disapproval, it does not mean that it necessarily will. Conversely, we also want to emphasize that the ability to provide CMS an explanation should not be regarded as a pathway to automatic approval in the absence of one or more provider attestations, as CMS will not approve an SDP where there is evidence that the payments would be funded by an impermissible arrangement. CMS will still perform our standard, comprehensive review to determine whether the SDP is approvable considering a variety of factors, including the underlying source(s) of non-Federal share and will consider all available information, which includes attestations and State explanations about missing attestations, as applicable.

As stated previously, for a State’s explanation for a missing attestation to be satisfactory to CMS, it must demonstrate why the absence of the attestation(s) is not indicative of a hold harmless arrangement. The State should demonstrate how it made a good faith effort to obtain the attestation and why it does not believe that the absence of the attestation(s) should be considered evidence of the existence of a hold harmless arrangement. A State could do this in many ways. For example, an explanation could include relevant information about the business status of the provider(s) in question, such as information about solvency, and demonstrate how these circumstances reflect that a hold harmless arrangement is not in place. In this example, a State might note if the providers in question lacked sufficient resources to obtain a timely review of the attestation by legal counsel. As another example, a State could include relevant information about the providers’ revenue. In this case, the State might describe its efforts to obtain all attestations and indicate that of 150 participating providers, only two providers with an extremely small amount of all-payer revenue (who may be less motivated to assist with SDP approval) did not file an attestation. A State could note further any information that may indicate a hold harmless arrangement does not exist with respect

to the SDP and related taxes, such as how the absence of a single attestation with all remaining participating providers attesting would tend to suggest that there is not an impermissible arrangement in place among providers eligible for an SDP. However, if the State’s explanation is insufficient to establish that a hold harmless arrangement is unlikely to exist, then CMS can and may deny the SDP.

As described in the proposed rule, CMS’s statutory obligation is to ensure proper and efficient operation of the Medicaid program. We will disapprove an SDP when we know the payments would be funded under an impermissible arrangement, or if upon request, the State does not provide sufficient information to establish that the non-Federal share source is permissible. The attestation requirement is an assurance measure that is in furtherance of that obligation, but at no point was it intended as the sole indicator of whether an SDP would be supported by a permissible source of non-Federal share or as the sole deciding factor for whether the SDP can be approved. We believe it would be unnecessarily punitive on States and unrealistic to not provide an opportunity to explain why one or more provider attestations could not be obtained, and for CMS to consider whether the circumstances for the failure to obtain such attestations might not suggest the existence of a hold harmless arrangement, before deciding whether to approve an SDP.

Comment: A few commenters stated that they did not agree with how CMS interprets the statute’s definition of hold harmless arrangements. Specifically, several commenters stated that CMS’ interpretation overstepped or misinterpreted the “plain language” of the statute. Some of those commenters asserted that the statute specifies that States must be responsible for arranging the hold harmless agreement. They stated that, if private actors create an arrangement without State involvement, it should not be considered a violation of the statute. They noted that the proposed rule would further codify what they consider to be CMS’ erroneous interpretation of the statute’s hold harmless definition, and illegally interferes with private providers engaging in private arrangements to mitigate the impact of a provider tax. Several commenters specifically referenced a lawsuit that was brought by the State of Texas against CMS that has resulted in the court preliminarily enjoining CMS from disapproving or

acting against certain financing arrangements within Texas.

Response: We do not agree with commenters’ characterization that the proposed regulation and the requirements of this final rule overstep the plain language of the statute. The statute requires all Medicaid payments be supported by financing that complies with section 1903(w) of the Act, which, as relevant to the provider attestation requirement in § 438.6(c)(ii)(H), defines a hold harmless arrangement to exist if 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. Regulations at § 433.68(f)(3) interpret this provision to specify 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. By providing a payment that is then redistributed through private arrangements that offset the amount paid by a taxpayer, a State has indirectly provided for a payment that guarantees to hold the taxpayer harmless.

As such, we do not agree with commenters’ assertion that the proposed rule would require providers to attest to anything beyond what is currently required under statute and regulation, as arrangements that redistribute Medicaid payments to hold providers harmless for the tax amounts they pay are prohibited under current law. 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.”¹²⁴

Regardless of whether the taxpayers participate mandatorily or voluntarily, or receive the State’s Medicaid payment directly from the State or managed care plan or indirectly from another provider or other entity via redistribution payments (using the dollars received as Medicaid payments or with other provider funds that are replenished by Medicaid payments), the taxpayers participating in these redistribution arrangements have a reasonable

¹²⁴ 73 FR 9694.

expectation that they will be held harmless for all or a portion of their tax amount. We have consistently noted that we use the term “reasonable expectation” because “State laws were rarely overt in requiring that State payments be used to hold taxpayers harmless.”¹²⁵

We acknowledge that on June 30, 2023, a Federal district court in Texas issued a preliminary injunction enjoining the Secretary from implementing or enforcing the Bulletin dated February 17, 2023, entitled “CMCS Informational Bulletin: Health Care-Related Taxes and Hold Harmless Arrangements Involving the Redistribution of Medicaid Payments,” or from otherwise enforcing the interpretation of the scope of 42 U.S.C. 1396b(w)(4)(C)(i) (section 1903(w)(4)(C)(i) of the Act) found therein. That injunction remains in effect, and we will abide by it as long as it remains in effect, in implementing the attestation requirements contained in § 438.6(c)(ii)(H) of this final rule.

Comment: One State commenter objected to the proposed rule because they currently have a pooling arrangement that the State says is compliant with Federal law and working well. Specifically, the commenter noted that in their State, providers have had various private agreements to redistribute funds among themselves for decades, with the full knowledge and approval of CMS.

Response: We do not agree with the commenter that an arrangement that pools and redistributes Medicaid payments to hold providers harmless for tax payments would comply with Federal law and regulations. 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. This requirement for a State financial interest in operating and monitoring its Medicaid program helps ensure that the State operates the 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 Federal and State taxpayers for the funds expended.

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 where applicable Federal requirements are met. These provisions are intended

to safeguard the Federal-State partnership, irrespective of the Medicaid delivery system or payment authority. The provisions do so 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. States are accordingly motivated to administer their programs economically and efficiently. Medicaid payment redistribution arrangements undermine the fiscal integrity of the Medicaid program by their apparent design 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. Further, they are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements and artificially inflate Federal Medicaid expenditures.

Comment: One commenter noted that in its State, some institutional providers have complex partnership and ownership relationships with other institutions, both within and outside of the State. The commenter anticipated needing more guidance as to what arrangements would be permissible.

Response: We recognize that the requirement to obtain attestations from providers that would receive an SDP places additional responsibilities on States, and we recognize that many States impose taxes on and pay providers that have multiple business and financial relationships with one another. Large ownership groups operate in multiple States and with different types of providers. CMS does not intend to interfere with the normal business operations of any providers, large or small. However, the final rule will help avoid arrangements in which providers are explicitly connecting taxes to payments in a manner that holds taxpayers harmless. CMS will work with each State as needed to ensure that the law can be applied appropriately in all circumstances, consistent with applicable statutory and regulatory requirements.

Comment: One commenter lauded what they called the “safe harbor Hold Harmless provisions” as an important tool for financing States’ share of Medicaid payments and recommended that, rather than finalizing the proposed rule, CMS should more vigorously enforce “safe harbor” compliance.

Response: We agree that enforcing the existing requirements concerning health care-related taxes would be beneficial.

As such, CMS believes that the attestation requirement is necessary to ensure that SDPs are financed appropriately.

In addition, the “safe harbor” threshold located at 42 CFR 433.68(f)(3)(i)(A) states that taxes that are under 6 percent of net patient revenue attributable to an assessed permissible class pass the indirect hold harmless test. This test is an important financing accountability requirement, but it is not addressed in this rulemaking. We also remind the commenter that the 6 percent indirect hold harmless limit does not mean that States are permitted to have direct hold harmless arrangements if the amount of the tax is less than 6 percent of net patient revenue. The 6 percent indirect hold harmless test is an additional requirement on top of, not in place of, the prohibition against having a direct hold harmless arrangement, including through indirect payments.

Comment: One commenter stated that CMS should not adopt a new substantive rule governing Medicaid financing that is limited to managed care, but rather such requirements should apply broadly to all delivery systems and payments by amending financing rules generally. The commenter stated concerns that an inconsistent application of a new policy would result in arbitrary and capricious distinctions between Medicaid FFS and managed care expenditures, as well as between Medicaid managed care directed and non-directed payments.

Response: We appreciate the commenter’s perspective on ensuring consistency across payment types and delivery systems. Partly in response to this shared concern, in the proposed rule, we requested 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 in future rulemaking. We appreciate the commenter’s feedback.

We also note that as part of our review of SDP proposals, we are increasingly encountering issues with State financing of the non-Federal share of SDPs that may not comply with the underlying Medicaid statute and regulations. In addition, concerns around the funding of the non-Federal share for SDPs have been raised by oversight bodies. Further, CMS at times denies approval of proposed State plan amendments affecting FFS payments due to unallowable sources of non-Federal share. States that have SDPs disapproved because of impermissible financing will also have the opportunity to engage in an administrative appeals process if they choose, similar to how

¹²⁵ *Id.*

States may administratively appeal the disapproval of a FFS payment State plan amendment.

Comment: We received a few comments that addressed this provision generally, and opposed implementation, but the commenters did not provide further explanation.

Response: We do not agree with these comments, we appreciate the concerns stated, and wherever possible we will seek to assist States with meeting these new requirements.

After reviewing the public comments, we are finalizing the following changes to the financing attestation provision in § 438.6(c)(2)(ii)(H):

- Updating the proposed language, “ensure that providers receiving payment under a State directed payment attest that providers do not participate in any hold harmless arrangement” to read, in paragraph (H)(1), “ensure that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement.”

- Updating the proposed language, “directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount” to read, in paragraph (H)(1), “directly or indirectly guarantees to hold the taxpayer harmless for all or any portion of the tax amount.”

- Updating § 438.6(c)(2)(ii)(H) with an organizational change to divide the provision into paragraphs (H)(1) and (H)(2).

- Updating the proposed language, “ensure that such attestations are available upon CMS request” to read, in paragraph (H)(2), “ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations.”

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 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 and applied 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 appropriate due to the variety of payment mechanisms that States use in their SDP arrangements. 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 section I.B.2.i. of the proposed rule and in this final 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 (or per services) in favor of paying for value and performance. We proposed 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 final 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. Therefore, we clarified this in SMDL #21–001,¹²⁶ and noted 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 proposed 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. The proposal would require that any 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 will preclude States from making any SDP payment based on historical utilization or any other basis that is not tied to the delivery of services in the rating period itself.

Our proposal also addressed SDPs that require reconciliation. In SMDL #21–001,¹²⁷ 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 include the SDP in the rate certification and then once actual utilization for the current rating year is known, we observe that in many cases 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

¹²⁶ <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf>.

¹²⁷ <https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf>.

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 will 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 this, we proposed a new § 438.6(c)(2)(vii)(B) which will 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 Act¹²⁸ 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 described in the proposed rule our belief that 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

¹²⁸ 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.

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.¹²⁹ These concerns led CMS to phase out the ability of States to utilize pass-through payments as outlined in § 438.6(d). In the proposed rule, we noted that we reached a similar conclusion in our review of SDP proposals which use reconciliation of historical to actual utilization; if 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.”¹³⁰

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 proposed 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 proposed 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 will provide more clarity to providers on payment rates and likely result in more timely

¹²⁹ 81 FR 27587 and 27588.

¹³⁰ 81 FR 27588.

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 and the amendments made in this final rule to § 438.6(c).

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. Prohibiting this practice and removing post-payment reconciliation processes as we proposed in § 438.6(c)(2)(vii)(B) will alleviate oversight concerns, align with the risk-based nature of capitation rates, as well as restore program and fiscal integrity to these kinds of payment arrangements.

We proposed to prohibit the use of post-payment reconciliation processes for SDPs; specifically, we proposed that States establishing fee schedules under § 438.6(c)(1)(iii) could not require that plans pay providers using a post-payment reconciliation process. These post-payment reconciliation processes that we proposed to prohibit here directs how the plans pay providers. We have 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.

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

We solicited public comments on our proposals.

We summarize and respond to public comments received on our proposal for tying utilization and delivery of services for fee schedule arrangements (proposed § 438.6(c)(2)(vii)) below.

Comment: Some commenters supported our proposal to prohibit States from requiring plans to make interim payments based on historical utilization and then reconciling these interim payments to utilization and delivery of services at the end of the rating period (meaning the proposal at § 438.6(c)(2)(vii)(B) and agreed that this change would ensure that payments made under an SDP be conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only, as

specified at proposed § 438.6(c)(2)(vii)(A). Commenters stated these were reasonable and appropriate guardrails to ensure that SDPs are prospective and appropriately funded within capitation rates.

Response: We appreciate commenters' support for these proposals. These provisions are fundamental and necessary protections to ensure the fiscal and program integrity of SDPs and the risk-based nature of Medicaid managed care.

Comment: Many commenters opposed the requirements specified at § 438.6(c)(2)(vii)(A) and (B). Some commenters stated concern that these proposals would preclude States and managed care plans from making SDP payments to providers based on historical data altogether. Other commenters stated concerns that these policies could create cash flow problems for providers and thus impact access to care. Other commenters stated concern that payments from the managed care plans to providers could not be completed within the rating period which would mean that plans and States could not comply with this requirement. Some commenters suggested including a grace period after the rating period ends to allow for claims run out to occur. These commenters stated concern that these provisions would create State challenges for verifying that SDP rate increases are properly paid on each claim when paying contemporaneously. Many commenters requested that CMS clarify what practices would be allowable within these requirements.

Response: We acknowledge that many commenters stated either concern that historical data, interim payments and reconciliation could not be used at all under § 438.6(c)(2)(vii)(A) and (B) or requested additional clarification to ensure that reconciliation was still available in addition to claims runoff practices. Our goal is to ensure the integrity of risk-based managed care. Payments to providers under SDPs must be based on utilization and delivery of services during the rating period in order to ensure that the payments are consistent with the nature of risk-based care and do not unnecessarily undermine the managed care plan's ability to manage its risk under the managed care contract.

To be clear, this provision, as proposed and as finalized here, does not prohibit all administrative reconciliation processes such as those standard provider payment processes associated with claims processing such as runoff, adjudication, and appeal which may not be completed within the

rating period. These processes can continue. We also note managed care plans should pay providers in a timely manner pursuant to § 447.46, and we believe this can be accomplished within the parameters of these requirements finalized in § 438.6(c).

For a broader example, we revisit our example from proposed rule (88 FR 28133) and adapt it to illustrate permissible uses of historical data, claims data, interim payments, reconciliation, and claims runoff.

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 uniform increase percentage payment of 3 percent per service rendered to the same inpatient hospital service providers. The total amount of the dollars to be paid during the rate period under the SDP was determined during capitation rate development using historical data from CY 2019, consistent with § 438.5(b)(1) and (c) and utilizing adjustments in rate development as appropriate in accordance with § 438.5(b)(4). During the rating period, the plans make estimated interim payments (negotiated base provider payment rates plus the 3 percent increase to those payment rates as directed by the SDP) quarterly to the qualifying providers based on utilization within a timeframe in the rating period (for example, an interim estimated payment is made in April based on utilization in January through March). When the claims runoff is complete, which may take as long as 16 months, the plans make a final payment to the providers based on total actual utilization for services rendered during the rating period.

Under this example, historical data are used appropriately in capitation rate development for the managed care plans, consistent with § 438.5(b)(1) and (c), and not as the basis for interim payments from the plans to providers. Estimated interim payments are made by the plans to providers based on actual experience for a timeframe within the rating period to ensure there is no disruption in cash flow for providers. Claims can be continued to be paid by the plans to the providers after the end of the rating period, provided they are for utilization that occurred within the rating period, either by date of receipt of the claim or date of service, depending on the State's consistent methodology. Payment adjustments from the plan to the provider can still be used to ensure the plan's payments

to providers have been accurately tied to utilization within the rating period. The regulation at § 438.6(c)(2)(vii)(B), as proposed and finalized, does not prohibit reconciliation of payments to actual utilization during the rating period when interim payments were also based on utilization during the rating period. There is no need for a capitation rate amendment as the State has prospectively and appropriately assigned the risk to the plans and developed actuarially sound capitation rates.

However, in the example previously, the most straight forward way for plans to pay providers consistent with the required uniform increase is to increase the base payment to providers by 3 percent. When the base payment is adjusted this way, there is no need for plans to make adjustments to provider payments at a later date, and providers will receive full payment initially, rather than waiting a potentially significant amount of time for the plan to reconcile to actual utilization.

Comment: Some commenters opposed the provisions specified at § 438.6(c)(2)(vii)(A) and (B) given concerns that these provisions would reduce or remove States' ability to mitigate risk using SDPs. Another commenter did not agree that retroactively adjusting the payment amount circumvents the prospective, risk-based nature of the managed care arrangement; instead, the commenter stated that SDPs are intended to allow States to direct payment amounts through managed care plans, which by their nature removes some of the risk from the arrangement.

Response: As we have stated in the past, we believe that allowing States to direct the expenditures of a managed care plan to make payments to providers in a specified manner can reduce the plan's ability to effectively manage costs, and as we described in the proposed rule preamble, this is why we finalized specific parameters for SDPs in the 2016 final rule (88 FR 28110). We disagree that it is reasonable and appropriate for SDPs to be designed in a manner to fully remove risk from the managed care plans participating in the SDP as this is contrary to the nature of risk-based Medicaid managed care. For these reasons, we are finalizing 438.6(c)(2)(vii)(A) and (B) as proposed.

Comment: One commenter recommended that CMS create "a threshold (perhaps 5 percent) of change in payment per-enrollee beyond which an additional [rate] certification would be required" rather than prohibiting the use of interim payments as specified in § 438.6(c)(2)(vii)(B) if CMS's primary

concern is that the SDP reconciliation would result in final capitation rates that are potentially different than the actuarially sound capitation rates. The commenter did not provide further details on this recommendation.

Response: We are unclear on the recommended alternative that the commenter suggested and there is not adequate detail to evaluate it further. We believe that States have appropriate flexibility under § 438.6(c)(2)(vii)(A) and (B), as we have outlined in the illustrative example above. All SDPs must be documented within rate certifications (see section I.B.2.l. of this final rule for further detail) and the types of changes in rates that do not require an amended rate certification are not changing in this rulemaking. For these reasons, we decline to revise § 438.6(c)(2)(vii)(A) and (B).

Comment: Some commenters opposed the provisions specified in § 438.6(c)(2)(vii)(A) and (B) as they noted that it would increase State administrative burden, and one of these commenters indicated it is administratively easier to reconcile payments from historical data. Some commenters also requested that if CMS does implement these provisions that they be delayed until ongoing challenges with the process of SDP preprint submissions, and CMS review and approval of these preprints are resolved.

Response: We do not agree that these provisions will create new administrative burden. As discussed in the proposed rule (88 FR 28134), retrospective reconciliation for SDP payments is administratively burdensome and we believe States can meet their goals using appropriate processes that eliminate the need to pay interim payments on experience outside of the rating period or conduct associated reconciliation processes. See a previous response to comment in this section in which we provide an illustrative example. We do not believe revisions to State and managed care plan processes to comply with § 438.6(c)(2)(vii)(A) and (B) would create excessive new administrative burden, as outlined in the illustrative example, and we are hopeful these changes could create administrative efficiencies. However, we acknowledge that States frequently pair separate payment terms with post payment reconciliation processes to ensure that the full separate payment term amount is paid out. Therefore, we are finalizing the applicability date for § 438.6(c)(2)(vii)(A) and (B) to align with the applicability date for the prohibition we are finalizing against separate

payment terms in § 438.6(c)(6). State will be required to come into compliance with § 438.6(c)(2)(vii)(A) and (B) no later than the first rating period beginning on or after 3 years after the effective date of the final rule instead of the proposed 2-year compliance period. For discussion on the elimination of separate payment terms and related changes to the proposed regulation text, refer to sections I.B.2.k., I.B.2.l., I.B.2.m. and I.B.2.p. of this final rule.

We agree that improvements in the SDP preprint submission process are necessary. We believe our proposals related to SDP submission timeframes will improve the fiscal oversight of these SDPs and CMS's review and approval of SDP preprints (see section I.B.2.e. of this final rule for further details); and as such, we decline to further delay the implementation of these provisions. We also acknowledge that if a minimum fee schedule SDP is not approved until after the start of the rating period, plans are not prohibited from making retroactive payments to providers so long as the payments are made consistent with § 438.6(c), including that the payments are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(vii)(A) and (B) as proposed.

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

We also proposed 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, current § 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. (As finalized in this rule, the same requirement is codified at

§ 438.6(c)(2)(vi)(A). 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. We proposed revisions to § 438.6(c) to address such barriers. First, we proposed to redesignate current paragraph (c)(2)(iii) as paragraph (c)(2)(vi) with a revision to remove the phrase “demonstrate in writing” to be consistent with the effort to ensure that SDP standards apply to all SDPs, not only those that require prior approval. We also proposed to redesignate current paragraph (c)(2)(iii)(A) as paragraph (c)(2)(vi)(A).

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 strengthen the link between SDPs that are VBP initiatives and quality of care, we proposed 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.

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,¹³¹ we reasoned that while capitation rates to the managed care plans will reflect an amount for incentive payments to providers for meeting performance targets, the plans should retain control over the amount and frequency of payments. We believe 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 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 proposed 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 will 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 noted that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds will remain with the MCO, PIHP, or PAHP. We believe this was important to ensure 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 lack of experience and robust data. And unfortunately, failed attempts to implement VBP arrangements

¹³¹ <https://www.federalregister.gov/documents/2015/06/01/2015-12965/medicaid-and-childrens-health-insurance-program-chip-programs-medicare-managed-care-chip-delivered> (pg 31124).

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 noted in the proposed rule that removing this prohibition could enable States to reinvest these unspent funds to further promote VBP and delivery system innovation. To the extent a state intends to recoup unspent funds from plans for any State directed payment, this would need to be described in the State's preprint.

To expand the types of VBP initiatives that will be allowed under § 438.6(c)(1)(i) and (ii) and ensure a focus on value over volume, we also proposed 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. These different types of VBP initiatives have different goals and conditions for payment, and we believe that establishing different requirements for them is necessary to establish the appropriate types of parameters for payment.

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.¹³² 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 poor outcomes related to 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 proposed to use new § 438.6(c)(2)(vi)(B) for requirements for SDPs that condition payment on performance. We also proposed to adopt 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). We proposed 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 proposed 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 (as required by § 438.6(c)(1)(iii)). At § 438.6(c)(2)(vi)(B)(1), we proposed to codify our interpretation of this policy by requiring 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 stated

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 proposed 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 will 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 solicited 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 proposed that the performance measurement period must not exceed the length of the rating period. Although we proposed to extend the length of time between provider performance and payment for administrative simplicity, we did not propose to extend the performance measurement time. Finally, we also proposed that all payments will need to be documented in the rate certification for the rating period in which the payment is delivered.

¹³² <http://hcp-lan.org/workproducts/apm-framework-onepager.pdf>.

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 proposed, 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,¹³³ 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 final 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 initiative SDPs, we proposed 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 proposed 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 proposed 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 that our proposals are consistent with how quality improvement is usually measured, as well as be responsive to oversight bodies and will help promote economy and efficiency in Medicaid managed care.

Population-Based Payments and Condition-Based Payments. As discussed previously in this section of this rule, 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 proposed to add new § 438.6(c)(2)(vi)(C) to establish regulatory pathways for approval of VBP initiatives that are not conditioned upon specific measures of performance.

We proposed 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 proposed 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) that 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 amount 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 proposed to require that population-based and condition-based payments be based upon either 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 during the rating period. 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 section 1903(m)(2)(A)(xi) of the Act and §§ 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 based upon the attribution of a covered enrollee to a provider, we proposed § 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; account 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.

States have submitted proposals for VBP initiatives that include prospective PMPM population-based payments with no direct tie to value or quality of care and that would be 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, 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 proposed 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)(3), we proposed 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)(3) 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

¹³³ 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>.

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 proposed that SDPs under § 438.6(c)(2)(vi)(C) 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 proposed 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 also proposed that States be required to set the target for such a performance measure to demonstrate improvement over baseline. 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) providing SDPs that are VBP initiatives as defined in § 438.6(c)(1)(i) and (ii) and that 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 proposed to modify § 438.6(c)(3)(i) to add that a multi-year written prior approval for SDPs that are for VBP initiatives described in paragraphs (c)(1)(i) and (ii) may be for of up to three rating periods to codify our existing policy. Requiring States to renew multi-year SDPs at least every 3 years will allow us to monitor changes and ensure that SDPs remains aligned with States' most current managed care quality strategy. We proposed 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 proposed 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 final rule.

We solicited public comments on these proposals.

We summarize and respond to public comments received on our proposals regarding value-based payments and delivery system reform initiatives (§ 438.6(c)(2)(vi)) below.

Comment: Many commenters were broadly supportive of our proposed changes to the VBP initiative SDP provisions (currently at § 438.6(c)(2)(iii)), including our proposals to remove existing requirements (currently at § 438.6(c)(2)(iii)(C) and (D)) that prevent States from setting the amount and frequency of payments or from recouping unspent funds from VBP initiative SDPs, respectively. Commenters stated support for removing barriers to allow for flexible collaboration and innovation. Some commenters encouraged CMS and States to engage with interested parties to determine if there are additional barriers to implementation of VBP initiative SDPs described in paragraphs (c)(1)(i) and (ii).

Response: We appreciate the support for the proposed policies regarding VBP initiative SDPs. Addressing barriers that prevent States from designing VBP initiative SDPs based on prospective payments is key to supporting States that wish to adopt innovative models intended to promote quality and value over volume, such as hospital global budgets and other delivery system reform initiatives. We will continue to engage with interested parties to assess barriers and support States wishing to implement VBP initiative SDPs.

Comment: Some commenters supported the removal of the prohibition on States recouping unspent funds from VBP initiative SDPs but requested that CMS provide further direction and requirements for how recouped funds can be spent.

Response: As proposed, we are removing this existing prohibition on recouping unspent funds because States have struggled to balance setting performance targets that are ambitious enough that, if achieved, they would meaningfully improve care quality and health outcomes but not so ambitious that providers are discouraged from participating or so unambitious that they do not result in improved quality or outcomes. We believe States will be more likely to implement VBP initiative SDPs if they are able to establish

ambitious performance or quality targets without being concerned that managed care plans will profit from weak provider performance.

We did not propose and are not finalizing spending requirements for recouped unspent State funds that were initially designated for payment of VBP initiative SDPs. We remind States that any recoupments made from plans as a part of VBP initiative SDPs are subject to the return of the Federal share via the CMS-64.

Additionally, we refer readers to section I.B.2.k. of the proposed rule for our discussion of proposed managed care contract requirements for SDPs. Specifically, under this final rule, States are required by § 438.6(c)(5)(iii)(D)(6) to document how any unearned payments will be handled, and any other significant relevant information. These contract requirements will help ensure that States and plans have explicit documentation of the goals of each VBP initiative SDP and the disposition of unspent funds.

Comment: One commenter requested clarification about how the newly proposed VBP initiative SDP criteria may impact existing VBP arrangements that span both Medicare and Medicaid as a part of integrated plans such as FIDE SNPs, and stated concern that the potential for conflicting reporting requirements could deter States from implementing VBP arrangements in a dual space.

Response: Because SDPs are not a venue for directing Medicare dollars, the proposed VBP initiative SDP criteria will not impact payment arrangements that exist under integrated Medicare Advantage (MA) plans, such as FIDE SNPs, where the State contracts with MA organizations offering the MA plan and directs how the MA plan pays its providers for Medicare covered services or MA supplemental benefits. However, if a State wishes to implement or direct payments by Medicaid managed care plans for benefits under the Medicaid managed care contract then the State would need to comply with 438.6(c). Written approval of SDPs described in §§ 438.6(c)(1)(iii)(A) and (B) is not required, but it is required for other SDP arrangements under § 438.6(c). For currently existing arrangements and the application of changes adopted in this final rule, please see section I.B.2.p. of this final rule regarding the applicability dates.

Comment: Many commenters supported the provisions for performance-based VBP initiative SDPs at proposed § 438.6(c)(2)(vi)(B). Specifically, commenters showed support for requiring that performance-

based VBP initiative SDPs use measurable and understandable performance targets as well the proposed expansion of the performance measurement period to up to 12 months prior to the start of the contract rating period.

Response: We appreciate the support of these provisions. In our experience, these proposals are consistent with how quality improvement is usually measured and will help promote economy and efficiency in Medicaid managed care.

Comment: Several commenters either opposed the proposal that performance-based VBP initiative SDPs must not condition payment on administrative activities, such as the reporting of data, or they suggested revisions to the provision so that “pay-for-reporting” would be allowed at least in the initial years of a performance-based VBP initiative SDP. Commenters noted that often these initiatives are multi-year and States need time to collect the data necessary to build baselines to measure performance against. Some commenters stated concern that it may not be possible to comply with the proposal to require States to identify baseline statistics and performance targets for all metrics tied to provider payment in the SDP because data for the most appropriate measure for the payment strategy is not yet collected.

Response: Because payment for performance-based VBP initiative SDPs must be based on provider performance tied to the delivery of covered services under the Medicaid managed care contract for the rating period, we have never allowed these types of SDPs to be based on “pay-for-reporting.” Our rationale has been and remains that the act of reporting is an administrative activity and not a covered service. To make this explicit, we proposed and are finalizing this requirement at § 438.6(c)(2)(vi)(B)(1). Although we recognize the challenges of gathering the baseline data needed for establishing the performance metrics and targets used in VBP initiative SDPs, we are finalizing paragraph (c)(2)(vi)(B)(1) as proposed. For situations in which States wish to support administrative activities that are necessary for successful implementation of VBP initiatives, we encourage them to explore alternative program designs. For example, a State could start first by designing a fee-based payment arrangement that is tied to utilization and delivery of services under the contract and to use provider reporting or participation in learning collaboratives as a condition of provider eligibility for the fee-based SDP. This allows States, plans and providers time to develop

their systems of reporting and to collect the data necessary to establish baselines and performance targets. Once established, the arrangement can be transitioned to a performance-based VBP initiative SDP and payment to providers can be tied to performance measured against the baseline.

Comment: Some commenters suggested revisions to the proposal that the performance measurement period must not precede the start of the rating period by more than 12 months; commenters suggested extending the period of time for which the performance period could precede the baseline to 18 or 24 months to allow for an adequate claims runout period, provider reporting, and data analysis.

Response: We believe that the flexibility to use a performance period that precedes the rating period by 12 months is sufficient to allow adequate time for claims runout and for States time to collect and analyze performance data for use in the payment arrangement. As an illustration, if a State that uses a calendar year contract rating period implements a performance-based VBP initiative SDP on January 1, 2025, the State could pay providers through December 31, 2025, based on performance that occurred as far back as January 1, 2024, because the performance measurement can proceed the start of the rating period in which the payment is delivered by up to 12 months. In this example, we believe that this would be enough time to allow for claims run out and quality measure reporting. If the State needs extra time to analyze the data and determine provider payments amounts, it should specify at the start of the payment arrangement that payments to providers will not occur prior to the 3rd or 4th quarter to establish clear expectations for managed care plans and providers.

Comment: A few commenters were opposed to the proposal requiring States to choose performance targets that show improvement over baseline for all measures used in SDPs that condition payment on performance. Commenters stated that it is impractical to require such improvement year after year.

Response: We proposed that the performance targets used in VBP initiative SDPs that condition payment on performance must show improvement over a baseline for a performance-based payment to occur to ensure that performance-based VBP initiative SDPs do not pay providers for performance that is declining. We recognize that the proposed provision was more restrictive than necessary to guard against that. Therefore, we are finalizing proposed

§ 438.6(c)(2)(vi)(B)(5) with a revision, which aligns with § 438.6(c)(2)(iv)(C), that performance targets must demonstrate either maintenance or improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment. States have flexibility to choose performance measures and targets that are meaningful to their managed care quality goals, and we will not preclude States from setting performance targets that represent maintenance of baseline performance if the State believes those targets help further State goals. We will work with States to ensure that these arrangements are dynamic and drive continual performance improvement rather than reward provider performance over several contract periods that should become the minimum expectation over time. However, if a State wishes to deliver payments to providers irrespective of their performance on specified measures, then those payment arrangements should be structured as fee-based SDPs under § 438.6(c)(1)(iii) and therefore must be tied to the delivery of a Medicaid-covered service(s) under the managed care contract (however, we note such an SDP is required to comply with all requirements, including that it advance at least one of the goals and objectives in the State’s quality strategy). If CMS finds that a State is using a VBP SDP to deliver payment irrespective of performance then, at minimum, CMS will not approve the subsequent SDP preprint renewal submission and may provide technical guidance to the State on how to transition the VBP SDP to a fee-based SDP.

Comment: Some commenters supported the proposed provisions at § 438.6(c)(2)(vi)(C) that establishes a pathway for approval of population-based and condition-based VBP initiative SDPs. Commenters stated that these proposals increase States’ flexibility in designing and implementing VBP initiatives by removing barriers.

Response: We appreciate the support for these provisions. Addressing regulatory barriers that limit payment for VBP SDPs to only being tied to provider performance during the rating period is key to allowing States to adopt and participate in innovative payment arrangements designed to promote quality and value over volume. These provisions, in tandem with removal of the restrictions preventing States from setting the amount and frequency of VBP initiative SDPs or recouping unspent funds from VBP initiative SDPs, will create a pathway for approval

of such SDPs that are based on prospective PMPM payments. We believe that these flexibilities will allow for the implementation of innovative models that include payment arrangements, such as hospital global budgets, which emphasize value and that rely on robust quality improvement frameworks but that to date have not been allowable under § 438.6(c).

Comment: A few commenters requested clarification regarding the provisions at proposed § 438.6(c)(2)(vi)(C) for population-based or condition-based payments used in SDPs. Commenters inquired about whether the provisions pertain only to VBP initiative SDPs described at § 438.6(c)(1)(i) and (ii), or if these provisions would also be applied to SDPs described at § 438.6(c)(1)(iii). Some commenters were also concerned about whether SDPs that include components of attribution and care management and that are currently allowed under the regulations at § 438.6(c)(1)(iii) would continue to be permitted under the new provisions.

Response: As proposed and finalized, § 438.6(c)(2)(vi)(C) applies solely to SDPs that are VBP, delivery system reform, and performance improvement initiatives as described in § 438.6(c)(1)(i) and (ii) that use population-based and condition-based payments. These new provisions for population-based and condition-based VBP initiative SDPs allow approval of certain types of innovative payment arrangements that focus on value and that, to date, have not been approvable under § 438.6(c)(1)(i) and (ii) either because they rely on prospective PMPM payments that are not tied to a specific measure of provider performance during the rating period or because they set the amount and frequency of payments or recoup unspent funds. Because innovative models that include prospective PMPM payments (such as hospital global budgets) alongside robust quality frameworks are emerging in the current landscape of value-based care, it is crucial to provide a regulatory framework for approving VBP initiative SDPs that include these models.

Several States have successfully designed SDPs described in § 438.6(c)(1)(iii) that include innovative payment models (such as PCMHs) by tying the prospective payments to a Medicaid covered service (such as case management) delivered under the managed care plan contract during the rating period. We will not preclude States from seeking approval of renewal preprints of previously approved SDPs using the described existing pathway if States choose. Instead, we are seeking to

remove barriers and to provide a more flexible pathway for approval of innovative payment models that focus on the delivery of quality care to Medicaid beneficiaries.

Comment: Commenters requested additional information regarding how population-based and condition-based payments must replace the negotiated provider rate for a set of services, how to account for the attribution of a patient population, and how these factors will affect the development of Medicaid managed care capitation rates.

Response: We proposed and are finalizing a pathway for States to implement population-based and condition-based payments, which are VBP initiative SDPs that are prospective payments tied to specific groups of Medicaid managed care enrollees covered under the contract; these payments must be based on either the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period to the covered group or upon the attribution of covered enrollees to the provider during the rating period. If the payment is based on the attribution of covered enrollees to the provider, the attribution methodology must use data that are no older than the 3 most recent and complete years of data; seek to preserve existing provider-enrollee relationships; account for enrollee preference in choice of provider; and describe when patient panels are attributed, how frequently they are updated. Additionally, we are finalizing the requirement that population-based and condition-based payments must replace the negotiated rate between an MCO, PIHP, or PAHP and providers for the Medicaid covered service(s) included in the payment and that 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 payment. We note that this final rule maintains the requirement that SDPs must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8.

We believe that the regulation text and explanations in the proposed rule and our summary of the proposed rule are sufficiently clear to establish the requirements for use of these types of payments. However, we appreciate that the implementation of these provisions will introduce new operational and technical considerations for States and interested parties, and we plan to publish guidance that includes practical examples of implementation strategies to help guide States as they design SDPs, particularly those that are VBP

initiatives that include population- and/or condition-based payments. Additionally, we encourage States interested in establishing VBP initiative SDPs to consult with their actuaries during rate development.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(vi)(B)(5) as proposed but with revisions to allow performance targets that demonstrate either maintenance of or improvement over baseline. We are finalizing all other provisions at paragraphs (c)(2)(vi)(B) and (C) as proposed but with minor grammatical revisions in paragraphs (c)(2)(vi)(C)(1) and (2) and with a technical correction in (c)(2)(vi)(C)(2). We are also finalizing the removal of certain requirements currently codified at § 438.6(c)(2)(iii)(C) and (D) (related to directing the timing and amount of expenditures and recouping unspent funds) and the redesignation of the current provision at § 438.6(c)(2)(iii)(A) to § 438.6(c)(2)(vi)(A).

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

We proposed 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 2017¹³⁴ 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).

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

¹³⁴ <https://www.medicare.gov/federal-policy-guidance/downloads/cib11022017.pdf>.

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 year’s preprint submission for renewal of the SDP for the following rating period. For example, one common condition of concurrence for Year 2 preprints is the provision of SDP evaluation results data for year one of the SDP with the Year 3 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 MACPAC¹³⁵ and GAO,¹³⁶ 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 availability of information on evaluation results for SDPs, even when the arrangements had been renewed multiple times. The report also noted examples of evaluation results showing 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 recommended that we should clarify the extent to which evaluation results are used to inform approval and renewal decisions.

We proposed several regulatory changes to enhance CMS’s ability to collect evaluations of SDPs and the level of detail described in the evaluation reports. CMS’s intent is to shine a spotlight on SDP evaluations and use evaluation results in determining future approvals of State directed payments. We also plan 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.

To strengthen reporting and to better monitor the impact of SDPs on quality and access to care, we proposed at § 438.6(c)(2)(iv) that the State must submit an evaluation plan for each SDP that requires written prior approval and that the evaluation plan must include four specific elements. 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 proposed at § 438.6(c)(2)(iv)(A) that the evaluation plan must identify at least two metrics that will 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 proposed 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 proposed 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 will not produce valid results due to the small sample sizes. The proposed 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 proposed at § 438.6(c)(2)(iv)(A)(2) to require that at least one of the selected metrics be a performance measure, for which we proposed a definition in § 438.6(a) as described in section I.B.2.i. of this final rule. We currently allow, and will continue to allow States to select a metric with a goal of measuring network adequacy, or 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 (such as enrollee experience or HIE interoperability goals), quality of care, or outcomes attribute to the providers receiving the SDP, 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 to care or other network adequacy measures, our proposal requires States to choose at least one additional performance metric that measures provider performance. Because we recognize that performance is a broad term and that the approach to evaluating quality in health care 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 did not

¹³⁵ 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>.

¹³⁶ 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>.

propose additional requirements for the other minimum metric so as not to preclude innovation. However, we 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,¹³⁷ the Home and Community-Based Services Quality Measure Set,¹³⁸ or the MAC QRS measures adopted in this final rule to facilitate alignment and reduce administrative burden. We acknowledged in the proposed rule that in some cases, these existing measures may not be the most appropriate choice for States' Medicaid managed care goals; therefore, we stated that 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.¹³⁹ ¹⁴⁰ 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 Sets¹⁴¹ or other standardized measure sets. CMS also expects that States consider examining parity in payment 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 proposed at § 438.6(c)(2)(iv)(B) to require States to

include baseline performance statistics for all metrics that will be used in the evaluation since this data must be established in order to monitor changes in performance during the SDP performance period. This aspect of our proposal is particularly necessary because we found in our internal study of SDP submissions that, among the SDP evaluation plan elements, a baseline statistic(s) was the most commonly missing element. We proposed the requirement 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 proposed 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 that States would also be responsive to recommendations for more clarity for SDP evaluation plans. We recognize and share the concerns raised by oversight bodies and interested parties 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 proposed to revise § 438.6(c)(2) to ensure CMS has access to evaluation plans and reports for review to determine if SDPs further the goals and objectives identified in the State's managed care quality strategy. We proposed 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), if the final State

directed payment cost percentage exceeds 1.5 percent.

Finally, we proposed 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) are intended to further identify the necessary components of a State's SDP evaluation plan and make clear that we have the authority to disapprove proposed SDPs if States fail to provide in writing evaluation plans and reports (if required) 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. We proposed 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 evaluation reporting requirement is limited to States with SDPs that require prior approval and exceed a certain cost threshold. However, we note that all SDPs, including those described in § 438.6(c)(1)(iii)(A) and (B), would still need to comply with the standards listed in the finalized § 438.6(c)(2)(ii). Therefore, even in situations where the SDP evaluation report would not need to be submitted to CMS for review at a specified time, the State is required to continue to evaluate the SDP to comply with § 438.6(c)(2)(ii)(D) and (F), and such evaluation must be made available to CMS upon request. We recognize that submitting an evaluation report will impose some additional burden on States. We proposed a 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 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 will allow States and CMS to focus resources on payment arrangements with the highest financial risk. We have selected the 1.5 percent threshold 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.4. of this final rule).

¹³⁷ 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>).

¹³⁸ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

¹³⁹ Executive Order 14009, <https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act>.

¹⁴⁰ Executive Order 14070, <https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage>.

¹⁴¹ 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>).

We proposed 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 § 438.6, for each State directed payment for which prior approval is required under § 438.6(c)(2)(i) and for each managed care program. In § 438.6(c)(7)(iii)(A), we proposed for SDPs requiring prior written approval that the final SDP cost percentage numerator be calculated as the portion of the total capitation payments that is attributable to the SDP. In § 438.6(c)(7)(iii)(B), we proposed 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). We explained in the proposed rule that 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 solicited 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 did not find it 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). The proposed numerator and denominator are intended to provide an accurate measurement of the final expenditures associated with an 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 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 noted in the proposed rule how we intend to use this interpretation of managed care program in other parts of this section of this final rule, including, but not limited to, the discussion of calculating the total payment rate in section I.B.2.f. of this final rule, measurement of performance for certain VBP arrangements discussed in section I.B.2.i. of this final rule and separate payment terms in section I.B.2.l. of this final rule.

With § 438.6(c)(7)(i) and in the definition of the phrase “final State directed payment cost percentage,” we proposed 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 will be developed in a consistent manner with how the State directed payment costs will be included in rate development, we proposed 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 we proposed that all States would be required to develop and

document evaluation plans for SDPs that require CMS’s written prior approval in compliance with the provisions proposed in § 438.6(c)(2)(iv), proposed § 438.6(c)(2)(v) requires States to submit an evaluation report for an SDP if the final SDP cost percentage is greater than 1.5 percent. We acknowledged that States may choose to submit evaluation reports for their SDPs regardless of the final SDP cost percentage, and, under our proposal, submission of the evaluation report could be done voluntarily even if not required. We proposed in § 438.6(c)(7) that, unless the State voluntarily submits the evaluation report, 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. Under this proposal, States would be required to provide the final SDP cost percentage to demonstrate that an SDP is exempt from the proposed evaluation reporting requirement. If, regardless of the final SDP cost percentage, a State elects to prepare and submit an evaluation report, the final SDP cost percentage report is not required. For SDP arrangements that do not exceed the 1.5 percent cost threshold, as demonstrated in the final SDP cost percentage report, and for SDPs for which there is no written prior approval requirement, we proposed that the State would not be required to submit an evaluation report (at proposed § 438.6(c)(2)(v)). However, we encourage States to monitor the evaluation results of all their SDPs. We recognize that in order to monitor the 1.5 percent threshold, we will need a reporting mechanism by which States will be required to calculate and provide the final SDP cost percentage to CMS. Therefore, we proposed (at new § 438.6(c)(7)(iv)) that, for SDPs that require prior approval, the State must 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 when the State has not voluntarily submitted the evaluation report. The submission of the final SDP cost percentage data would be submitted 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. 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 described an alternative approach in the proposed rule that would require States to submit the final SDP cost percentage to CMS upon completion of the calculation, separately and apart from the rate certification. However, consistency across States for when the final SDP cost percentage is submitted to CMS for review is important and, we believed receiving the final SDP cost percentage and the rate certification at the same time will enable CMS to review them concurrently.

As proposed, the denominator for the final SDP cost percentage will 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 final rule for details on the proposals for separate payment terms) paid by States to managed care plans. We noted in the proposed rule that calculating the final SDP cost percentage will 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 concluded that 2 years is an adequate amount of time to accurately perform the calculation and proposed that States must submit the SDP cost percentage report no later than 2 years after the rating period for which the SDP is included. Under this proposal, for example, the final SDP cost percentage report for a managed care program that uses a CY 2024 rating period will be submitted to CMS with the CY 2027 rate certification.

For the evaluation reports, we proposed to adopt three requirements in new § 438.6(c)(2)(v)(A). First, in § 438.6(c)(2)(v)(A)(1), we proposed 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 proposed 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 proposed to require that States publish their evaluation reports on their public facing website (the public facing website is 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 2, 55 percent of proposals included results data in Year 3, and 66 percent of Year 4 proposals included the results of the evaluation. For this reason, we did not propose that States submit an annual evaluation and proposed instead 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 must be submitted to CMS every 3 years after.

In § 438.6(c)(2)(v)(A)(2), we proposed 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. Under the proposal, 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. The evaluation plan would contain results from the first 3 years after the applicability date for the evaluation plan. The approach to implementation was intended to 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 will provide sufficient time to collect complete data and demonstrate evaluation trends over 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 will contain results from years four through six after the applicability date for the evaluation plan. States will 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 did not propose 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 will expect States to include the evaluation history in the report to provide the most accurate picture.

We recognize and share the concerns that oversight bodies and other interested parties have stated 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 proposed 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. The proposed changes are designed to help us to better monitor the impact of SDPs on quality and access to care and will 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 also proposed a concurrent proposal at § 438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which will give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs. The proposed optional EQR activity will reduce burden associated with these new SDP requirements and is discussed in more detail in section I.B.5.c. of this final rule. We described in the proposed rule, and invited public comment on, a requirement that States procure an independent evaluator for SDP evaluations in the final rule based on comments received. In consideration of the myriad new proposed requirements within this final rule, we weighed the value of independent evaluation with increased State burden. We noted in the proposed rule a concern 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. We proposed that the final SDP cost percentage be submitted 2 years following completion of the applicable rating period, and that if the final SDP cost percentage exceeds the 1.5 percent, States will be required to submit an evaluation report to CMS. 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 will not know whether an evaluation is required until 2 years following the rating period. We solicited comment on whether we should instead require 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 final rule.

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

We summarize and respond to public comments received on quality and evaluation requirements for SDPs (§ 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7)) below.

Comment: Several commenters were broadly supportive of our proposed SDP evaluation plan policies at § 438.6(c)(2)(iv). These commenters stated appreciation for the framework we proposed and our goal to incentivize quality improvement efforts through SDP evaluations. Some commenters also offered specific support for our efforts to monitor and quantify the extent to which SDPs advance the identified goals and objectives in a State's managed care quality strategy.

Response: We appreciate the support for the proposed SDP evaluation plan policies. As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, we recognize the importance of ensuring that SDPs contribute to Medicaid quality goals and objectives. Meaningful evaluation results are critical for ensuring that these payments further improvements in quality of care.

Comment: Some commenters opposed the proposed standard at § 438.6(c)(2)(ii)(F) requiring all SDPs to result in the achievement of the stated goals and objectives identified in the State's evaluation plan(s) for the SDPs, noting concern that it will result in States setting overly modest targets to avoid putting initiatives at risk if performance does not meet the established targets.

Response: We believe that States should have the flexibility to choose meaningful targets based on the goals of

the payment arrangement within their Medicaid managed care program and its quality strategy. Even modest goals, such as maintaining a certain level of access to care or provider performance, can be worthwhile and are allowable under § 438.6(c)(2)(iv)(C). We understand the commenters' concerns about underachievement and unnecessarily low-quality targets putting SDP initiatives at risk, and we encourage States to request technical assistance from CMS for choosing targets that are commensurate to the size and scope of their SDP and that are compliant with § 438.6(c)(2)(iv).

Ultimately, we believe that requiring SDPs to achieve the identified goals and objectives in their evaluation plans is a reasonable way to ensure that SDP spending supports the delivery of quality care to Medicaid managed care enrollees. In alignment with our original intent in the proposed rule to be able to request an evaluation report from a State to assess compliance with the standard at § 438.6(c)(2)(ii)(F), we are revising paragraph (c)(2)(ii)(F) to make abundantly clear that, at CMS's request, States must provide an evaluation report for each SDP demonstrating the achievement of the stated goals and objectives identified in the State's evaluation plan.

Comment: Some commenters stated concern that requiring SDPs to meet the goals and objectives in the State's evaluation plan for that SDP year after year is unreasonable because clinical outcome data can be unpredictable and vulnerable to external factors. One commenter requested further clarification on what flexibilities would be in place for unforeseen circumstances that impact quality and performance (such as a provider strike, a natural disaster, a new training protocol, or an electronic medical record migration) that may take time to resolve.

Response: This standard gives CMS the authority to disapprove renewal SDPs that repeatedly pay providers despite failure to meet the identified quality strategy goals. For SDPs that require written prior approval and have a final State-directed payment cost percentage greater than 1.5 percent, States will be required (by § 438.6(c)(2)(v)) to submit evaluation reports every 3 years that contain the 3 most recent and complete years of available data. We believe that this gives States adequate opportunity to show trends and explain anomalies or other issues over time so long as States show attainment of their goals. If an evaluation report fails to show attainment of any of the identified

quality strategy goals, we will work with the State to help ensure that the subsequent evaluation report, which would be required after another 3 years, demonstrates that the quality goals or outcomes have been *attained*. However, if the subsequent evaluation report does not show attainment of the identified quality strategy goals, we would not approve a renewal of the SDP. Ultimately, spending through SDPs should promote quality care to Medicaid managed care enrollees and SDPs that consistently fall short of their targets likely indicate misalignment with the State's quality strategy.

We appreciate that clinical outcomes can be unpredictable and vulnerable to external factors as suggested by the commenters. In the case of emergency and natural disasters that may impact clinical outcome data, States could evaluate if flexibilities under section 1135 of the Act would be applicable and beneficial. For other unforeseen circumstances, we are available to provide technical assistance to States to understand the impact of these unforeseen circumstances on the SDP's evaluation and determine how best to reflect the information in the evaluation report.

Comment: Some commenters stated concern about the administrative burden of the evaluation plans and suggested that CMS implement either an optional requirement or a minimal level of monitoring for SDPs that do not require CMS written prior approval of associated preprints.

Response: We acknowledge that SDP evaluations pose some administrative burden. While having an evaluation plan that meets the requirements in § 438.6(c)(2)(ii)(D) is a requirement that all SDPs must meet, States will not be required to submit their evaluation plans for SDPs that are exempt from the written prior approval process, which will significantly decrease administrative burden. However, States are required to monitor and evaluate access and quality for all SDPs to ensure and document compliance with § 438.6(c)(2)(ii)(F) which will require each SDP to result in achievement of the stated goals and objectives in alignment with the State's evaluation plan. Further, we note evaluation plans and reports must be made available to CMS upon request for all SDPs, including for SDPs that are exempt from the written prior approval process per § 438.6(c)(2)(ii)(F). States may consider leveraging existing monitoring and evaluation frameworks to meet these requirements.

Comment: Some commenters were opposed to the expanded evaluation

plan requirements for SDPs that are designed solely to maintain access to care. Other commenters recommended that § 438.6(c)(2)(iv)(A) be revised to allow States to select only access measures for these types of SDPs. Commenters noted that maintaining access is a worthwhile goal, and requiring performance measures may not be appropriate for the community or payment arrangement. Some commenters encouraged CMS to provide guidance on how to choose appropriate measures.

Response: While we recognize and agree that preserving access to care is a worthwhile goal for some SDPs, monitoring access to care should not be done in a vacuum that excludes monitoring provider service delivery, quality of care, or outcomes. We believe that requiring States to choose at least 2 metrics, one of which must be a performance measure, will ensure adequate monitoring of both access and quality. States have flexibility to determine which goal(s) from their quality strategies best align with the goals of each SDP, and States have flexibility to choose metrics in § 438.6(c)(2)(iv)(A)(2) that are appropriate for the payment arrangement, provider type, and population served. As such, there is ample flexibility for States to identify metrics that are most appropriate for evaluating each SDP in § 438.6(c)(2)(iv)(A)(1) which requires the metrics to be specific to the SDP, and when practicable and relevant, attributable to the performance by the providers for enrollees in all a State's managed care program(s) to which the SDP applies. We encourage States to request technical assistance to help determine appropriate measures that comply with the requirements in § 438.6(c)(2)(iv)(A).

We also remind States of the reporting requirements finalized in Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting in the August 31, 2023 **Federal Register** (88 FR 60278)¹⁴² which established requirements for mandatory annual State reporting of the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP), the behavioral health measures on the Core Set of Adult Health Care Quality Measures for Medicaid, and the Core Sets of Health Home Quality Measures for Medicaid. This rule requires States,

the District of Columbia (DC) and certain territories to mandatorily report on these Core Set measures at the State level. Additionally, Subpart G of this final rule contains requirements and the initial mandatory measure list (which will be reported at the plan level) for the Medicaid and CHIP Managed Care Quality Rating System. We encourage States to evaluate the appropriateness of the measures required on these measure sets against their measures for each SDP to leverage efficiencies and reduce administrative burden. We also encourage States to stratify all disparity sensitive measures by at least one dimension in their SDP evaluation plan, whenever possible.

Comment: One commenter opposed proposed § 438.6(c)(2)(iv)(A)(1) and suggested removal of the requirement that evaluation metrics must be attributable to the performance by the providers for enrollees in each of the State's managed care program(s) noting that some programs may be carve outs for specific service or set of services, making it difficult to evaluate them relative to larger managed care programs.

Response: The proposed provision at § 438.6(c)(2)(iv)(A)(1) requires that the chosen metrics are attributable to the performance by the providers for enrollees in all the State's managed care program(s) to which the SDP applies, when *practicable and relevant*. We proposed the standard "when practicable and relevant" to allow flexibility to account for situations in which the type of data required for managed care program-level specificity may be either impossible to obtain or may be ineffective in measuring the performance of the providers for the identified quality goal(s) and objective(s). We refer the commenter to section I.B.2.j. of the proposed rule where we discussed examples of situations where measuring performance at the specific program level would not be considered practicable or relevant. Additionally, for SDP evaluations, we believe it would be practicable and relevant to attribute metrics to the providers participating in the SDPs when the selected metrics can be calculated at the provider-level based on data reporting practices. For example, if provider data are reported to the State at the managed care program level and include providers contracted with several payers, the evaluation could pool the data from a group of providers participating in the SDP to conduct the evaluation. We encourage States to leverage existing quality reporting for this purpose, and we will continue to offer technical assistance to

States to help both select relevant metrics that can be specified at the provider level and identify strategies to analyze and isolate data to those participating SDP providers for their SDP evaluations.

Comment: Many commenters supported our proposed SDP evaluation reporting requirements at § 438.6(c)(2)(v), including the proposed 3-year submission timeframe and the submission threshold of 1.5 percent of the final SDP cost percentage.

Response: We recognize that submitting an evaluation report that complies with the requirements in § 438.6(c)(2)(v) would impose some additional burden on States but believe the 1.5 percent final SDP cost percentage threshold allows States and CMS to focus resources on payment arrangements with the highest financial risk.

Comment: Many commenters supported the proposed requirement that evaluation reports be made publicly available on States' websites noting that these proposals would help to bring more transparency to Medicaid managed care spending. A few commenters encouraged CMS to also consider making SDP evaluations publicly available on *Medicaid.gov*, similar to the process currently used for section 1115 demonstration evaluations.

Response: We appreciate the suggestion, and we intend to make States' evaluation results available on *Medicaid.gov*.

Comment: One commenter requested more details on how CMS intends to operationalize the new 3-year submission timeframe for evaluation reporting. The commenter stated concern about how CMS will use SDP evaluations to make renewal decisions for SDPs that are reviewed on an annual basis when the evaluation reports are not required every year, noting that this could introduce uncertainty and frustration for States, managed care plans, and providers.

Response: In determining whether to approve an existing SDP once the original approval period is over (that is, a renewal of an SDP), CMS will take into account the achievement of the identified goals and objectives from States' quality strategies based on a review of the evaluation report (outlined in § 438.6(c)(2)(v)) required for that SDP. Because those evaluation reports, when required, are collected on a 3-year running cycle, we can only make renewal determinations based on the achievement of goals and objectives when States have submitted the report. In the interim years, SDP approval determinations will be made based on

¹⁴² <https://www.federalregister.gov/documents/2023/08/31/2023-18669/medicaid-program-and-chip-mandatory-medicare-and-childrens-health-insurance-program-chip-core-set>.

the adequacy of the State's responses to the preprint showing that the SDP has met all of the other applicable standards in § 438.6(c)(2)(ii). With regards to the evaluation elements, States will continue to submit their evaluation plans each year with the annual preprint submission for SDPs that require written prior approval at § 438.6(c)(2)(iv). In years when States are not required to submit evaluation reports, renewal determinations will also take into account the adequacy of the evaluation plan, its required elements, and any updates to those required elements.

To illustrate, after a State receives approval of its initial SDP submission, a State would expect to submit its evaluation report with its Year 5 renewal preprint submission as § 438.6(c)(2)(iv)(B) requires that the State submit the initial evaluation report no later than 2 years after the conclusion of the 3-year evaluation period; States are required to continually monitor the progress towards their goals and objectives during the 3 years. We believe this gives States adequate time to collect and monitor data and to anticipate trends. In this example, Year 5 is the first year that CMS would make an approval determination based on the achievement of the stated goal(s) and objective(s) in alignment with the evaluation plan, as well as based on the other requirements in § 438.6(c). In Years 2, 3, and 4, approval determinations will be made based on the adequacy of the plan and its required elements, and any other information provided by the State on this topic in the preprint, as well as based on the other requirements in § 438.6(c). If helpful, States can submit interim reports for feedback from CMS to help alleviate the uncertainty of interested parties.

If a State continues the SDP beyond Year 5, the next evaluation report, which would be used in making renewal determinations that take into account compliance with paragraph (c)(2)(ii)(F), will be required in Year 8 as § 438.6(c)(2)(iv)(B) requires subsequent evaluation reports to be submitted to CMS every 3 years. In Years 6 and 7, approval determinations will be made based on the adequacy of the plan and its required elements and compliance with the other requirements in paragraph (c) (including paragraphs (c)(2)(ii)(A) through (E) and (G) through (J)).

In addition, we proposed and are finalizing § 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 as finalized at § 438.6(c)(2)(v). We believe this optional activity could reduce burden associated with this requirements and is discussed in more detail in section I.B.5.c. of this final rule. We can provide technical guidance on evaluations that are commensurate to the size and scope of SDPs for which written prior approval is required under § 438.6(c)(2)(i).

Comment: Some commenters were in favor of revising the 1.5 percent threshold for evaluation report submission, suggesting that it should be higher because the administrative burden of providing the report could discourage States from using SDPs to advance quality and value-based goals. One commenter opposed the 1.5 percent threshold altogether in favor of requiring evaluation reports on all SDPs requiring written prior approval.

Response: We appreciate the comments and continue to believe that the 1.5 percent threshold strikes the right balance between the reduction of State administrative burden and the availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(ii)(D), (c)(2)(iv) and (v) as proposed. As described in I.B.2.l, the final regulation at § 438.6(c)(6) prohibits separate payment terms; therefore, we are finalizing § 438.6(c)(7) with modifications to be consistent with that policy decision. We are finalizing § 438.6(c)(2)(ii)(F) with a revision to clarify that, at CMS's request, States must provide an evaluation report to demonstrate that an SDP resulted in achievement of the stated goals and objectives in alignment with the State's evaluation plan.

k. Contract Term Requirements (§ 438.6(c)(5) and 438.7(c)(6))

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.

Per 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), contractual requirements for SDPs should be sufficiently detailed for managed care plans to operationalize each payment arrangement in alignment with the approved preprint(s).¹⁴³ The State Guide includes examples of information that States could consider including in their managed care contracts for SDPs.¹⁴⁴ However, despite this guidance, there is a wide variety of ways States include these requirements in 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 proposed 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). Minimum requirements for SDP contract terms will 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's review of managed care contracts, and ensure compliance with the approved SDP preprint. At § 438.6(c)(5)(i) through (v), we proposed

¹⁴³ <https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf>.

¹⁴⁴ <https://www.medicaid.gov/medicaid/downloads/mce-checklist-state-user-guide.pdf>.

to specify the information 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 is designed to 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 proposal 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 provides 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 and is a requirement to 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 proposed to require that specific elements be included in the contract at a minimum. For SDPs that are minimum fee schedule arrangements, we proposed 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 proposed the requirement at paragraph (c)(5)(iii)(A)(3) to be 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 proposed 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 proposed 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, CMS updates many Medicare 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 will have to identify, for each SDP using a Medicare fee schedule, the specific Medicare fee schedule and the time period for which the Medicare fee schedule to be used during the rating period is in effect for Medicare payment. As another example, the Medicare physician fee schedule (PFS) includes factors for different geographic areas of the State to reflect higher cost areas; the Medicaid managed care contract will 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 proposed 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 proposed 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. 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. Therefore, this proposed requirement would ensure that the exemption process exists and that the managed care contract describes it, in addition to the preprint.

For contractual obligations described in paragraph (c)(1)(i) and (ii) that condition payment based upon performance, we proposed 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 is intended to 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 proposed 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 will be using a separate payment term as defined in § 438.6(a) to implement the SDP. We noted in the proposed rule that this information would provide additional clarity for oversight purposes for both States and CMS.

We also proposed 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. That proposed timeframe was consistent with the timeframe proposed for documenting separate payment terms in the managed care contract under § 438.6(c)(6)(v).

Finally, we proposed a new regulatory requirement at § 438.7(c)(6) to require that States must submit the required rate certification documentation for SDPs (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 current § 438.6(c)(2)(ii)) or 120 days after the date CMS issued written prior approval of the SDP, whichever is later. We proposed 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) currently requires that any rate amendments 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 reminded 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). (This proposal was in section I.B.2.l. of the proposed rule and is also discussed in section I.B.2.l. of this final rule.)

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

We solicited public comments on our proposals.

We summarize and respond to public comments received on our proposals for contract term requirements for SDPs and submission of associated rate certifications (§§ 438.6(c)(5) and 438.7(c)(6)) below.

Comment: Some commenters stated support for accurate documentation of SDPs in the applicable managed care plan contracts and noted that timely incorporation of this SDP documentation, and associated submission of the contracts to CMS, is essential to ensure efficient and proper administration of the Medicaid program. A few commenters suggested that CMS consider making § 438.6(c)(5) applicable sooner than proposed.

Response: We agree that timely and accurate documentation of SDPs in applicable contracts and rate certifications is critical to efficient and proper administration of the Medicaid program. Because SDPs are contractual obligations between the State and its managed care plans, it is imperative that they be documented in the contract with sufficient granularity for plans to operationalize the SDP accurately as approved. Therefore, we are finalizing the minimum contract documentation requirements proposed in § 438.6(c)(5)(i) through (iv). Due to the separate payment term prohibition being finalized in § 438.6(c)(6) (see section I.B.2.l. of this final rule for further details), we are not finalizing § 438.6(c)(5)(v) as proposed and § 438.6(c)(5)(vi) is finalized, with modifications, as paragraph (c)(5)(v). We also appreciate the suggestion to make § 438.6(c)(5) applicable sooner than proposed but believe that States will need to sufficient time to implement this requirement, in concert with other requirements finalized in this rule and therefore, decline to change the applicability date of this provision. As proposed and finalized, the requirements in § 438.6(c)(5)(i) through (iv) are applicable for any rating periods beginning on or after 2 years after the effective date of this final rule and the requirement finalized at § 438.5(c)(5)(v) (proposed at (c)(5)(vi)) is applicable for any rating periods beginning on or after 4 years after the effective date of this final rule. See section I.B.2.p. of this

final rule for more discussion of the applicability dates for the regulatory amendments regarding SDPs.

Comment: One commenter recommended that CMS require a general statement in managed care contracts specifying that the managed care plan is expected to incorporate a rate adjustment for certain providers or services as a result of an SDP. The commenter stated that providers may advocate for increased State general revenue appropriations for provider reimbursement rates and States then increase the Medicaid FFS reimbursement rates and make a corresponding capitation rate adjustment to account for base provider payment rate assumptions aligned with the Medicaid FFS reimbursement rates. However, without an SDP, the managed care plans are not bound to incorporate these rate increases into their provider rates. The commenter stated that it is important that a State be able to memorialize legislative direction.

Response: SDPs are contractual requirements whereby States direct their managed care plans' expenditures, and we are finalizing requirements § 438.6(c)(5) to ensure that SDPs are clearly described and documented in managed care plan contracts. However, that is different from when a State and its actuary use information as part of rate development, such as provider payment rate assumptions aligned with Medicaid FFS reimbursement rates, to make adjustments to base capitation rates. Without a contractual obligation that directs the managed care plans' expenditures (and such contractual obligations are required to comply with our regulations), an adjustment included in rate development and that meets the requirements for a rate adjustment in § 438.7, is not an SDP.

Comment: A few commenters supported our proposal to require States to submit managed care plan contracts and rate certifications that include SDPs no later than 120 days of the start date or approval date while other commenters questioned the feasibility of the contract submission timeframes proposed in § 438.6(c)(5)(vi). One commenter noted that 120 days may not be sufficient time for the State to process contracts from language development, legal review, and State clearance to managed care plan execution. Some commenters stated that using a "later of" submission date scheme was unnecessarily complicated, prone to error, and would leave managed care plans and providers unclear on final details about the SDP for too long. A few commenters noted that contracts and rate certifications

should be submitted at the same time as the SDP preprint to ensure that they are all consistent. A few commenters stated it is critical that managed care plans receive timely information about SDPs as delays in programming managed care plans claims processing and reporting systems accurately have the potential to delay payments to providers.

Response: We noted in the proposed rule that contracts or amendments can be submitted to CMS in draft form so long as it includes all required elements in § 438.6(c)(5)(i) through (iv), as applicable, to meet the requirement proposed and finalized in this rulemaking to document SDP terms in contract documents in a certain timeframe (88 FR 28144). Between the publication of the proposed rule and this final rule, CMS published the CMCS Informational Bulletin “Medicaid and CHIP Managed Care Monitoring and Oversight Tools” on November 7, 2023.¹⁴⁵ Within the CIB, CMS published guidance on the components of a complete submission for managed care plan rate certifications, contracts, and SDP, respectively. Like the submission requirement finalized in § 438.6(c)(2)(viii), the submission requirement finalized at § 438.6(c)(5)(v) must be met for approval of the associated Medicaid managed care contract(s). To make this requirement even clearer, we are finalizing § 438.6(c)(5)(v) with a revision to replace “contracts that are submitted to CMS . . .” to “contract that must be submitted to CMS . . .” If a State does not submit the required contract and rate certification documenting the SDP within 120 days of the SDP start date, CMS will require the State to cease SDP implementation and submit a corrective SDP amendment establishing a prospective SDP start date, as is required for all amendments to approved SDPs.

Similar to our reasoning for revising the SDP submission timeframe in § 438.6(c)(2)(viii) (see section I.B.2.e. of this final rule), we are persuaded by comments that our proposal was overly complex with the “later of” submission timelines. We also believe that we need to ensure consistency between the final regulations at § 438.6(c)(5)(vi) for contract submission and § 438.7(c)(6) for rate certification submission given their relationship to each other’s approval.

We stated in the proposed rule that we intended to make our processes more responsive to States’ needs while ensuring that reviews linked to SDP approvals are not unnecessarily delayed

(88 FR 28116). Given the finalized version of § 438.6(c)(2)(viii) for SDP preprint submission (see section I.B.2.e. of this final rule), we believe simplification of the timeframes for submission of the contract and rate certifications inclusive of SDPs is also needed to prevent unnecessary delays for States, managed care plans, and providers. In section I.B.2.e. of this final rule, we acknowledged the importance of contracts that include SDPs containing timely and accurate information on each SDP to enable managed care plans to implement them as intended. Proper implementation of an SDP also reduces uncertainty for providers expecting to receive payments from it. After careful consideration, we will finalize a single submission timeframe that is clear, facilitates compliance, and does not cause unnecessary delays in review and approval. Therefore, we are finalizing § 438.6(c)(5)(v) (originally proposed at § 438.6(c)(5)(vi)) to require all SDPs to be specifically described and documented in the managed care contracts that must be submitted to CMS no later than 120 days after the start date of the SDP and we are not finalizing “or 120 days after the date CMS issued written approval of the SDP under (c)(2) of this section, whichever is later.” As noted previously and in the proposed rule, submission of the draft contract documents reflecting the SDP terms will establish compliance with the deadline in § 438.6(c)(5)(v) so long as those draft contract documents include all of the required elements in § 438.6(c)(5)(i) through (v), as applicable. As proposed and finalized, § 438.6(c)(5) does not require a final signed copy of the contract amendment within 120- days of the start of the SDP. However, States are required to submit a final signed contract action that complies with all content requirements before CMS will approve the managed care contract. Section 438.6(c)(5)(v) as finalized requires States to submit contracts documenting SDPs no later than 120 days after the SDP start date. The submission requirement at § 438.6(c)(5)(v) may be met using a draft complete contract or draft excerpt of the contract that provides the information about the SDP required by § 438.6(c). This submission deadline applies to all contracts (and, as required by § 438.7(c)(6), discussed in detail later in this response, all rate certifications) that include SDPs, regardless—of whether the SDP requires written prior approval from CMS.

As discussed in section I.B.2.e. of this final rule, we are finalizing

§ 438.6(c)(2)(viii) to require States to submit all required complete documentation for each SDP requiring written approval before the specified start date of the payment arrangement. Required documentation for the SDP includes at least the completed preprint, the total payment rate analysis and the ACR demonstration as described in § 438.6(c)(2)(iii) and the evaluation plan as required in 438.6(c)(2)(iv) as applicable. Therefore, States would be required to submit the preprint to CMS prior to the start date of the SDP and then the corresponding contract(s) and rate certification(s) inclusive of the applicable SDP no later than 120 days following the start date of the SDP. We believe this submission timeline is the clearest and least burdensome for States, facilitates States submitting contracts that contain accurate information about each SDP, enables managed care plans to implement payment arrangements accurately, and facilitates timely payments to providers.

Lastly, we are finalizing the proposed applicability deadlines for § 438.6(c)(5). Those deadlines provide States sufficient time to come into compliance with the requirements finalized in § 438.6(c)(5). We are finalizing § 438.6(c)(8)(iii) and (v), respectively, to require compliance with the minimum contract documentation requirements in § 438.6(c)(5)(i) through (iv) 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 are finalizing § 438.6(c)(5)(v) to require compliance with the 120-day contract submission timeframe by 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. We believe staggering these applicability dates by 2 years provides States ample time to consider contracting best practices and design processes to ensure timely submission of the required SDP contract documentation.

In response to part of the comments about the submission of “rate certifications,” the discussion about the timing of submission to CMS of contracts that contain SDPs are equally applicable to rate certifications. To align rate certification submission timeframes with that of contracts, we are also finalizing § 438.7(c)(6) with revisions compared to the proposed rule. We are finalizing § 438.7(c)(6) to specify a single submission timeframe of no later than 120 days after the start date of the SDP. We are also not finalizing as part of § 438.7(c)(6) the phrase “for which the State has obtained written approval under § 438.6(c)(2)(i)” as that is not

¹⁴⁵ <https://www.medicicaid.gov/sites/default/files/2023-11/cib11072023.pdf>.

consistent with long standing rate certification requirements (as specified at § 438.7(b)(6)) that a description of any special contract provisions related to payment must be included in the rate certification. For clarity, we remind States that § 438.7(b)(6) is applicable regardless of whether an SDP requires written prior approval of a preprint and for all special contract terms specified in § 438.6 (including incentive payments, withholds, and pass-through payments). We believe finalizing § 438.7(c)(6) as described here provides States time to ensure that rate certifications accurately and consistently reflect each SDP. We are finalizing as proposed (but redesignated to § 438.7(f)(2)) that § 438.7(c)(6) as revised here is applicable no later than the first rating period for managed care plans beginning on or after 4 years of the effective date of this final rule; this applicability date aligns with the applicability of the 120-day contract submission timeframe finalized in § 438.6(c)(5)(v). (This proposal was in section I.B.2.l. of the proposed rule and is also discussed in section I.B.2.l. of this final rule.)

Comment: Some commenters stated concern about the administrative burden of incorporating such detailed information about each SDP in applicable managed care plan contracts. A few of these commenters suggested CMS reduce burden by allowing States to incorporate SDPs in contracts via formal reference to the approved preprints or through an all-plan letter.

Response: Our goal with this provision was to ensure transparency for SDPs, improve clarity for the managed care plans that are responsible for implementing these payment arrangements, and to ensure fidelity to SDP design and approval. As noted in the proposed rule, despite guidance from CMS, States have used a wide variety of approaches to include SDP requirements in their contracts, many of which lack critical details to ensure that managed care plans implement the contractual requirement consistent with the approved SDP. We believe that the minimum requirements for SDP contract terms finalized in § 438.6(c)(5)(i) through (iv) will ensure that managed care plans receive detailed direction on each SDP, facilitate CMS's review of managed care contracts, and facilitate compliance with the approved SDP preprint so that providers receive timely and accurate payments. State directed payments must be included in a State's rate certification per § 438.7(b)(6) and final capitation rates for each MCO, PIHP, and PAHP and must be identified in the applicable contract submitted for

CMS review and approval per § 438.3(c)(1)(i) (88 FR 28142). References to an approved preprint is not sufficient to meet this requirement. The preprint is the vehicle for CMS review and approval of SDPs, when required, and they were never intended to serve as a vehicle for managed care plan communication or direction. We do not believe it is reasonable to expect managed care plans to interpret an SDP preprint to operationalize an SDP, and States need to provide clear and transparent contractual requirements for SDPs in the managed care plan contracts to ensure successful implementation. For these same reasons and because an SDP is ultimately a contractual obligation between the State and managed care plans, we also do not believe that it is appropriate for States to provide the information specified in § 438.6(c)(5)(i) through (iv) to their plans via all-plan letters or other communications outside of the contract itself.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are:

- finalizing § 438.6(c)(5)(i), (ii) and (iv) as proposed;
- finalizing § 438.6(c)(5)(iii) as proposed with grammatical minor edits to (§ 438.6(c)(5)(iii)(B) and (C) to remove, “the contract must include the following”;
- not finalizing the proposed provision (proposed at paragraph (c)(5)(v)) related to contract terms for separate payment terms;
- finalizing, at new § 438.6(c)(5)(v), a requirement for submission of minimum contract documentation for an SDP to CMS no later than 120 days after the SDP start date but not the proposal for submission within 120 days of CMS's written prior approval if that is later than the start date of the SDP; and
- finalizing § 438.7(c)(6) to require submission of rate certifications that includes an SDP no later than 120 days after the start date of the SDP but not the proposal for submission within 120 days of CMS's written prior approval if that is later than the start date of the SDP. See sections I.B.2.l. and I.B.2.m. of this final rule for further discussion of separate payment terms and rate certifications related to SDPs.

The dates when these new requirements apply to SDPs are addressed in section I.B.2.p. of this final rule.

l. Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J) and (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 proposed to redesignate the existing regulatory requirement at § 438.6(c)(2)(i) as (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 also proposed to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices. We proposed this edit because inclusion of the language “generally accepted actuarial principles and practices” is duplicative of the language included in § 438.4.

We noted in the proposed rule a concern 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) in connection with the SDP, potentially creating unnecessary State administrative burden associated with the preprint development process. However, we did not propose to change 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. As noted in the proposed rule, although we believe that an actuary must develop the capitation rates to ensure they are actuarially sound and account for all SDPs when doing so, establishment of SDPs is a State decision and States should have the flexibility to determine if they wish to involve actuaries in the development of each specific SDP arrangement. Practically, 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 will 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) that the capitation rates 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 did not propose changes to the requirements for actuarially sound capitation rates; therefore, we will retain and reaffirm here applicability of the requirements 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 did not receive any comments on the proposed redesignation of the existing regulatory requirement at § 438.6(c)(2)(i) as (c)(2)(ii)(f) and the proposed amendment 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 and to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices. After reviewing public comments and for the reasons outlined in the proposed rule and here, we are finalizing § 438.6(c)(2)(ii)(f) as proposed.

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, we have 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 rates¹⁴⁶ in alignment with the standards described in § 438.5(f), or through a “separate payment term”¹⁴⁷ 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 allotments if the State is making quarterly payments to their plans). The State then reviews the encounter data for the service(s) and provider class identified in the approved preprint for the quarter that has just ended and divides 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 negotiated provider payment rate by the managed care plan for rendered services. The State then pays the quarterly allotment to the managed care plans, separate from the capitation rate payment, and directs the plans to use that allotment for additional retroactive payments to providers for the utilization that occurred in the quarter that just ended. The State repeats 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).

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; we have 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 requested 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 the existence of the separate payment term amounts paid into account. When examined in conjunction with the capitation rates, we have 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 will 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

¹⁴⁶ 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.

¹⁴⁷ 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>.

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 proposed 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 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 CY 2020 to 55 percent of all SDPs that began in CY 2021.¹⁴⁸

In our January 2021 SMDL, we published additional guidance on SDPs, and stated our growing concern with the increased use of separate payment terms.¹⁴⁹ 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 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 will 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.

Based on data we have collected, as well as discussions with States, we understand there are several reasons why States use separate payment terms. For example, States have noted challenges with including VBP arrangements in capitation rates. They have stated 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 its managed care 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. States have noted that 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 will not ensure plans do not use this funding, or portions of this funding, for other purposes. Additionally, even with the proper tracking, States will 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 several States today, some States have noted challenges in utilizing such an approach, particularly if the SDP is targeting a narrow set of providers because it can be difficult to specifically target funding to a certain group of providers through the standard process of capitation rate development.

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 have resorted 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 discussed in section I.B.2.h. of this final rule, we have significant concerns with this practice and we are prohibiting such payment methodologies in new § 438.6(c)(2)(vii).

States also have told us 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 the State's managed care plans did not have the ability to update or modify their claims payment systems in a manner that will 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. We noted in the proposed rule that States believe there is utility in the use of separate payment terms for specific programmatic or policy goals. Although we acknowledged in the proposed rule that separate payment terms are one tool

¹⁴⁸ Our internal analysis examines trends based upon when a payment arrangement began. Since States have different rating periods, this can refer to different timeframes for different States. For example, payment arrangements that began in CY 2020 will 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.

¹⁴⁹ <https://www.medicare.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf>.

for States to be able to make targeted investments in response to acute concerns around access to care, 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 proposed establishing regulatory requirements regarding the use of separate payment terms to fulfill our obligations for fiscal and programmatic oversight. Currently, we consider separate payment terms to be payment to the plan for services covered under the contract with the managed care plan that is subject to 1903(m)(2)(A) requirements 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 separate payment terms have an impact on the assessment of actuarial soundness and certification of capitation rates. Based on this, we proposed to regulate them under 1903(m)(2)(A) authority. Section 1903(m)(2)(A) of the Act is limited to MCOs so CMS is, consistent with well-established practice and policy, extending the same requirements to PIHPs and PAHPs using section 1902(a)(4) authority to adopt methods of administration for the proper and efficient operation of the State Medicaid plan. 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

We proposed 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).

We recognize 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 use of a separate payment term. To be clear, CMS does not consider this practice to be an adjustment to base rates or part of capitation rate development; instead it meets the proposed definition of a separate payment term and we stated in the proposed rule that arrangements like this would have had to comply with all proposed requirements for using separate payment terms for an SDP in the proposed revisions to § 438.6(c)(6).

We proposed a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms. We proposed a new § 438.6(c)(6)(i) to require that all separate payment terms to be reviewed and approved as part of the SDP review process 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 proposed requirement would have codified this operational practice. We believed when developing the proposed rule that 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 believed this would also enable us to track of the use of separate payment terms more quickly and accurately.

Because we proposed to require that separate payment terms would be 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 believed we should explicitly address those SDPs that do not require written prior approval to ensure clarity for States. Therefore, we proposed 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). Under this proposal, such payment arrangements would have been required to 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 proposed 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. We believed that 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 have facilitated monitoring and oversight and helped to 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 proposed 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 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 through a 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.¹⁵⁰ This proposed requirement would have strengthened this practice by requiring that the amount included in both the rate certification(s) and contract(s) for each separate payment term could not exceed the amount documented in the approved SDP preprint. 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 emphasized in the proposed rule 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 believed that a regulation prohibiting States from exceeding the total dollars for the separate payment term identified in the State directed payment documentation would be appropriate and important.

We also described in the proposed rule an alternative that would require 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 have acted as both a minimum and a maximum; the State's contract and rate certifications would have had to include exactly the total dollar amount identified in the SDP approved by CMS. We did not propose this alternative because of a concern 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 solicited comments on both our

proposal to require that the total dollars documented in the SDP approved by CMS under (c)(2) would have acted 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 were 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 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. We believed 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, 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. We believe that this lack of risk for the plan 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 provided the following examples in the proposed rule.

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 will 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 will 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 rate setting. 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, FFS, 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 described in Example 2 above, we proposed to require as part of § 438.6(c)(6)(v) that States 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 believed requiring States to document the separate payment term within these timeframes would be 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. Under this proposal, CMS would not require a final signed copy of the amendment within this proposed 120-day timeframe; however, consistent with current regulations and practice, States would still be required to submit a final signed contract action prior to CMS's approval of the managed care contract.

To further the fiscal and programmatic integrity of separate payment terms, we proposed 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 was first

¹⁵⁰ As noted in section I.B.2.f. of this final 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 SMDL #21-001 published on January 8, 2021. We proposed to codify this requirement in § 438.6(c)(2)(ii)(I).

approved by CMS as an amendment to the approved State directed payment. We recognized that a change in payment methodology could 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, we proposed to require that CMS approve the amendment to the preprint before the separate payment term could be amended. This proposal was also intended to ensure that some level of risk is maintained, and that States do not retroactively add additional funding to the managed care capitation rates with the goal of removing all risk from the SDP arrangement. Such actions do not align with the fundamental principles of risk-based managed care or Medicaid managed care rate setting.

We also discussed an alternative 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 was no change in the non-Federal portion of the total aggregate dollars. This alternative would account for how the Federal portion of the total aggregate dollars may fluctuate due to Federal statute changes that are outside the State's control. We acknowledged that due to this, the total dollars, which includes the Federal share, could not be perfectly predicted by States at the start of a State's rating period. We did not propose this alternative proposal out of concern that it could have negative unintended consequences but solicited comment on both the exception we proposed and the alternative exception that we considered.

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 proposed 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 required 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 the proposals discussed above that would require States to document separate payment terms in their managed care rate certifications, we also proposed changes to § 438.7. Specifically, we proposed to add a new § 438.7(f) requiring 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 proposed 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 would provide a complete picture of all payments made by States to plans under risk contracts.

We also proposed 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 proposed that the State could 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 did 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 proposed 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.¹⁵¹ Understanding the estimated impact of the separate payment term on a rate cell basis has been helpful for assessing the actuarial soundness of the capitation rates. In § 438.7(f)(3), we proposed that no later than 12 months following the end of the rating period, the State would have to submit documentation to CMS that included 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

¹⁵¹ 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>.

approval to facilitate oversight and monitoring of the separate payment term.

Finally, we proposed 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 was aligned with the proposed contract requirement in § 438.6(c)(6)(v).

As previously noted, we stated that we preferred 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 and the proposed addition of §§ 438.6(c)(6) and 438.7(f) were 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, we invited comment on requiring all SDPs to be included only through risk-based adjustments to capitation rates and eliminating the State's ability to use separate payment terms altogether in the final rule based on comments received. We indicated in the proposed rule that we were considering prohibiting the use of separate payment terms to align with CMS's stated preference and greater consistency with the nature of risk-based managed care.

Another alternative we outlined, and invited comment on, was prohibiting the use of separate payment terms for SDPs described in paragraph (c)(1)(iii). Under this alternative, States would only be able to use separate payment terms for VBP initiatives described in paragraphs (c)(1)(i) and (ii). This alternative would still have allowed States to use separate payment terms for some payment arrangements and could have incentivized States to consider quality-based payment models that could better improve health outcomes for Medicaid managed care enrollees. We believed this alternative could address the difficulties States and their actuaries potentially face when incorporating some VBP initiatives into capitation rate development as compared to fee schedules as described in paragraph (c)(1)(iii).

For each of these two alternatives, we acknowledged that many States currently use separate payment terms and that finalizing either alternative to prohibit the use of separate payment terms for SDPs could cause some disruptions. CMS therefore sought

public comment on whether or not we should consider a transition period in order to mitigate any disruptions.

We solicited public comment on our proposals.

We summarize and respond to public comments received on whether either of these alternative approaches we are considering should be adopted in the final rule, below.

Comment: We received a wide array of comments on our proposals in §§ 438.6(c)(6) and 438.7(f) on the use of separate payment terms, as well as on our discussion in the proposed rule preamble regarding whether to eliminate the use of them. We did not receive any comments on § 438.6(c)(2)(ii)(f). Many commenters supported our proposal to codify States' ability to implement SDPs using separate payment terms in regulation to formally recognize what has been an operational flexibility to date. Most of these commenters did not support our specific proposals in § 438.6(c)(6) to require that the total amount of each separate payment terms be documented in the SDP preprint and managed care plan contract and to prohibit exceeding the approved amount without obtaining approval of an SDP amendment. These commenters stated that States should not be hampered from using separate payment terms as they provide greater transparency, ensure that payments flow to providers as intended, minimize administrative burden for States, and make it easier for States to track SDPs. Some commenters noted that separate payment terms are a useful tool for targeting investments in response to acute concerns around access to care. A few commenters supported finalizing some of the proposed guardrails as they could mitigate risks associated with the use of separate payment terms.

Conversely, other commenters agreed with CMS that SDPs are best implemented through adjustments to base capitation rates. These commenters noted that accounting for SDPs through adjustments to base capitation rates is consistent with the transfer of risk to managed care plans for all of their contractual obligations. These commenters encouraged CMS to eliminate or at least limit the use of separate payment terms to enable managed care plans to fulfill their contractual obligations, including SDPs, using the actuarially sound capitation payments provided by the State. These commenters noted that CMS would need to consider giving States and their actuaries time to transition; one commenter suggested that if CMS eliminated separate payment terms a transition period of 3 years should be

provided for States to accommodate necessary changes.

Response: We stated our concern regarding the appropriateness of separate payment terms in risk-based managed care programs and proposed a list of seven new requirements in regulation that we believed when developing the proposed rule could assert a measure of control on an increasingly problematic practice (see 88 FR 28144 through 28146). The comments in support of the continued use of separate payment terms with none of the guardrails proposed in § 438.6(c)(6) added to our concern that some States are increasingly relying on this payment mechanism to circumvent risk-based payment to managed care plans. More specifically, it is a way to circumvent compliance with the requirement that SDPs be developed in accordance with § 438.4, and the standards specified in §§ 438.5, 438.7, 438.8, and generally accepted actuarial principles and practices. Since being finalized in 2016, § 438.6(c)(2)(i) has required that all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of that section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices; as explained earlier in this section, we are finalizing a revision to this standard in new paragraph (c)(2)(ii)(f). However, after reviewing public comments, we are concerned that the proposed parameters do not adequately address how the use of separate payment terms for SDPs erodes the risk-based nature of payment to managed care plans and fiscal integrity in Medicaid managed care.

We originally permitted the use of separate payment terms to provide flexibility to States as they adjusted to using SDPs. We expected States to transition over time to including all SDPs in capitation rates in a risk-based manner and outlined our concerns with the use of separate terms in guidance published in 2021.¹⁵² Public comments on our proposals in § 438.6(c)(6) reflect that some States believe they need to use separate payment terms to have transparency, accuracy, and administrative simplicity. However, we are concerned that the use of separate payment terms for SDPs erodes the risk-based nature of payment to managed care plans and fiscal integrity in Medicaid managed care. These separate payment terms are separate funding streams for services covered under the

contract over which plans have no control and for which they bear no risk. As we noted in the proposed rule, we have found that amounts included in separate payment terms can represent a significant portion of the total payment made under the Medicaid managed care contract. 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. These payments are commonly made separate and apart from capitation rates. Commentors reaffirmed that separate payment terms are developed by the State rather than the State's actuaries, and the reasonableness of the amount of the separate payment term is not generally certified by States' actuaries (See 88 FR 28145 for further details). Separate payment terms are commonly paid in allotments divorced from a per member per month basis. The nature of separate payment terms makes assessing the total payments made by the State to the plan on a prospective basis more difficult and severely hampers CMS's ability to ensure the capitation rates are actuarially sound.

As noted in the proposed rule and reaffirmed by commentors, the total dollar amount of separate payment terms is not informed by an analysis of what constitutes actuarially sound Medicaid managed care capitation rates, or what constitutes reasonable, appropriate and attainable costs in Medicaid managed care payment. In our experience, the amounts paid over the course of the year change from month to month or quarter to quarter. These changes in the payments to providers are again driven not by furthering particular goals and objectives identified in the State's managed care quality strategy, but rather by the specific dollar amount dedicated to the payment arrangement.

Robust encounter data reporting requirements in § 438.242, including paragraph (c)(3) requiring reporting of the allowed and paid amounts, should provide sufficient transparency to validate accurate payment to providers. We remind States that the encounter data reporting requirements in § 438.242(c)(2) specifically require managed care plan contracts to 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. Should States determine that standardized encounter data formats do not provide sufficient detail to validate accurate payments as specified in an approved SDP, States should identify additional levels of required detail and

¹⁵² <https://www.medicaid.gov/sites/default/files/2021-12/smd21001.pdf>.

reporting from plans in their managed care plan contracts.

After reviewing public comments on proposed § 438.6(c)(6), our concerns persist, and we are not persuaded that codifying separate payment terms as a permissible option for SDPs, even with the additional fiscal integrity guardrails proposed, aligns with the regulatory objectives of SDPs or the overall structure of risk-based managed care.

Therefore, we are not finalizing § 438.6(c)(6) as proposed and will instead, as we invited comments on, adopt a new provision at paragraph (c)(6) requiring that all SDPs be incorporated into Medicaid managed care capitation rates as adjustments to base capitation rates and prohibiting the use of separate payment terms. In § 438.6(c)(8)(iv), we establish that this new prohibition is applicable beginning with the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after July 9, 2024, which will provide three rating periods for States to transition from use of separate payment terms. The heading for new paragraph (c)(6) is “Payment to MCOs, PIHPs, and PAHPs for State Directed Payments” and the finalized regulatory text requires that the final capitation rates for each MCO, PIHP, or PAHP as described in § 438.3(c) must account for all SDPs and that each SDP must be accounted for in the base data, as an adjustment to trend, or as an adjustment as specified in §§ 438.5 and 438.7(b). The final rule regulatory text also prohibits the State from either withholding a portion of the capitation rate to pay the MCO, PIHP, or PAHP separately for a State directed payment, or requiring an MCO, PIHP, or PAHP to retain a portion of the capitation rate separately to fulfill the contractual requirement of a State directed payment. Consistent with this final policy, we will also not finalize the proposed rate certification requirements for separate payment terms in § 438.7(f) nor the definition of “separate payment term” at § 438.6(a).

Comment: Some commenters noted that separate payment terms are effective at removing financial incentives for managed care plans to steer utilization away from specific services and deny coverage of services by providers that receive SDPs.

Response: We do not believe that separate payment terms are necessary or appropriate as a tool to address such concerns. States are required to ensure adequate mechanisms are in place to monitor their managed care programs, including actual spending and utilization patterns, generally and after implementation of an SDP for accurate

execution, as well as to prevent unintended consequences. States have identified multiple ways to address this without the use of a separate payment term. For example, States can implement payment arrangements that link payments to provider performance instead of utilization. This approach has been effective at lessening any financial incentives for inappropriate steering by managed care plans. Other examples include States using tiered payment structures, requiring plans to include all the providers in a particular provider class as network providers, or using risk mitigation strategies consistent with the requirements in § 438.6(b)(1). Under this final rule, States are also now permitted to recoup unspent SDP funds from plans as long as the recoupment methodology, recoupment process and any other necessary details for recoupment are detailed in the SDP preprint and the contract documentation required in § 438.6(c)(5); previously States were only permitted to recoup funds for certain types of SDP arrangements. We are available to provide States with technical assistance on ways to address this issue, with or without the use of SDPs.

Comment: Some commenters noted concerns with incorporating SDPs through adjustments to base rates. These comments noted that while Medicaid program changes are included in the rate setting process at the rate cell level, rates are not currently adjusted at the provider level for SDPs.

Response: We noted in the proposed rule preamble that more than half of current SDPs are incorporated into managed care rate development as adjustments to base rates. This indicates that States are able to make adjustments at the provider level as part of capitation rate development as appropriate. Further, States are required to use validated encounter data as base data for rate development among other sources of data per § 438.5(c) and encounter data contains provider level information. At § 438.242(c)(3), States must require via their managed care contracts that MCOs, PIHPs and PAHPs submit all enrollee encounter data, including allowed amount and paid amount. This information should allow States to account for the impact of SDPs in actuarially sound capitation rates. To evaluate the effectiveness of SDPs, States must be able to ensure that the payment arrangement is being implemented as intended by monitoring payments at the provider level. This aligns with other provisions finalized in this rule—such as monitoring the payment analysis required in § 438.207(b)(3) and requiring provider

level reporting of actual SDP expenditures through T-MSIS. We also are finalizing a requirement at § 438.6(c)(5)(iv) that the MCO, PIHP or PAHP contracts must include any encounter data reporting and separate reporting requirements necessary for auditing the SDP in addition to the reporting requirements in § 438.6(c)(4).

Comment: Several commenters that supported the use of separate payment terms for SDPs stated that CMS’s concerns about separate payment terms removing risk from managed care plans for SDP expenditures are inconsistent with the original purpose for SDPs; that is, to provide an exception and permit States to direct payment. These commenters stated that the text of § 438.6(c)(1) “Except as specified in this paragraph (c), . . .” explicitly condones exceptions to risk-based Medicaid managed care.

Response: We disagree with this interpretation of the regulatory text and this misinterpretation further highlights the need to eliminate the use of separate payment terms in SDPs. SDPs are an exception to the prohibition on States paying for or specifying payment rates for providers in a risk-based managed care system and were never intended to be an exception to the risk-based payment requirements. The exception to the prohibition on State payment or direction of payment by the plan to providers is an effort to balance our belief about the level of discretion managed care plans need to manage risk for their populations with the unique policy goals and interests of States.

Currently, § 438.6(c)(2) explicitly requires, “All contract arrangements that direct the MCO’s, PIHP’s, or PAHP’s expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.” This requirement is retained in this final rule in § 438.6(c)(2)(ii)(J) for all SDPs specified in § 438.6(c)(1)(i) through (iii), with a revision to remove compliance with “generally accepted actuarial principles and practices” and to add the standards specified in §§ 438.7 and 438.8; these changes are discussed earlier in section I.B.2.1. of this final rule. As noted in earlier responses and in the preamble to the proposed rule, we have historically required States to account for separate payment terms in rate certifications because they can have a significant impact on the assessment of actuarial soundness of the capitation rates. As we noted, in some cases, the provider payment rates assumed in 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. As specified at § 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 MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract. This requirement includes all SDPs included in a risk-based contract.

Comment: Other commenters noted that safety-net providers would be at particular risk if CMS prohibited States' from using separate payment terms for SDPs. One commenter stated that safety-net providers are often not in a position to negotiate rates and are forced to accept whatever payment a managed care plan deems appropriate, which can result in these providers being at risk more than the managed care plan.

Response: We appreciate commenters raising this concern. As noted in the proposed rule, we recognize that some providers that serve a higher share of Medicaid enrollees, such as safety net hospitals and rural hospitals, tend to have less market power to negotiate higher rates with commercial plans (88 FR 28125). We recognize that SDPs can be used effectively to further the State's overall Medicaid program goals and objectives, which can include increased access to care. However, we disagree with commenters that using separate payment terms is necessary for States to accomplish such goals. States have significant flexibility in designing SDPs under this final rule, including determining the provider class. We have approved SDPs that defined provider classes based on payer case mix or solely focused on safety net providers, including VBP initiative arrangements that are targeted to safety net providers and reward them based on performance on quality metrics. All of these options can be implemented without the use of a separate payment term.

Comment: Many commenters noted that eliminating separate payment terms would be a notable departure from current practice as CMS has been approving SDPs with separate payment terms for 6 years. Eliminating separate payment terms, according to commenters, could cause significant disruption for existing SDPs. Some commenters also suggested that limiting States' ability to use separate payment terms could threaten the viability of existing SDPs and jeopardize CMS's compliance with the statutory mandate to safeguard equal access to care.

Response: We recognize that nearly half of SDPs that we have approved use separate payment terms. We are confident that States can transition existing SDPs that use separate payment terms into adjustments to base rates, and recognize this transition will take time and that States are facing a number of competing priorities. As noted earlier, we are revising the applicability date for § 438.6(c)(6) to the first rating period that begins on or after 3 years following the effective date of the final rule. We believe that this transition period will provide States time to work with interested parties and actuaries to incorporate SDPs into capitation rates through standard rate development practices.

Further, we disagree with commenters that limiting State's ability to use separate payment terms could jeopardize compliance with the statutory requirement to safeguard equal access to care. SDPs are an optional tool that States can use to direct the expenditures of MCOs, PIHPs or PAHPs; States are not required to utilize SDPs. There are separate regulatory requirements that require States that contract with an MCO, PIHP or PAHP to deliver Medicaid services to address network adequacy and access to care regardless of the use of SDPs. For example, States must develop and enforce network adequacy standard consistent with § 438.68, ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs and PAHPs in a timely manner in compliance with § 438.206, ensure that each MCO, PIHP and PAHP gives assurances to the State and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with § 438.207. Further, the managed care capitation rates must be adequate to meet these requirements as required under § 438.4(b)(3).

Comment: Some commenters supported maintaining States' ability to use separate payment terms but opposed defining separate payment terms as a finite and predetermined amount documented in the managed care plans' contract and instead suggested only requiring States to document (1) a specific dollar amount or (2) a percentage unit price or increase in the contracts. A few commenters stated concern that requiring that SDPs incorporated into rates as separate payment terms not exceed the total dollars documented in the written prior approval for each SDP was a cap on total spending.

Response: As noted in prior responses, we are not finalizing the regulatory framework we proposed at §§ 438.6(c)(6), 438.7(f) or the definition proposed in § 438.6(a) for separate payment terms. We take this opportunity to clarify that States could use an SDP to require managed care plans to pay a specific dollar amount or a percentage increase as a uniform increase or a fixed unit price as a minimum and/or maximum fee schedule without using a separate payment term. When the uniform increase is a fixed dollar amount or a fixed percentage increase, States can use standard rate development processes to include it as an adjustment to capitation rate development; the same is true for a minimum and/or maximum fee schedule. Accounting for SDPs in the standard rate development process removes the need to reduce the payments as expenditures near the predetermined amount. Incorporating SDPs into capitation rates in every situation accounts for changes in enrollment and utilization without arbitrarily changing the amount per service paid to providers.

Comment: Some commenters noted that requiring SDPs to be included in capitation rates instead of separate payment terms puts States at greater financial risk if program enrollment is greater than projected and puts providers at risk if utilization is lower than projected. These commenters noted that they believe including SDPs in separate payment terms would help promote fiscal stability.

Response: We acknowledge that changes in utilization and program enrollment are inevitable, and States must ensure that they provide the most robust data available to their actuaries to facilitate the development of accurate capitation rates that reflect all contractual requirements for managed care plans, including any SDPs. State's actuaries are experienced in addressing unforeseen changes through the development of risk mitigation strategies, which is an appropriate mechanism for addressing uncertainty in risk-based managed care programs.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.6(c)(2)(ii)(J) as proposed, finalizing a prohibition on separate payment terms at § 438.6(c)(6) as described in this section, and are not finalizing § 438.7(f).

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

We also proposed two additional changes to § 438.7(c) to address adjustments to managed care capitation rates that are used for SDPs. (A third change to § 438.7(c) to add a new paragraph (c)(6) is addressed in section I.B.2.k. of this final rule.) Specifically, we proposed 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. We noted that proposed § 438.7(c)(5) was necessary, at minimum, to ensure 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 proposed 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. Currently, 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 that are unrelated to special contract provisions, including SDPs, and ILOS provisions. Providing this same flexibility for changes to capitation 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, we proposed to clarify the requirements for submitting rate certifications and amendments to rate certifications.

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

We solicited public comment on our proposals.

We summarize and respond to public comments received on our proposals related to including SDPs through adjustments to base capitation rates (§ 438.7(c)(4) and (5)) below.

Comment: Many commenters supported our proposals to add clarity to how SDPs are documented in rate certifications and improve alignment between §§ 438.7(b)(6) and 438.7(c). Some commenters also supported our proposal to keep the long-standing practice in § 438.7(c) that does not permit States to utilize de minimis flexibility to amend capitation rates for SDPs and expand it to include ILOSs. This commenter supported the requirement that States must always submit amendments to the rate certifications when changes are required for SDPs or ILOSs. One commenter requested that CMS consider revising its proposal at § 438.7(c)(4) as they believed the proposal would increase State administrative expenses and not result in improved oversight.

Response: We appreciate the support and agree that these provisions will support program integrity and our contract and rate certification reviews by requiring additional specificity for any changes in the capitation rate per rate cell, regardless of the size of the change. We disagree with the commenter that the requirement for States to submit a revised rate certification for any changes in the capitation rate per rate cell for special contract terms (described in § 438.6, which includes SDPs) and ILOS provisions (described in § 438.3(e)(2)) would not improve oversight. This new provision will ensure consistency with the existing regulatory requirement at § 438.7(b)(6) which requires a description of any of the special contract provisions related to payment in § 438.6 that are applied to the contract, as well as ensure that we are aware of changes being made to each SDP's impact on capitation rates. Additionally, this level of detail

facilitates robust review of rate certifications by ensuring specificity on any capitation rate changes. We acknowledge, as pointed out by the commenter that this provision could increase State administrative burden if a revised rate certification is solely done for a change to an SDP or ILOS arrangement and not for other programmatic purposes; as a result, we have revised the associated Collection of Information for § 438.7 Rate Certifications (see section II.B.4. of this final rule for further details) to address this burden. However, the increased burden is outweighed by the benefits from additional program oversight afforded by submission of amended rate certifications when an SDP or ILOS results in changes to the capitation rate payable to the Medicaid managed care plan. Even relatively small changes in SDPs and ILOS, both areas of growing interest and State uptake, can have notable fiscal impacts and depending on the nature of the change, may also trigger an associated SDP and contract amendment that CMS would not know to request, absent a required rate certification action.

Comment: Some commenters supported our proposal at § 438.7(c)(5) to limit the retroactive adjustments that can be made to capitation rates resulting from an SDP where these adjustments 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. Other commenters opposed limitations on retroactive adjustments that can be made to capitation rates resulting from an SDP, stating that there are circumstances not related to a material error when retroactive adjustments to capitation rates are appropriate. The commenters offered the example of the COVID-19 PHE, when the actuarial assumptions used to develop rates were uncertain and necessitated continual monitoring and adjusting noting that this uncertainty is likely to continue through the "unwinding" of the continuous coverage requirement. Commenters further noted that it is possible for there to be significant disparities between the amounts paid by States to managed care plans for SDP arrangements and the amounts subsequently paid by the managed care plans to providers. Without sufficient oversight and the ability to adjust capitation rates as

needed, the commenters noted that managed care plans could be incentivized to steer utilization away from the providers receiving SDPs. The commenters noted that retroactive adjustments are an effective tool to mitigate this risk by ensuring that managed care plans cannot benefit financially from such behavior.

Response: We appreciate the range of comments on our proposal to limit retroactive adjustments to capitation rates for an SDP. SDPs are utilized in a risk-based contract; therefore, capitation rate development must be developed in a risk-based manner. While we recognize the challenges States face in developing capitation rates impacted by the COVID-19 PHE, we believe that the uncertainty faced by actuaries and States was not specific to SDPs but applied across all aspects of rate development. For this reason, we recommended that States implement risk-sharing arrangements such as 2-sided risk corridors in response to the uncertainty. Risk corridors that comply with the regulatory requirements in § 438.6 are an effective tool in mitigating risk from uncertainty and can be used by States during this period of unwinding, as well as in other instances. We remind States that, in accordance with § 438.6(b)(1), risk sharing mechanisms may not be added or modified after the start of the rating period. Regardless of unique circumstances such as PHEs, we believe that SDPs should be accounted for in rate certifications and that retroactive adjustments 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 are necessary to correct an error. We remind States that they are required to return to CMS the Federal government's share of any remittance a State collects, taking into account the applicable Federal matching rate. See for example, § 437.74(b). We also remind States that they have an ongoing responsibility to monitor all aspects of managed care programs as required in § 438.66, including contract requirements such as SDPs (see § 438.66(b)(14)). States must ensure that managed care plans are operationalizing SDPs consistent with approved Medicaid preprints, when written approval of a preprint is required, and consistent with Federal requirements in 42 CFR part 438. This State monitoring should also take into consideration as appropriate any provider and enrollee complaints or concerns related to

inappropriate plan actions, including those that constitute efforts to steer utilization away from the providers receiving SDPs. State oversight of the implementation of SDP contractual obligations by plans is critical to ensuring not only fiscal integrity, but that the SDP furthers the State's goals and objectives of the SDP identified by the State.

Comment: One commenter appreciated the additional clarity that CMS provides regarding actuarial certification standards but encouraged CMS to maintain sufficient flexibility in the rules to allow each State to work with CMS through the SDP approval process in meeting SDP requirements and for managed care plans to retain flexibility to design and enter incentive payments with providers in accordance with their own private negotiations.

Response: We appreciate the commenters' support for the clarification regarding actuarial certification standards in §§ 438.7(c)(4) through (6). We take this opportunity to clarify that the regulations at §§ 438.6(c) and 438.7(c)(4) through (6) are for SDPs; that is, contract requirements whereby the State directs a managed care plan's expenditures. Provider incentive payments that a plan and provider negotiate without State direction or involvement are not SDPs. For further discussion on provider incentive payments, refer to section I.B.3.a. of this final rule.

Comment: One commenter stated that requiring SDP funds to be built into managed care plans' capitation rates would reduce transparency and create opportunities for managed care plans to leverage funds meant for providers to advance quality outcomes.

Response: Since SDPs were codified in the 2016 final rule, we have consistently stated that they were to be built into the capitation rates as 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(s) covered under the terms of the contract. Although we have historically permitted flexibility through the use of separate payment terms for SDPs, as outlined in the proposed rule (88 FR 28144–28148), we have consistently raised concerns about the use of separate payment terms given the construct of a risk-based contract. As further noted in section I.B.2.l. of this final rule, we are not finalizing § 438.6(c)(6) as proposed but will instead phase out the use of separate payment terms and require that all SDPs

be included in base capitation rates no later than the first rating period beginning on or after three years following the effective date of this rule. State directed payments are part of risk-based managed care contract and as such, must be built into capitation rates. The regulations adopted in this final rule are clear on that. In addition, we are finalizing other provisions (such as § 438.6(c)(5) requiring specific documentation requirements in managed care plan contracts for SDPs) that will improve the accuracy of how SDPs are implemented. Lastly, we now publish approved SDP preprints on Medicaid.gov to improve transparency. Together, these provisions will ensure more accurate and timelier implementation of SDPs while ensuring appropriate levels of oversight by CMS.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.7(c)(4) and (5) as proposed. We are finalizing § 438.7(c)(6) with revisions as described further in section I.B.2.k. of this final rule.

n. Appeals (§ 430.3(e))

As outlined under § 438.6(c), SDPs are arrangements that allow States to require managed care plans to make specified payments to health care 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 that 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 complies, we issue written prior approval. Subsequent to written prior approval, the SDP is permitted to be included in the relevant managed care plan contract and rate certification documents. This process is required by CMS for most SDPs.

As discussed throughout this final rule, the volume of State requests for written prior 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 issued 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, financing, 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, typically when CMS and States have found themselves unable to reach agreement on SDP proposals and we have been 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. We believe it is appropriate to establish a process for formally disapproving proposals that do not comply with the Medicaid requirements and regulations. Accordingly, this final rule will strengthen the SDP process, as well as further specify the requirements for SDPs under our regulations.

A disapproval of 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 that issue formal disapprovals, such as those for State plan amendment submissions and disallowances of State Medicaid claims, there should be a formal process for States to appeal CMS's disapproval of 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 States. We believe that States will

benefit from an established, efficient administrative process with which they are familiar. However, nothing in this final rule precludes any State from seeking redress in the courts.

Under our authority under section 1902(a)(4) of the Act to establish methods for proper and effective operations in Medicaid, we proposed 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) Departmental 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 and conducts *de novo* (from the beginning) 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 as 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, after a State receives a final written decision from CMS communicating its disapproval of that State's SDP preprint, the State would have 30 days to file a notice of appeal with the Board. (45 CFR 16.7(a)). The case would then be assigned a presiding Board member who would conduct the conference or hearing if one is held. (45 CFR 16.5). Within 10 days of receiving the notice of appeal, the Board would acknowledge the notice and outline the next steps in the case. (45 CFR 16.7(b)). Under existing 45 CFR 16.16, the Board may 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 arguments for why CMS's final decision was in error, and its appeal file, which would include the documents on which its arguments are based. (45 CFR 16.8(a)). Then, CMS would have 30 days to submit its brief in response as well as any additional supporting documentation not already contained in the record. (45 CFR 16.8(b)). The State would be given fifteen days to submit an optional reply. (45 CFR 16.8(c)). The Board may extend any given deadline, but only if the party provides "a good reason" for an extension. (45 CFR 16.15(a); *Id*) (noting that "the Board has the flexibility to

modify procedures to ensure fairness, to avoid delay, and to accommodate the peculiar needs of a given case").

Under the Board's process, parties would be encouraged to work cooperatively to develop a joint appeal file and stipulate to facts, reducing the need to separately submit documentation. (45 CFR 16.8(d)). 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 16 and 45 CFR 16.4 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* (of one's accord; voluntarily), should it determine that its decision-making would be enhanced by such proceedings. (45 CFR 16.11(a)). Generally, Board's proceedings are conducted by videoconference, or in person in Washington, DC, but may be held in an HHS Regional Office or "other convenient facility near the appellant." 45 CFR 16.11(c)). The Board's decisions are issued by the Board in three-member panels. (45 CFR 16.5(a)). Under 45 CFR 16.23, the paramount concern of the Board is to take the time needed to review a record fairly and adequately to produce a sound decision. Under 45 CFR 16.18, the Board, in consultation with the parties, may suggest use of mediation or other alternative dispute resolution services to resolve the dispute between the parties or clarify issues.

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**. (42 CFR 430.70). The hearing will 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. (42 CFR 430.72). Before the hearing, issues may be added, removed, or modified, to also be published in the **Federal Register** and with 20 days' notice to the State before the hearing, unless all issues have been resolved, in which case the hearing is terminated. (42 CFR 430.74).

Under this process, the State and CMS will be given 15 days to provide comment and information regarding the removal of an issue. (42 CFR 430.74(c)). Before the hearing, other individuals or groups will be able to petition to join the matter as a party within 15 days after notice is posted in the **Federal Register**. (42 CFR 430.76). The State and CMS will be able to file comments on these petitions within five days from receipt. *Id.* The presiding officer will determine whether to recognize additional parties. *Id.* Alternatively, any person or organization will be able to file an *amicus curia* (friend of the court) as a non-party, should the presiding officer grant their petition. *Id.* The parties will have the right to conduct discovery before the hearing to the extent set forth under § 430.86 and to participate in prehearing conferences consistent with § 430.83.

At the hearing, parties would make opening statements, submit evidence, present, and cross-examine witnesses, and present oral arguments.¹⁵³ The transcript of the hearing along with stipulations, briefs, and memoranda will be filed with CMS and may be inspected and copied in the office of the CMS Docket Clerk. (42 CFR 430.94). After the expiration of the period for post hearing brief, the presiding officer will certify the record and recommendation to the Administrator. (42 CFR 430.102(b)(1)). The Administrator will serve a copy to the parties who have 20 days to file exceptions or support to the recommendation. (42 CFR 430.102(b)(1)–(2)). The Administrator will then issue its final decision within 60 days. (42 CFR 430.102(b)(3)). 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. (42 CFR 430.102(c)). Should the Administrator preside

directly, they will issue a decision within 60 days after expiration of the period for submission of post hearing briefs. (42 CFR 430.102(a)).

We believe the Board will 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 will 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 procedural 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 will be adequate for appeals of any disapproval of a State directed payment, for the reasons described above, we believe the processes under the Board will be the most appropriate proposal for inclusion in § 430.3(d).

We solicited public comments on whether the Board or OHI appeals processes will best serve the purposes of resolving disputes fairly and efficiently. We summarize and respond to public comments received on Appeals (§ 430.3(d)) below.

Comment: A few commenters supported our proposal at § 430.3(d) to use the HHS Departmental Appeals Board for the administrative appeals process and agreed that having a formal process is appropriate given that written prior approval is required for most SDPs.

Response: We agree that the Board is the most appropriate entity to adjudicate an agency appeal process for denial of written prior approval for SDPs. We believe that States will benefit from and appreciate an established, consistent administrative process with which they are familiar. We are finalizing § 430.3(d) as proposed, however, we are redesignating as § 430.3(e) to reflect new § 430.3(d) in the interim final rule *Enforcement of State Compliance with Reporting and Federal Medicaid Renewal Requirements under the Social Security Act* (88 FR 84733) published December 2023.¹⁵⁴

Comment: Many commenters stated concern that establishing an administrative appeals process for denials of written prior approval of an SDP would deny a potential appellant access to the courts. Some commenters stated that the courts would be the preferred venue for appeals of SDP denials based on statutes outside of the parameters of § 438.6(c) (for example, financing issues governed by the statute).

Response: The administrative process finalized at § 430.3(e) is at the option of the appellant, and States may seek redress in the courts at any time (88 FR 28150). It was never our intent to imply that use of an administrative appeals process was a barrier or deterrent for States electing to utilize the courts. As we stated in the proposed rule, we believe that an administrative appeals process is a timelier and more cost-effective path to resolution than the court system. Nothing in this final rule precludes any party from seeking redress in the courts. To the comment on appeals of SDP denials based on statutes outside of the parameters of § 438.6(c), the Board has sufficient legal authority and expertise to adjudicate appeals regardless of their statutory basis. However, as we clarify above, States always have the option to utilize the courts if they prefer.

Comment: Some commenters supported the use of an administrative process but stated concern at the timeliness of decisions and the effect on the SDP's use during a specific rating period. Some commenters stated that the CMS OHI would be a more expeditious decisionmaker in practice, despite the Board's faster timelines in regulation. Some commenters stated that both bodies were frequently backlogged rendering them ineffective for issues such as SDPs and recommended that an expedited appeal process be codified. One commenter noted OHI's ability to waive hearings as an efficiency that could be useful for SDP appeals. Another commenter stated concern that the amicus mechanism of the Board would slow their process.

Response: We share the commenters' goal of an expeditious process for the benefit of all parties. We are confident that the Board has the capacity to effectively adjudicate appeals of SDP disapproval by CMS. We do not have concerns that the amicus mechanism of the Board will prove a hindrance as it is an existing part of their processes, and the option exists in the courts and OHI as well. Regardless, we do not believe that utilization of the courts would produce a faster resolution. To the suggestion that OHI would provide

¹⁵³ 42 CFR 430.83.

¹⁵⁴ 45 CFR part 16 (Notice of Proposed Rulemaking—CMS—2447—IFC).

faster resolution because of their ability to waive hearings as an efficiency, we note that under 45 CFR part 16, the Board does not automatically schedule a hearing, but rather “only if the Board determines that there are complex issues or material facts in dispute, or that the Board’s review would otherwise be significantly enhanced by a hearing.”

Comment: Some commenters supported using OHI as opposed to the Board for subject matter expertise. Some of these commenters stated that OHI’s expertise in SPAs was more akin to SDPs and thus, the more appropriate venue.

Response: We acknowledge that OHI could also be an appropriate venue for SDP appeals; however, we do not agree that their expertise in SPAs makes them more competent than the Board to hear an appeal of disapproval by CMS of an SDP. On balance, we believe the Board’s shorter goal resolution time 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 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 (88 FR 28151).

Comment: One commenter objected to codification of any appeals process for SDP program approvals because, unlike the State plan amendment process or other administrative actions subject to appeals processes, SDPs are merely providing direction to MCOs under an existing, approved authority.

Response: We do not agree that SDPs are not appropriate for an administrative appeals process. As stated in the proposed rule, there is an administrative process for SDPs under § 438.6(c), which includes review and, when appropriate, issuance of written approval prior to the SDP being included in the corresponding managed care plan contract and rate certification (88 FR 28149). As such, we believe the issuing of a disapproval by CMS of SDPs is an administrative action suitably addressed through an administrative appeals process when requested.

Comment: Some commenters stated concern with the remedy should an appellant prevail in an appeal of an SDP disapproval. The commenter stated that

Medicaid managed care is a prospective payment system and if the contract year ends and the appeal is not resolved, clarity is needed on whether the SDP will only be approved going forward or if it could be approved retroactively. Another commenter echoed the same comment but emphasized that this concern is particularly acute in performance-based payments. One commenter requested that the remedies available be made explicit in regulation.

Response: The Board has broad discretion in the appropriate remedy should an appellant prevail in its appeal, and we do not intend for this regulation to either limit or broaden the Board’s powers. For example, the Board could opt to issue a remedy to permit the State to implement the SDP retroactive to the arrangement start date proposed by the State in the initial SDP preprint submission. Generally, we share commenters’ concerns that any issue should be resolved in a timely fashion. We note that these concerns exist now under our existing informal resolution process, but we believe that an administrative process will provide cost and time efficiencies for all parties as an alternative venue. Nothing in this final rule precludes any party from seeking redress in the courts.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, at § 430.3, we are redesignating paragraph (d) as paragraph (e) and finalizing as proposed.

o. Reporting Requirements To Support Oversight and Inclusion of SDPs in MLR Reporting (§§ 438.6(c)(4), and 438.8(e)(2)(iii)(C) and (f)((2)(vii))

States’ increasing use of SDPs has been cited as a key area of oversight risk for CMS. Oversight bodies and other interested parties, including GAO and MACPAC, have issued reports recommending that we collect and make available provider-specific information about Medicaid payments to providers, including SDPs.¹⁵⁵ 156 157 158

¹⁵⁵ 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>.

¹⁵⁶ 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>.

¹⁵⁷ 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>.

As discussed in this final rule, CMS’s 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 SDPs¹⁵⁹ nor do we review the actual amounts that managed care plans pay providers. 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, to what extent actual expenditures differ from the estimated dollar amounts identified by States in the approved preprint by CMS, and whether Federal funds are at risk for impermissible or inappropriate payment.

We proposed 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.”¹⁶⁰ 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 will support CMS oversight activities to better understand

¹⁵⁸ U.S. Government Accountability Office, “Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency,” December 14, 2023, available at <https://www.gao.gov/products/gao-24-106202>.

¹⁵⁹ Because CMS does not routinely perform retrospective review of SDPs, the Medicaid Managed Care Rate Development Guide requires States using separate payment terms to (1) submit documentation to CMS that 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. As part of this final rule, CMS is finalizing a prohibition on separate payment terms, see § 438.6(c)(6) and section I.B.2.1. of this final rule for further details.

¹⁶⁰ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf>.

provider-based payments across delivery systems.

To address the need for additional information on the actual amounts paid as SDPs, we proposed to require Medicaid managed care plans to include SDPs and associated revenue as separate lines in the 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; the proposed rule specified these requirements by proposing to amend § 438.8(k) to ensure that Medicaid SDPs will be separately identified in annual MLR reporting.

Specifically, at § 438.8(e)(2)(iii)(C), we proposed 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 proposed 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 proposed 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. We sought comment on this proposal.

We also proposed 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) would require 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) would require reporting of Medicaid managed care plan revenue from the State to make these payments. We proposed, 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 sought public comment on this proposal.

For separate CHIPs, we did 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 proposed to amend § 457.1203(f) to exclude any references to SDPs for managed care plan MLR reporting. For clarity, we also proposed 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, we proposed that 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 proposed to require two additional line items. The first item at § 438.74(a)(3)(i) would require 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) would require State reporting of the amount of payments, including amounts in the capitation payments, that the State makes to Medicaid MCOs, PIHPs, or PAHPs for approved SDPs under § 438.6(c). We proposed, 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 believed this was 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 sought public comment on this proposal.

We did not propose to adopt the new SDP reporting requirements at § 438.74 for separate CHIPs 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 proposed

to amend § 457.1203(e) to exclude any references to SDPs in State MLR reporting.

While we expected that some managed care plans and States may oppose these proposals as increasing administrative burden, we believed 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 will support CMS's understanding of provider-based payment across delivery systems.

We also proposed 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's 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."¹⁶¹ 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.¹⁶² 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 will facilitate our understanding of provider-level Medicaid reimbursement across delivery systems.

We proposed to develop and provide the form through which the reporting

¹⁶¹ 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>.

¹⁶² 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>.

would occur so that there will be one uniform template for all States to use. We proposed in § 438.6(c)(4) the minimum data fields that will need to be collected to provide the data needed for CMS 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. Under the proposal, 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."¹⁶³ Similarly, we believe States and their managed care plans already collect provider-level SDP data, including the negotiated rate between the plan and provider and any additional SDPs. We sought 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 potentially support this SDP reporting, and stated in the proposed rule that we could use 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 in section 1903(bb) of the Act for Medicaid FFS supplemental payments under both State plan and demonstration authorities consistent with section 1902(a)(30)(A) of the Act.^{164 165} 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 State plan amendment that will provide for a supplemental payment, beginning with supplemental payments data about payments made on or after October 1, 2021.¹⁶⁶

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 will 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 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 FFP.

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 stated in the proposed rule we could consider taking a similar approach for SDPs by adding reporting in MBES to capture provider-specific SDP payment data.

As another option, we described 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. As noted in the proposed rule, 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 final 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. Utilizing T-MSIS in this manner could substantially reduce unnecessary or duplicative reporting from States, be an effective method to collect the data with minimal additional burden on managed care plans and States and enable comprehensive analyses since the data will be included with all other T-MSIS data.

Lastly, we described using 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 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 described the potential option of permitting States to submit the proposed reporting using a Word or Excel template sent to a CMS mailbox. While this option 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.

Based on our evaluation and description of other options, using T-MSIS appears to be the most efficient option and we proposed 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

¹⁶³ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf>.

¹⁶⁴ 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.

¹⁶⁵ 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.

¹⁶⁶ <https://www.medicaid.gov/sites/default/files/2021-12/smd21006.pdf>.

§ 438.6(c)(4)(v),¹⁶⁷ 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. Under this proposal, States would submit this data to CMS no later than 180 days after each rating period. We proposed a 180-day deadline because we believed this timeframe would permit 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 proposed in § 438.6(c)(4) that States comply with this new reporting requirement after the rating period that begins upon our release of the reporting instructions for submitting the information required by this proposal. We sought 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 final rulemaking would be better suited for SDP reporting. We also sought 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 proposed 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 in their managed care contracts any reporting requirements necessary for auditing SDPs in addition to the reporting necessary to comply with § 438.6(c)(4).

We described these data reporting proposals as a two-prong approach, with the MLR proposed requirements serving as a short-term step and the provider-specific data reporting proposed in § 438.6(c) being a longer-term initiative. We noted that this approach would ensure the appropriate content and reporting flows to CMS while also giving States sufficient time to prepare for each proposal based on the level of new burden. We acknowledged that States and managed care plans may consider this an unnecessary increase in administrative burden but noted 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 will provide CMS more

complete information when evaluating, developing, and implementing possible changes to Medicaid payment policy and fiscal integrity policy. As we noted in the proposed rule (88 FR 28160), our intent was to improve monitoring and oversight of actual plan and State expenditures with regards to payment arrangements in § 438.6(c) (that is SDPs).

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

We solicited public comment on these proposals.

We summarize and respond to public comments received on our proposals related to reporting of SDPs in the medical loss ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), 438.74, 457.1203(e) and (f)), and SDP reporting requirements to support oversight (§ 438.6(c)(4)) below.

Comment: Some commenters supported including SDPs in MLR reporting as a reasonable step to increase transparency and improve oversight of SDPs.

Response: We agree that including SDPs in MLR reporting will increase transparency and improve CMS and State oversight of SDPs. We are finalizing § 438.8(e)(2)(iii)(C) with technical clarifications to require States and managed care plans to report State directed payments made by managed care plans to providers under § 438.6(c) as incurred claims within the MLR numerator and to refer to the newly defined term "State directed payment-" in § 438.2. We are finalizing § 438.8(f)(2)(vii) to require States and managed care plans to report all State payments made to Medicaid managed care plans for arrangements under § 438.6(c) be included in the MLR denominator as premium revenue and to refer to the newly defined term "State directed payment." We are finalizing the regulation text in § 438.8(f)(2)(vii) to remove the word "approved" as we require the MLR denominator to include all State directed payments, including those that are exempted from written prior approval as well as those that require written prior approval from CMS under § 438.6(c)(2)(i). All SDPs, including those that do not require CMS written approval under § 438.6(c)(2)(i), are within the scope of these new regulatory provisions. State directed payments that are paid to managed care plans as separate payment terms must also be included as plan revenue within the MLR denominator until the rating period in which separate payment terms are no longer permissible (see section

I.B.2.l. of this final rule for discussion of separate payment terms).

Comment: Many commenters questioned the feasibility of the SDP line item MLR reporting proposals in §§ 438.8(k)(1)(xiv) and (xv) noting that the required SDP line item reporting would prove administratively burdensome for managed care plans given the necessary changes to financial reporting systems and processes. Commenters indicated it would be significantly challenging to identify and report managed care plan expenditures associated with minimum fee schedule SDPs and managed care plan revenue associated with those SDPs incorporated into capitation rates as these arrangements are not easily identifiable especially when the SDP has been accounted for within base capitation rates for several years. Commenters raised similar challenges with distinguishing between multiple SDPs that impact the same services or provider classes. Commenters stated additional technical guidance would be necessary to clarify how plans should calculate the portion of the capitation rates attributable to these SDPs, and commenters noted there was minimal value to CMS or States of this information given other available SDP data. Commenters cautioned against overly rigid regulatory language that could result in distorted MLR reporting that does not accurately reflect SDP arrangements. One commenter requested additional time for States and plans to comply with §§ 438.8(k)(1)(xiv) and (xv) noting the extensive system and MLR reporting template changes that would be required for implementation.

Response: We appreciate the feasibility concerns raised by commenters as to how managed care plans would separately report SDPs within the plan-level MLR reports required under § 438.8(k) and as part of the State's annual summary MLR reporting required under § 438.74. While we are finalizing provisions at § 438.8(e)(2)(iii)(C) and 438.8(f)(2)(vii) to require that all SDPs be included in plan-level and State summary MLR reports, we agree that requiring plans and States to report SDPs on a line item basis would require extensive State and plan administrative work, as well as CMS technical assistance. In the proposed rule (88 FR 28160), we noted that our intent was to improve monitoring and oversight of actual plan and State expenditures with regards to payment arrangements in § 438.6(c). After careful consideration, we believe that at this time, we can work towards these goals using other provisions that

¹⁶⁷ In the proposed rule (88 FR 28153), we mistakenly cited to 438.6(c)(4)(i)(E) instead of proposed 438.6(c)(4)(v).

we are finalizing, including the requirement that all SDPs be incorporated as adjustments to the risk-based capitation rates and the SDP T-MSIS reporting requirements (see sections I.B.2.m. of this final rule and earlier paragraphs of this section in this final rule for further discussion). Therefore, we are not finalizing §§ 438.8(k)(1)(xiv) and (xv) or 438.74(a)(3) through (4) to require State and plan line-level reporting of SDPs. Because we are not finalizing the line item-level reporting provisions in §§ 438.8(k)(1)(xiv) and (xv) or 438.74(a)(3) nor the respective compliance dates in proposed §§ 438.8(k)(xvi) or 438.74(a)(4), States will likely not be required to make as many modifications to systems and MLR reporting templates. We continue to believe that it is reasonable to require States to comply with the requirement in §§ 438.8(e)(2)(iii)(C) and 438.8(f)(2)(vii) that States and plans include all SDPs within MLR reporting no later than 60 days following the effective date of this final rule. We will monitor implementation of this final rule and may consider additional future rulemaking if necessary.

Comment: Many commenters supported the proposal for States to report SDP expenditure data in the T-MSIS. Several commenters stated that it would lead to greater transparency and accountability, as well as facilitate and provide insights to provider reimbursement rates. Some commenters appreciated that T-MSIS could enable better data aggregation. One commenter stated that reporting aggregate spending on SDPs as a separate line on CMS-64 reports could help validate whether the data submitted to T-MSIS are complete. Another commenter supported the specific requirement to have provider-level payment amounts. Some State commenters questioned how certain data characteristics of SDPs would be reported in T-MSIS; however, we did not receive comments from State Medicaid agencies opposing the use of T-MSIS for SDP reporting.

Response: We agree that explicitly requiring States to report SDP expenditure data to T-MSIS will lead to greater transparency, oversight, and accountability. Even though States are already required to report all enrollee encounter data per § 438.818, including the allowed and paid amounts, explicitly identifying SDPs as part of that reporting will ensure clarity as T-MSIS evolves over time and includes more granular levels of data to support CMS oversight and monitoring. More robust and comprehensive data will improve data integrity, and T-MSIS

captures detailed beneficiary, service, and provider data that provides important insights for administering and overseeing the Medicaid program, including CMS's monitoring of State compliance with SDP payment limits, contractual requirements, and alignment with CMS approval of the SDP. We note that the allowed, billed, and paid amounts do not need to be inclusive of pass-through payments under the final version of § 438.6(c)(4) as part of SDP T-MSIS reporting. This is a technical correction as pass-through payments are not required to be tied to utilization or the delivery of services and therefore would not be included in the same financial transaction as SDPs.

Although we realize that requiring States to report SDPs through T-MSIS will require encounter system changes for both States and managed care plans, we believe that the additional detail provided by T-MSIS is critical given the high levels of spending associated with SDPs. We will evaluate actual SDP expenditures. SDP reporting through T-MSIS will provide detailed information on the characteristics of enrollees who receive services paid for using SDPs, the kinds of services that are provided through these arrangements as well as the providers who received the payments. In 88 FR 28160, we noted that our intent was to improve monitoring and oversight of actual plan and State expenditures with regards to payment arrangements in § 438.6(c).

Having detailed information on enrollees, procedure and diagnosis codes, and provider identifiers available from T-MSIS will allow CMS to analyze potential reimbursement and health disparities in one or more States. T-MSIS SDP encounter data will allow for comparisons of reimbursement for specific services across a State for SDP and non-SDP providers. For example, with the procedure codes available from T-MSIS, we could analyze primary care reimbursement for a State with an SDP for teaching hospitals compared to reimbursement for primary care providers without SDPs and determine if primary care reimbursement disparities exist in the state. The enrollee characteristic detail combined with the service and diagnosis codes in T-MSIS will allow CMS to determine if SDPs are providing improved access to high-risk enrollees or to groups of enrollees who have historically lacked access to critical services.

The detailed information from T-MSIS will also provide CMS with information to assist in determining if an SDP should be renewed. The SDP provider-level data from T-MSIS will allow CMS to verify if SDP payments

were made according to the provisions in the contract. For example, we will be able to determine if the managed care plans made payment in accordance with the SDP as included in the State's managed care contract. Having the actual spending amounts from T-MSIS encounter data will allow CMS to compare the projected amount(s) provided by the State in the preprint to the actual payments made by the managed care plan to ensure compliance with the SDP as included in the State's managed care contract. This comparison will also provide important insights into the accuracy of States' total payment rate analysis and inform CMS' review of future total payment rate analyses provided for the same payment arrangements to ensure compliance with § 438.6(c)(2)(ii)(I) and (c)(2)(iii) as applicable. If a State's total payment rate analyses are not appropriately adjusted to account for errors later identified in comparing projected spending to actual expenditures, CMS may not renew the SDP for future years.

SDP reporting through T-MSIS will also improve program integrity. The detailed records will allow us for most encounter-based SDPs (for example, uniform dollar increases, minimum or maximum fee schedules) to identify and confirm compliance with the SDP as included in the State's managed care contract by showing SDP payment amounts. The finalized regulation at § 438.6(c)(4)(v) requires that for each encounter, the State must report the allowed, billed and paid amounts and that the 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, and any other amounts included in the total amount paid to the provider. This requires the State to report, on each encounter or financial transaction, the total amount paid which includes the managed care plan's negotiated payment amount, the amount of the State directed payment, and any other amounts included in the total amount paid to the provider. While some payment arrangements, like uniform dollar increases, may lend themselves to more easily disaggregating a separate SDP amount from the negotiated rate, CMS recognizes that other types of SDPs (for example, minimum or maximum fee schedules), particularly those that have been in effect for a significant period, may not due to the nature of the SDP. Currently CMS has an established process that reviews T-MSIS data needs, proposes revisions to the T-MSIS submission file format(s), and provides opportunity for

States' review and comment. CMS intends to use this process for any updates that may be needed to the T-MSIS file layout and technical specifications to facilitate reporting of the total paid amount for SDPs than the file currently supports. These detailed records will provide CMS with a better understanding of how SDPs are implemented by States and managed care plans. Currently, we review SDP payments and calculations through MLR audits and financial management reviews (FMRs) on a State-by-State basis. With the encounter-level data from T-MSIS, we will be able to review the SDP data for more than one State at a time and can identify potentially inappropriate payments as part of more comprehensive and timely reviews of these payments once the reporting requirement applies. In addition, we will be able to analyze how well plans are administering the distribution of SDPs across provider classes specified in the approved SDPs; that is, are managed care plans making the payments to providers as required by the State and are the payments made on a timely basis.

Comment: A few commenters stated that MBES would be the more appropriate system for reporting SDP data since it is already used to collect provider-level data on UPL payments. One commenter suggested MBES would not take as much time to implement as submission to T-MSIS. Another commenter suggested that the MBES forms that already collect provider-level data on UPL FFS supplemental payments could be modified to reduce State administrative burden.

Response: After further consideration, we disagree that MBES is a more appropriate vehicle for this data collection as State reporting of managed care expenditures within MBES is focused on capitation payments paid from the State to the managed care plans, not amounts paid by the managed care plan to a provider for a service delivered to a specific Medicaid managed care enrollee. In addition to widespread support by commenters, we conclude that T-MSIS is the more appropriate tool to capture this information as T-MSIS will provide substantially more detail on the affected enrollees, services, and providers and will allow for more sophisticated analyses of access and payment. Current regulations at § 438.242(c)(3) require States to submit all enrollee encounter data, and we have operationalized that using T-MSIS. Using T-MSIS as well for the new SDP reporting will align well with SDPs that are specifically tied to an encounter or claim, such as

minimum fee schedules or uniform dollar or percentage increases.

Further, current regulations at § 438.242(c)(2) requires 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. Building additional data fields in T-MSIS to capture more details about the paid amount, including elements that would allow CMS to understand more about the payment amount negotiated by the managed care plan, amount of the SDPs, and any other amounts included in the total payment amount paid to the provider, is appropriate and in alignment with the current regulatory requirements at § 438.242(c)(2).

Because of the numerous comments supporting the use of T-MSIS for State SDP reporting as well as the level of detail available from T-MSIS that will enable robust analysis of State SDP implementation, we believe T-MSIS is the appropriate vehicle for State SDP reporting. In addition, we note that the required file format for encounter data can support the additional, more detailed reporting requirements for SDPs. As previously noted, CMS currently has a standardized process that reviews T-MSIS data needs, proposes revisions to the T-MSIS submission file format(s), and provides opportunity for States' review and comment. After consideration of States' comments, the review cycle incorporates modifications that are in line with the standardized data formats required in § 438.242(c).

Comment: One commenter recommended that CMS ensure there was adequate time to collect the appropriate data and noted that the proposed effective date of this requirement would not give States sufficient time to begin gathering this information. The commenter indicated that States may need 2 to 3 years from the effective date of the final rule to begin this reporting.

Response: We do not agree with the commenter that States will be unable to report the data specified in § 438.6(c)(4) by the applicability date for several reasons. First, States have been responsible for submitting data to T-MSIS or its predecessor system since 1999 so they are very familiar with its requirements and processes. Second, most of the data elements specified in § 438.6(c)(4)(i) through (iv) are existing data fields in T-MSIS and States currently report these data; these fields include provider identifiers, enrollee identifiers, managed care plan identifiers, procedure and diagnosis

codes, as well as allowed, billed and paid amounts. Under § 438.242(c)(3) States and plans are already required to report paid amounts as part of encounter data submissions; the new SDP reporting requirement at § 438.6(c)(4)(v) now requires that the required paid amounts must include the amount that represents the managed care plan's negotiated payment amount, the amount of the State directed payments, and any other amounts included in the total paid to the provider. Any revisions made to T-MSIS in the future to include additional fields that capture different data will be introduced using standard T-MSIS modification and instruction procedures.

Lastly, after careful consideration of existing CMS processes for the release of T-MSIS specifications and the compliance dates typically established therein, we are modifying our applicability date for § 438.6(c)(4) in proposed § 438.6(c)(8)(vi) from the first rating period beginning on or after the release of T-MSIS reporting instructions by CMS to the applicability date set forth in the T-MSIS reporting instructions released by CMS. Our method of releasing new reporting instructions includes preparation time for States and managed care plans as we are aware that any changes to data systems require substantial programming and testing before implementation. For these reasons, we believe § 438.6(c)(4) as finalized in this rule provides States with ample time to comply.

Comment: Some commenters supported the choice of T-MSIS as the repository for SDP data, but shared concerns regarding some of the details of the data itself. One commenter urged close Federal-State partnership to finalize the elements and approach for the reporting. One commenter wanted to ensure that there was a uniform template for reporting. Another commenter requested that CMS explore ways that additional explanatory information can be included to accompany the dollar amounts being reported.

Response: We agree that T-MSIS is the appropriate data collection tool for SDP reporting. The required minimum data fields to be collected are specified in § 438.6(c)(4), which we are finalizing with the addition of “, as applicable” after “Minimum data fields to be collected include the following” to be clear that for some SDPs, such as value-based SDP arrangements in which there may not be an identifiable tie to a specific procedure code because the SDP provider payments are tied to

provider performance over the entire rating period, all of the minimum data fields may not apply. As indicated by preliminary T-MSIS specifications released in Fall 2023, we believe this data can be successfully captured elsewhere in T-MSIS, via financial transaction reporting, for example. To ensure consistent and accurate reporting, we also plan to publish additional associated T-MSIS reporting instructions through the established methods and mechanisms used for disseminating T-MSIS information to States. To the suggestion for additional explanatory information for the SDP data in T-MSIS, we remind commenters that approved SDP preprints are now available on [Medicaid.gov](https://www.Medicaid.gov). These preprints contain the information that was submitted by the State for written prior approval and reflects the purpose of each SDP.

Comment: One commenter was not sure that States and managed care plans collect the necessary data, in particular the negotiated rate between the plan and provider and any additional SDPs that are made to the provider. The commenter was particularly concerned that for fee schedule-related SDPs, managed care plans often are not provided enough information to calculate the amount paid and in order to comply with the proposals in this section, managed care plans will need to be allowed greater insight into how these calculations are made at the State level.

Response: We remind States and managed care plans that as specified in § 438.242(c)(3), all MCO, PIHP, and PAHP contracts must require the submission of all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS under § 438.818. We expect States and managed care plans to ensure the SDP data elements required under § 438.6(c)(4) meet the requirements for the encounter data submissions, including any calculation methods for the SDP. We expect the SDP T-MSIS reporting to follow the same process for data collection that is currently required for encounter data. That is, the SDP information required in § 438.6(c)(4) will be part of each encounter record that is submitted in accordance with § 438.242(c)(3). Encounters with SDP data will not be submitted on a different schedule or timeline than other encounter data and will not use different transaction types except for some SDPs that are VBPs. We acknowledge that not all SDPs are paid on an FFS basis that clearly identifies allowed and paid amounts, and certain types of SDPs such as VBP provider

incentive payments may not conform to this encounter data format. We would expect that some VBP SDPs, including provider incentive payments, would utilize a T-MSIS financial transaction format which differs from the T-MSIS encounter data format. The submission timing requirements for the T-MSIS VBP SDP financial transactions would not differ from those for T-MSIS encounters; those timing requirements for encounter data are delineated in § 438.242(c). Regardless, the submission of complete and accurate data to T-MSIS is critical to program oversight and managed care plans and States should ensure that reporting requirements are clear and consistently implemented. If States have questions about submission of data to T-MSIS, they should contact their CMS T-MSIS contact for technical assistance.

Comment: Some commenters cautioned CMS on any additional administrative reporting burden. One commenter stated that CMS should ensure that any reporting requirements, including around SDPs that advance VBP, could be met through the broader reporting at § 438.6(c)(4). Some commenters cautioned that any additional reporting around SDPs that advance VBP would disincentivize Medicaid agencies from using SDPs as a tool to transform payment and care delivery. Other commenters stated CMS should limit the trend toward more and more reporting, and suggested CMS combine the reporting requirements or eliminate some to further streamline. Conversely, a few commenters recommended that the reporting be more extensive than what was proposed in § 438.6(c)(4).

Response: We appreciate the range of comments on our reporting proposals. We attempted to strike the right balance between oversight and transparency, and additional administrative burden. As we noted in the proposed rule, we believe utilizing T-MSIS for reporting 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 (88 FR 28153). As the commenters pointed out, VBP arrangements are sometimes difficult to capture in a data repository such as T-MSIS given the fixed file formatting and complex relationship between the trigger for the SDP, such as achievement of specific quality measures or global budgets, and the payment amount of the SDP. We intend to further revise T-

MSIS reporting in the future to better enable States to report more complex SDP data easily and effectively.

Comment: Some commenters were concerned about the accessibility of the data, and that the information should be publicly posted on the State's Medicaid website or [Medicaid.gov](https://www.Medicaid.gov). Another commenter stated concern that the data was too transparent, stating that the requirements to report enrollee identifiers is troubling for data protection issues. For behavioral and mental health, commenters stated concerns that the reporting of identifying data and procedure information could violate HIPAA protections. Another commenter was concerned that requiring reporting on the allowed payment amounts by managed care plans may inappropriately expose plan competitive information, and that aggregate information by provider class and total utilization is the appropriate level of detail.

Response: States and managed care plans are currently required to report encounter data, including for mental health and SUD services, under various authorities including section 1903(i)(25) and (m)(2)(A)(xi) of the Act. While it is not feasible to publish raw T-MSIS data or the underlying State data on a website given that it contains protected health information, certain deidentified T-MSIS data are available for research purposes. State T-MSIS submissions are used to create a research-optimized version of the data known as the T-MSIS Analytic File. Researchers who desire access to Research Identifiable Files (RIF) must meet specific requirements before obtaining access to these data. All summary data published from T-MSIS, including Data Briefs, complies with applicable HIPAA and Privacy Act requirements.

Comment: Some commenters stated concern that requiring States to report the total dollars expended by each MCO, PIHP, and PAHP for SDPs within 180 days of the end of the rating period is not adequate time for claims runout, receipt, and processing of encounter data by the State, and submission to CMS.

Response: We appreciate the commenters' concern and acknowledge that all paid claims data would likely not be complete within 180 days of the end of a rating period, which was the deadline for submission of the SDP reporting data proposed in § 438.6(c)(4). In addition, it will be difficult for States to process, validate, and submit the encounter data to CMS within the proposed 180-day timeframe. Given these considerations, we are finalizing

the regulation to require States to report the total dollars expended by each managed care plan for SDPs no later than 1 year after the end of the rating period.

Comment: Some commenters shared concerns that reporting T–MSIS data would not go far enough to advance CMS’s oversight goals and requested clarification of what CMS would do if T–MSIS data identified regulatory violations. The commenter also noted that CMS should use independently obtained information about the performance of the State’s program, and not rely solely on attestations by States, to analyze and determine compliance.

Response: We are committed to our oversight role of the Medicaid program. CMS will review SDP data that is submitted via T–MSIS and will follow up with States as appropriate, including enforcement of regulatory requirements. CMS reserves its authority to enforce requirements in the Act and implementing regulations, including by initiating separate deferrals and/or disallowances of Federal financial participation.

States have been submitting their program data to CMS via T–MSIS and its predecessor since 1999, and we often rely on that data for program monitoring and analysis. We do not rely on T–MSIS alone and collect information from States in multiple ways, including MCPAR, NAAAR, and MLR reports. In addition, other oversight bodies such as the GAO and OIG, as well as MACPAC, provide information to CMS on the performance of States’ programs. We believe § 438.6(c)(4) will strengthen the information in T–MSIS specific to SDPs, but we will continue to develop and utilize a comprehensive approach to monitoring managed care program and plan performance.

Comment: A few commenters questioned whether SDPs that use minimum fee schedules would be submitted to T–MSIS. These commenters stated that parsing the total paid amount to report how much is attributable to the SDP and how much is due to the plan’s negotiations with the provider would require an untenable level of effort.

Response: We understand the commenters’ concerns but point out that SDPs that use minimum fee schedules should already be reported to T–MSIS and the requirements finalized in § 438.6(c)(4) do nothing to change that at this time. Currently, when managed care plans submit their paid amounts in encounter data to States, those paid amounts inherently reflect the minimum fee schedule by reporting the paid amount. Currently CMS has

standardized process that reviews T–MSIS data needs, proposes revisions to the T–MSIS submission file format(s), and provides opportunity for States’ review and comment. CMS intends to use this process for any updates that may be needed to the T–MSIS file layout and technical specifications needed to obtain any additional, more detailed reporting for the total paid amount for SDPs that the file currently supports. After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing, 457.1203(e), as proposed. We are finalizing §§ 438.8(e)(2)(iii)(C) and (f)(2)(vii) with technical clarifications and modifications to use the newly defined term “State directed payment” and to clarify the scope of the provisions. We are finalizing § 438.6(c)(4) with revisions to modify the 180-day timeframe to “1 year” and add “, as applicable” At the end of the introductory text in § 438.6(c)(4). We are finalizing 438.6(c)(4)(v) with a technical edit to remove “the amount for any pass-through payments under paragraph (d) of this section,” in acknowledgement that pass-through payments are separate financial transactions not tied to the delivery of services to Medicaid managed care enrollees and therefore, are not identifiable within encounter-level data. We are not finalizing proposed §§ 438.8(k)(1)(xiv) through (xvi) or § 438.74(a)(3) through (4) to require SDP line-level reporting in the State summary and managed care plan specific MLR report.

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

We proposed 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 proposed 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 proposed 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 proposed that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(D) and (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 also considered 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 proposed the first rating period beginning on or after 3 years after the effective date of the final rule because we believed it strikes a balance between the work States will need to do to comply with these proposals and the urgency with which we believed these proposals should be implemented in order to strengthen and ensure appropriate and efficient operation of the Medicaid program. We solicited comment on the proposal and alternatives.

We proposed 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 proposed a longer timeline for compliance. We stated that we were also 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 proposed the longer period for States to adjust and come into compliance. We solicited comment on the proposal and alternative.

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

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

We solicited public comment on these proposals.

We summarize and respond to public comments received on our proposals for the applicability and compliance dates (§§ 438.6(c)(4) and (c)(8), and 438.7(g)(2)) for various proposals related to SDPs below.

Comment: We received several comments encouraging us to consider earlier applicability dates than those proposed in §§ 438.6(c)(4) and (8), and 438.7(g)(2) and (3) in recognition that many of the provisions would improve monitoring and oversight efforts related to State directed payments. Other commenters noted the array of new documentation requirements, including those proposed in § 438.6(c)(5), and requested that applicability dates for all SDP provisions be revised to be implemented at a later date than proposed in recognition of State burden.

Response: As described in the proposed rule (88 FR 28153), we carefully considered each proposed effective date for an applicable SDP provision compared to the benefit incurred to the State or additional administrative work that the State must undertake. We continue to believe that the proposed applicability dates strike the right balance, so we are finalizing most applicability dates as originally proposed in §§ 438.6(c)(8), and 438.7(g)(1) and (3), with technical revisions to the regulation citations to reflect that the separate payment term provisions proposed in §§ 438.6(c)(6)(i) through (iv) and 438.7(f) are not being finalized. We are modifying the applicability date in § 438.6(c)(8)(vi) to better align with existing CMS processes for the release of T-MSIS data reporting instructions and the compliance date established within such guidance. Finally, we are modifying the T-MSIS reporting deadline in § 438.6(c)(4) from 180 days to 1 year to acknowledge the time needed for more accurate and complete encounter data reporting. We are also modifying the applicability date for § 438.6(c)(2)(vii) to no later than 3

years after the effective date of the final rule to align with the applicability date for the prohibition on separate payment terms in § 438.6(c)(6). As this provides States an additional year to come into compliance with § 438.6(c)(2)(vii), we believe this is a reasonable modification. For discussion on the elimination of separate payment terms and related changes to the proposed regulation text, refer to sections I.B.2.k., I.B.2.l. and I.B.2.m. of this final rule.

After reviewing public comments, we are finalizing § 438.6(c)(8)(i) without the reference to paragraph (c)(6)(i) through (iv) given changes to regulatory text that remove this proposed text (see section I.B.2.l. of this final rule for further details) and, we are adding a reference to § 438.6(c)(1), which was excluded in error. We are also finalizing § 438.6(c)(8)(iii) with revisions to remove paragraph (c)(2)(ix) which is not being finalized (see section I.B.2.e. of this final rule for further details), and to remove the references to paragraphs (c)(5)(v) and (c)(2)(ii)(H), given the proposed requirement at § 438.6(c)(5)(v) is not being finalized (see section I.B.2.k. of this final rule for further details), and the updated applicability date for (c)(2)(ii)(H), respectively. To reflect the later applicability date for § 438.6(c)(2)(ii)(H), we are adding paragraph (c)(8)(vii) to say “[p]aragraph(c)(2)(ii)(H) no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028.” To reflect the later applicability date for § 438.6(c)(2)(vii), we are finalizing the reference to paragraph (c)(2)(vii) in paragraph (c)(8)(iv) instead of paragraph (c)(8)(iii) (see section I.B.2.h. of this final rule for further details). We are also finalizing § 438.6(c)(8)(iv) with a revision to add paragraph (c)(6) in recognition of the requirement that all separate payment terms be eliminated no later than the first rating period on or after 3 years after the effective date of the final rule (see section I.B.2.k. of this final rule for further details). Finally, we are revising § 438.6(c)(8)(v) with revisions to remove the reference to paragraph (c)(6)(v) which is not being finalized and to refer to (c)(5)(v) (instead of proposed paragraph (c)(5)(vi)) to account for changes in the regulation text compared to the proposed rule (see sections I.B.2.l. and I.B.2.k. respectively of this final rule for further details). Since we are also not finalizing § 438.7(f) as proposed, § 438.7(g) is redesignated as § 438.7(f) and we are not finalizing references therein to paragraphs (f)(1) through (4) (see section I.B.2.l. of this final rule for further

details). We are also not finalizing the regulatory text proposed at § 438.7(g)(2) as we determined this was unnecessary as § 438.7(c)(4) and (5) are effective with the publication of this final rule; and therefore, § 438.7(g)(3) is redesignated as § 438.7(f)(2).

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 proposed 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 MLR standards for the private market and Medicare Advantage standards for MA organizations. As we noted in the preamble to the 2015 managed care proposed rule,¹⁶⁸ alignment with private market 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

¹⁶⁸ <https://www.govinfo.gov/content/pkg/FR-2015-06-01/pdf/2015-12965.pdf>.

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) will 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 common standard will allow comparison of MLR outcomes consistently from State to State and among private, 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 private market MLR requirements; however, CMS finalized some regulatory changes to the private market MLR requirements in 45 CFR 158.140, 158.150, and 158.170 effective July 1, 2022.¹⁶⁹ To keep the Medicaid and CHIP managed care regulations aligned with these revised private market provisions, we proposed 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 proposed 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 proposed revisions to standards for provider incentives to remain consistent with our goals of alignment with the private market MLR regulations 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. While the same MLR requirements are made applicable to PIHPs and PAHPs under authority in section 1902(a)(4) of the Act, the requirements are enforced under section 1904 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 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 will 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 422.210.¹⁷⁰ 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 §§ 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

¹⁶⁹ <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>.

¹⁷⁰ 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.

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 allow for managed care plans that are integrated with a medical or hospital system to move revenue out of the managed care plan and into the affiliated medical or hospital system. Additionally, this practice could artificially inflate future capitation rates. To address these concerns, we proposed additional requirements on provider incentive arrangements in § 438.3(i).

In § 438.3(i)(3) and (4) for Medicaid, and included in separate CHIP regulations through an existing cross-reference at § 457.1201(h), we proposed 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 required 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 proposed, 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 proposed 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 noted 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 also required 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 proposed 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 proposed 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 proposed that States and managed care plans will 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. We 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 sought public comment on this proposal. Other changes proposed to § 438.3(v) are outlined in section I.B.3. and section I.B.4 of this final rule.

We also proposed to amend § 438.608 to cross-reference these requirements in the program integrity contract requirements section. Specifically, we proposed to add § 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 Private Market Regulations for Provider Incentive Arrangements¹⁷¹

Effective July 1, 2022, the private market regulations at 45 CFR 158.140(b)(2)(iii), which are applicable to health insurance issuers offering group or individual health insurance coverage, were updated to clarify that only provider bonuses and incentives payments tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards 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 private market issuers and Medicaid and CHIP managed care plans, which is important given the high number of health plans that participate both in the private market and Medicaid and CHIP, as well as the frequent churn of individuals between private market, Medicaid, and CHIP coverage. To address the potential for inappropriate inflation of the MLR numerator, as well as facilitate data comparability, we proposed 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 will 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 will 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 will 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 will 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 will be structured in managed care plans' provider contracts, transparency around these arrangements will improve. In addition, by requiring the contracts to include more specific documentation requirements, CMS and States will 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 or provider. The

¹⁷¹ <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>.

proposals will 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 sought comment on these proposed requirements, including whether any additional documentation requirements should be specified in regulation. We proposed 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. We sought comment on this proposal.

We summarize and respond to public comments received on Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.3, and 457.1203) below.

Comment: One commenter supported the proposal to require compliance with the new contract requirements for provider incentive arrangements on or after 60 days after the publication of the final rule. However, several commenters opposed the proposal regarding the effective date of these requirements for contracts with managed care plans. The commenters suggested that managed care plans need more time to engage with their contracted providers and conduct the legal reviews necessary to modify and finalize the incentive contracts. Many of the commenters suggested a one-year implementation timeframe, one commenter suggested 180 days, and one commenter suggested January 1, 2025.

Response: We appreciate these comments and considered them when finalizing the effective date of the new contract requirements for provider incentive arrangements in § 438.3(i). We acknowledge that 60 days may not be long enough to engage with the contracted providers and complete the legal review necessary to implement new provider incentive arrangements, as raised by several commenters. After considering the public comments, we believe 1 year after publication of this final rule is sufficient time to complete the necessary contract actions to come into compliance with these requirements. As such, we are finalizing an effective date for these new contract requirements for provider incentive arrangements as the first rating period beginning on or after 1 year after the

effective date of this final rule for the provider incentive changes in §§ 438.3(i), 438.608(e), and applicable to separate CHIP through the existing cross-references at § 457.1200(d).

Comment: One commenter supported the proposal that State contracts with managed care plans require incentive payment contracts between managed care plans and network providers to have a defined effective period that can be tied to the applicable MLR reporting periods. Several other commenters opposed this proposal, with some commenters asking for more flexibility to align performance periods in § 438.3 with a calendar year to create better alignment across products and payors. In addition, one commenter stated that the proposal was prescriptive and vague, as it was unclear whether CMS was requiring the performance-related activity or the evaluation period to occur in the MLR reporting period.

Response: We believe that by requiring an incentive payment contract period of performance to be tied to a MLR reporting period, program integrity and transparency around these arrangements would vastly improve. Specifically, a defined performance period will allow for States and CMS to have better oversight over provider incentive payment arrangements and ensure that provider incentive payments are made in accordance with the contract, are made for the appropriate performance period, and can be tied to an MLR reporting period. The proposed and finalized requirement at § 438.3(i)(3)(i) would also allow for flexibility in determining the effective period for incentive payment contracts between managed care plans and network providers. Managed care plans and network providers would continue to have the option to implement effective periods on a calendar year, or other appropriate temporal basis that they choose as long as the incentive payment contract is clearly associated with a specific MLR reporting period. Under this proposal, the contract would be required to include a defined start and end date for the effective period so provider incentive payments can be tied to a specific MLR reporting period. By having a defined effective period, States and CMS would be able to confirm and verify the appropriateness of provider incentive payments included in the MLR for the relevant MLR reporting period.

Comment: A few commenters opposed the proposal to require that provider incentive contracts be signed prior to the performance period. Commenters contended that this requirement is overly restrictive and

could deter managed care plans and network providers from implementing otherwise appropriate arrangements that support or improve access and quality of care. Some commenters suggested removing this requirement, and one commenter suggested that CMS should allow contracts to be signed within the first 60 days of the measurement period as long as there is no performance data available. One commenter requested CMS to clarify whether it is permissible for managed care plans to include prospective provider incentive arrangements that are not finalized until after the MLR filings are submitted.

Response: We respectfully disagree that the requirement for incentive payment contracts to be signed prior to the performance period is overly restrictive and would deter managed care plans and network providers from implementing otherwise appropriate arrangements. Provider incentive payments should be included as incurred claims in the MLR numerator and be tied to the MLR reporting period in which they are to be reported. Because of the importance of such contract payments in MLR calculations, we believe that allowing such contracts to be signed after the beginning of the performance period creates 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. Furthermore, it is a standard contracting practice for all parties to sign a contract prior to the period of performance to signal acceptance of the terms of the contract. We believe that allowing for contracting deadlines to occur after the beginning of the performance period would add further complexity to the provider incentive contracting process. Requiring such contracts to be signed before the period of performance increases transparency into provider bonuses and incentives, improves care by ensuring that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care, and protects Medicaid and CHIP managed care plans against fraud and other improper payments. Therefore, we believe it is in the best interest of the Federal government, States and other interested parties to require that all incentive payment contracts be signed prior to the performance period for the payments in order to be appropriately included in the MLR numerator.

Regarding the comment about whether it is permissible for managed care plans to include prospective provider incentive arrangements that are not finalized until after the MLR filings

are submitted, Federal regulations require that provider incentive payments be included as incurred claims in the MLR numerator and be tied to the MLR reporting period in which they are reported. Provider incentive payments that do not meet those requirements of a specific MLR reporting period may not be included.

Comment: Several commenters supported the proposal that State contracts with managed care plans must require that incentive payment contracts between managed care plans and network providers include well-defined quality improvement performance metrics that the provider must meet to receive the incentive payment. One commenter requested CMS to clarify if there is a difference between “well-defined quality improvement performance metrics” described in the Contract Requirements for Provider Incentive Payment Arrangements section of the 2023 proposed rule at § 438.3(i)(3)(iii) and “clearly defined, objectively measurable, and well-documented clinical or quality improvement standards” proposed in the MLR Standards section of the 2023 proposed rule at § 438.8(e)(2)(iii)(A) and found in the private market regulations at 45 CFR 158.140(b)(2)(iii).

Response: We believe that by requiring the contracts to include well-defined quality improvement performance metrics which providers must meet, CMS and States will be better able to ensure that providers are in compliance with the terms of the incentive payment contract and eligible to receive the payment. This in turn will help CMS and States ensure that incentive payments are not being used to inappropriately increase the MLR to avoid potential payment of remittances or inflate future capitation rates.

We did not intend for there to be a difference between “well-defined quality improvement performance metrics” proposed in the Contract Requirements for Provider Incentive Payment Arrangements section of the 2023 proposed rule at § 438.3(i)(3)(iii) and “clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards” proposed in the MLR Standards section of the 2023 proposed rule at § 438.8(e)(2)(iii)(A). We appreciate the commenter highlighting this inconsistency in language. To further clarify our intent with this requirement and align this provision with similar private market regulations, we revised the proposed language at § 438.3(i)(3)(iii) to include the following language, “clearly-defined, objectively measurable, and well-documented

clinical or quality improvement standards,” which also reflects the language used in the private market regulations at 45 CFR 158.140(b)(2)(iii). The finalized revision to § 438.3(i)(3)(iii) is equally applicable to separate CHIP through the existing cross-reference at § 457.1201(h). We note that even with this slight revision to the proposed language at § 438.3(i)(3)(iii), managed care plans will continue to have the flexibility to determine any appropriate non-clinical metrics, such as quality improvement or quantitative performance metrics, to include in the incentive payment contracts.

Comment: Several commenters supported the proposal that State contracts with managed care plans require that incentive payment contracts between managed care plans and network providers specify a dollar amount that can be clearly linked to successful completion of the metrics. A few commenters requested additional flexibility with this requirement. Specifically, the commenters requested that beyond a specified dollar amount, CMS should allow for a percentage of a verifiable dollar amount. Commenters stated that this flexibility reflects current incentive payment practices and would allow for flexibility in how the provider incentive contracts are written, while maintaining the link between quality improvement and/or performance metrics and the receipt of incentive payments.

Response: Our intent with implementing this requirement is that by requiring provider incentive contracts to include a specified dollar amount or percentage of a verifiable dollar amount, CMS and States will be able to have better oversight over provider incentive payments to ensure that provider bonus or incentive payments are used appropriately. In considering comments received, we believe that providing additional flexibility regarding the financial terms of the incentive arrangement continues to meet our intent while reflecting current incentive arrangement practices identified by some commenters. As such, we are revising our proposal in § 438.3(i)(3)(iv) to also allow for the incentive payment contracts between managed care plans and network providers to specify either a dollar amount or a percentage of a verifiable dollar amount that can be clearly linked to successful completion of the metrics. We note that the specification of the percentage of a dollar amount is an alternative to the specification of a dollar amount in the contract. The finalized revision to § 438.3(i)(3)(iv) is equally applicable to separate CHIP

through the existing cross-reference at § 457.1201(h).

Comment: One commenter supported the proposal to prohibit the use of attestations as supporting documentation for data that factors into the MLR calculation.

Response: We believe that by requiring the contracts to include specific documentation requirements, CMS and States will be better able to ensure that provider incentive payments are not being used to inappropriately increase the MLR to avoid paying potential remittances or inflate future capitation rates.

Comment: A few commenters supported the proposal that State contracts with managed care plans must require that managed care plans make the provider incentive contracts and supporting documentation available to the State both upon request and at the routine frequency that the State established.

Response: We believe that by requiring State contracts with managed care plans to include more specific documentation requirements, CMS and States will be better able to ensure that provider incentive payments are not being used to inappropriately increase the MLR to avoid paying potential remittances or inflate future capitation rates.

Comment: One commenter noted that the proposed changes for provider incentives should not be finalized until CMS determines that the changes would not make VBP arrangements more difficult to implement in Medicaid managed care.

Response: The commenter did not provide any reasons as to why the proposed changes to the Medicaid MLR regulations would make VBP implementation more difficult. We do not believe that the proposed and finalized changes for provider incentives will make it more difficult for States and managed care plans to implement VBP. As one goal of VBP is to reduce excessive health spending and growth by limiting administrative waste,¹⁷² we believe that the changes finalized in this rule at §§ 438.3, 438.8, and 457.1203 are very much aligned with the goals of VBP.

Comment: Several commenters supported the requirement for performance metrics in provider incentive arrangements and alignment with private market MLR regulations. Commenters noted that this change will

¹⁷² Value-Based Payment As A Tool To Address Excess US Health Spending. Health Affairs Research Brief, December 1, 2022. DOI: 10.1377/hpb20221014.526546.

prevent managed care plans from inappropriately transferring expenditures to providers to inflate their MLR and avoid paying remittances to States. Other commenters noted the importance of alignment with the private market regulations for consistency and equity across Federal health programs.

Response: Having a consistent methodology across multiple markets will allow for administrative efficiency for States as they monitor their Medicaid and CHIP managed care plans and for issuers and managed care plans to collect and measure data necessary to report and calculate their MLRs. We believe the requirement for prospective quantitative quality or performance metrics will increase transparency around these arrangements and ensure that bonuses and incentives are paid to providers that demonstrated furnishing high-quality care and will protect Medicaid and CHIP against fraud and other improper payments. In addition, CMS and States will 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 or provider.

Comment: Several commenters urged CMS to exercise greater oversight of Medicaid and separate CHIP managed care plans that own or are owned by companies that also own networks of providers and other health care services. The commenters described some potentially problematic reporting or business practices used by some vertically integrated health plans. The commenters noted that some large managed care plans channel excessive health care dollars to their affiliated health care providers and vendors and thereby increase health system costs while increasing profit for the managed care plan's parent company.

Response: We understand these concerns regarding managed care plans that are integrated with health care providers, and we will continue to encourage State oversight of Medicaid and separate CHIP managed care plan compliance with MLR reporting requirements for the different types of provider arrangements or payment models employed by managed care plans. As part of this effort, we encourage States to consider the impact of vertical integration on the reporting and treatment of provider payments under the MLR framework codified in § 438.8. Going forward, our Federal MLR reviews of the State Medicaid and

CHIP managed care programs will also review State oversight practices for vertically integrated health plans' provider incentives.

Comment: Several commenters suggested that CMS require managed care plans to use the measure sets developed by the Core Quality Measures Collaborative (CQMC) for provider incentives. The commenters stated that the work done by a multidisciplinary committee to review and approve these measures makes them preferable to other measures a managed care plan may select for provider incentives.

Response: We appreciate the commenters' noting the CQMC performance measure review initiative and acknowledge the importance of alignment and harmonization in quality measurement. While we are not requiring the use of the CQMC measure sets, if a managed care plan's provider bonus and incentive program is based on CQMC measure sets, then any payments made based on the CQMC would qualify as a bonus or incentive includable in the MLR calculation. We believe that each State's Medicaid and CHIP managed care program is unique, and States are best positioned, in collaboration with managed care plans and interested parties, to design and determine the most appropriate metrics to use for provider incentive arrangements. Additionally, the private market MLR regulations did not specify a set of provider incentive metrics and as noted in the preamble of the proposed rule, we aim to remain aligned with the private market MLR regulations to the extent possible (88 FR 28154). Therefore, we decline to specify clinical or quality improvement standards for provider incentives in this final rule.

Comment: Several commenters stated that requiring performance metrics for provider incentives will lead to fewer providers participating in managed care networks and may lessen the ability of managed care plans to encourage creative solutions for access, such as providing bonus payments for evening and weekend physician office hours.

Response: We acknowledge that some providers may decline to participate in a managed care network if a provider incentive or bonus payment is tied to a clinical or quality improvement standard when previously these payment arrangements had not been held to this kind of standard. However, we believe that this would impact only a small percentage of providers as most providers share in Medicaid's and CHIP's goal of promoting the highest quality outcomes and safest care for all beneficiaries. The requirement for provider incentive payments to be based

on clinical or quality improvement standards does not prevent managed care plans from developing innovative responses to improve access. In the commenter's example, the managed care plan could develop a provider incentive or bonus payment that requires physician offices to add evening and/or weekend hours but also requires improved access outcomes for one or more populations, for example, an increase in the proportion of adolescent enrollees who received a well-care visit.

Comment: Several commenters noted that excluding provider incentive payments that are based solely on total cost of care targets in the MLR numerator could have unintended consequences and negatively affect VBP arrangements in Medicaid managed care. One commenter noted that some CMS VBP programs, such as the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) program,¹⁷³ have arrangements where a percentage of the shared savings payment is linked directly to quality metrics and is separate from the total shared savings or loss from the ACO. The commenter stated concern that the portion of the shared savings arrangement that was not linked directly to quality metrics could not be included as a provider incentive payment in the MLR. The commenter recommended that incentive payments based on total cost of care targets be included in MLR calculations.

Response: We continue to support innovative alternative payment models that deliver efficient and high-quality care. We further note that the Medicaid managed care regulations in part 438 do not prohibit States and managed care plans from adopting a wide range of value-based payment models. The amendment to § 438.8(e)(2), which we are finalizing as proposed, is instead limited in applicability to the treatment and reporting of these amounts for MLR purposes. We believe that VBP models can reduce inappropriate utilization and lead to better outcomes, or lower costs, without compromising the quality of care. We confirm that the fact that a provider incentive or bonus program has a shared savings or other cost efficiency element does not disqualify the entire incentive or bonus from being classified as incurred claims, as long as the incentive or bonus is tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers. States and managed care

¹⁷³ <https://innovation.cms.gov/innovation-models/aco-reach>.

plans employing such models or arrangements should be able to demonstrate this outcome through the use and documentation of appropriate clinical or quality metrics and thus such incentive or bonus payments would be eligible for inclusion in the MLR calculation as incurred claims. Further we are not aware of any CMS VBP initiatives (such as Medicare shared savings initiatives and alternative payment models) that do not include clinical or quality standard requirements. We clarify that when directed by a State to make provider incentive payments based on a VBP methodology, Medicaid managed care plans must include the full amount of these provider incentives in their MLR reports. That is, Medicaid managed care plans should include the full amount of provider incentives paid in their MLR reports if those payments are SDPs. Under § 438.6(c), States are required to tie SDPs to clinical or quality standards; however, if an SDP provider incentive or a portion of an SDP provider incentive is part of a VBP program, is tied to the total cost of care, and is not based on clinical or quality improvement standards, the managed care plan must include the SDP provider incentive expenditures based on the total cost of care in the MLR report. We encourage States to develop mechanisms for managed care plans to report SDP provider incentive payments separately from non-SDP provider incentive expenditures.

After consideration of public comments, we are finalizing § 438.8(e)(2) as proposed. We are also finalizing our proposals related to the Standards for Provider Incentives in § 438.3(i)(3) and § 438.3(i)(4). However, we are modifying a few proposals as described below. We are revising our proposal at § 438.3(v) to make these provisions effective on or after 60 days following the effective date of this final rule. We are instead finalizing that these provisions are effective for the rating period beginning on or after 1 year following the effective date of this final rule, based on public comments that 60 days may not be long enough to engage with the contracted providers and complete the legal review necessary to implement new provider incentive arrangements. Additionally, we are modifying our proposal at § 438.3(i)(3)(iii) describing the performance metrics, based on public comment that consistency is needed between the private market regulations and Medicaid managed care regulations. Therefore, we are finalizing revised text at § 438.3(i)(3)(iii) to mirror the text in

the private market regulations at 45 CFR 158.140(b)(2)(iii). Finally, based on public comments, we are modifying our proposal at § 438.3(i)(3)(iv) that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of performance metrics to provide additional flexibility that would better align with current incentive payment practices. As such, we are finalizing the proposal at § 438.3(i)(3)(iv) to also allow a percentage of a verifiable dollar amount in the contract, as an alternative to a specific dollar amount, that can be clearly linked to successful completion of the metrics. We are finalizing the effective date for this provision as the first rating period beginning on or after 1 year after the effective date for the provider incentive changes in §§ 438.3(i), 438.608(e), and the existing cross-references at § 457.1200(d) for separate CHIP. The finalized revisions to § 438.3(i)(3)(iii) and (iv) are equally applicable to separate CHIP through the existing cross-reference at § 457.1201(h).

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

The preamble to the HHS Notice of Benefit and Payment Parameters for 2023 that adopted the updates to the private market regulations that took effect on July 1, 2022, noted 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 27350). Therefore, to provide further clarity on the types of costs that may be included in MLR calculations, CMS modified the private market MLR regulations for QIA expenditures in 45 CFR 158.150(a) to specify that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting and rebate calculation purposes.

In Medicaid and separate CHIP regulations at §§ 438.8(e)(3) and 457.1203(c) respectively, we permit the inclusion of QIA expenses for activities that meet the private market MLR requirements, but we did not include language specifying that managed care plans may only include expenditures directly related to activities that improve health care quality when reporting QIA costs for MLR purposes in order to align with the private market regulations. As a result, the current Medicaid MLR regulations do not explicitly require managed care plans to exclude indirect or overhead QIA

expenditures. Because the Medicaid regulation did not expressly disallow indirect or overhead QIA expenditures, we did not challenge States or Medicaid or CHIP managed care plans when these types of costs were included as QIA costs in the MLR numerator, which could result in inappropriately inflated MLRs as well as a different standard existing in the private market and Medicaid and CHIP. This difference in standards could pose a potential administrative burden for managed care plans that participate in Medicaid, CHIP and the private market because managed care plans and issuers may include different types of expenses in reporting QIA.

To align Medicaid and CHIP MLR QIA reporting requirements with the private market requirements and to improve clarity on the types of QIA expenditures that should be included in the MLR numerator, we proposed 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 private market regulation that specifies that only those expenses that are directly related to health care quality improvement activities may be included in the MLR numerator. This change will provide States with more detailed QIA information to improve MLR reporting consistency, allow for better MLR data comparisons between the private market and Medicaid and CHIP markets, and reduce administrative burden for managed care plans that participate in Medicaid, CHIP and the private market. We proposed that these requirements will 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. We sought comment on the applicability date for these proposals.

We summarize and respond to public comments received on Prohibited Costs in Quality Improvement Activities (§§ 438.8(e)(3) and 457.1203(c)) below.

Comment: Many commenters supported the proposed exclusion of administrative costs in QIAs and alignment with private market regulations. Commenters noted that this alignment will promote consistency and equity across Federal health programs and will ensure an MLR calculation that more closely reflects the true value of services delivered.

Response: We agree that this alignment will result in more accurate MLR calculations and improve the value of managed care plans for Medicaid and CHIP beneficiaries.

Comment: Several commenters urged CMS to review how managed care plans are categorizing their utilization management expenses. These commenters noted that utilization management activities are often undertaken with the primary purpose to contain costs and encouraged CMS to set clear guardrails around when, if ever, such activities can be categorized as QIA.

Response: We agree with the commenters that certain utilization management activities are designed to contain costs rather than improve quality. To that end, under current regulations at §§ 438.8(e)(3)(i) and 457.1203(c), Medicaid and CHIP managed care plans cannot include in QIA any prospective or concurrent utilization management costs or any retrospective utilization management costs that do not meet the definition of QIA in 45 CFR 158.150. We remind States that they are required to monitor all managed care programs per § 438.66, including the QIA expenditures reported by managed care plans to determine if any of the reported expenditures have the primary goal of cost containment and should be excluded from the MLR numerator as QIA. States should also ensure that where managed care plans report all expenses from any given cost center as QIA, to the extent the cost center also performs non-QIA functions, only those qualifying expenses are included in the numerator. In such cases, the State should ensure that the managed care plan provides the State with documentation, such as time studies, showing how it determined the portion of time that staff expended on QIA programs versus non-QIA programs. In the future, our Federal MLR reviews of State Medicaid programs will also specifically examine State oversight practices for the review of utilization management expenses in QIA.

Comment: Several commenters requested that we allow health equity accreditation costs in QIA.

Response: Medicaid and CHIP managed care plans are currently permitted under §§ 438.8(e)(3)(i) and 457.1203(c) respectively, to include the costs associated with accreditation fees that are directly related to the quality of care activities in 45 CFR 158.150(b). The private market MLR regulations in 45 CFR 158.150(b)(2)(i)(A)(5) specifically note “accreditation fees directly related to quality of care activities” as

permissible QIA expenditures. Therefore, if a health equity activity that requires accreditation meets the definition of QIA at 45 CFR 158.150, such accreditation costs can be reported as QIA expenses under §§ 438.8(e)(3)(i) and 457.1203(c).

Comment: Several commenters requested alignment with Medicare QIA regulations, rather than the private market MLR regulations governing QIA, particularly for those plans serving beneficiaries that are eligible for both Medicare and Medicaid. The commenters stated that alignment with the Medicare Advantage regulations would better streamline and align program requirements for dually eligible beneficiaries. In addition, one commenter noted that CMS recently published a request for information for an integrated MLR for integrated dual eligible special needs plans (D-SNPs)¹⁷⁴ and recommended that CMS develop a prototype for a Medicaid-Medicare aligned model MLR.

Response: The proposed alignment with the private market MLR regulations governing QIA reflects the historical alignment of other Medicaid MLR regulations with private market MLR regulations. This proposed change does not affect Medicare MLR reporting for plans that serve individuals who are eligible for both Medicare and Medicaid. Those managed care plans should continue to report their Medicare MLR consistent with the Medicare regulations. We continue to review MLR reporting across CMS programs for potential opportunities to further align policies where such alignment makes sense based on how Medicaid and CHIP managed care plans operate compared to Medicare Advantage organizations and private market issuers.

Comment: Many commenters requested more detail and definitions about the types of overhead and indirect costs prohibited for QIA. A commenter noted that some managed care plans may have implemented QIAs that have associated administrative costs, such as a QIA that provides vouchers for culturally acceptable nutritious food that supports diabetes management and nutritional health. This commenter indicated that administrative expenditures for these types of QIAs that are part of quality improvement plan goals should be allowed in the MLR. One commenter noted that CMS

should provide guidance if a managed care plan cannot report overhead expenses for QIA.

Response: In the proposed and finalized QIA changes, we did not delineate between QIAs used as part of quality improvement plan goals and other types of QIAs to ensure consistency in MLR reporting and to align with the private market MLR regulations. We decline to specify the types of administrative costs that would be prohibited for QIA in the regulation as those types of costs are numerous, and providing a list of prohibited costs in the regulation could lead to the inappropriate inclusion of costs that were not specified in the regulation. Many examples of inappropriate administrative costs were provided in the HHS Notice of Benefit and Payment Parameters for 2023 final rule preamble and include office space (including rent or depreciation, facility maintenance, janitorial, utilities, property taxes, insurance, wall art), human resources, salaries of counsel and executives, computer and telephone usage, travel and entertainment, company parties and retreats, IT systems, and marketing of issuers’ products (87 FR 27351). In the example provided by the commenter, if the administrative expenses referred to fall into any of these categories, then the expenses cannot be included in QIA.

If a managed care plan indicates that it cannot separate indirect or overhead expenses for QIA, the State should disallow the entirety of QIA expenditures in the MLR. We remind States they are required to monitor managed care programs per § 438.66, which should include developing oversight processes along with managed care plan reporting tools to identify overhead and indirect expenses inappropriately reported as QIA expenditures.

Comment: Several commenters noted that although salaries and non-salary benefits are usually considered administrative costs, these costs should be allowable in the MLR as QIA expenditures. One commenter specified that salary and benefit costs for staff who are directly responsible for QIA should be allowed as QIA expenditures.

Response: We agree with the commenters that salary and non-salary benefits of employees performing QIA functions are directly tied to QIA, and we consider the salary costs, as well as the costs of the employee benefits to be direct QIA expenses. We take this opportunity to clarify that since §§ 438.8(e)(3) and 457.1203(c) were finalized in the 2016 final rule, Medicaid and CHIP managed care plans have been able to include the portion of

¹⁷⁴ We summarized and responded to public comments at pages 27776 through 27778 at <https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and>.

salaries and non-salary benefits that are part of a compensation package for staff performing QIAs that is attributable to QIAs in the MLR. The revision finalized at § 438.8(e)(3) does not change that, it only prohibits managed care plans from including as QIA fixed costs and other administrative costs that provide no benefit to enrollee health.

We understand that salary and benefit costs for staff who are performing the QIAs make up a substantial portion of QIA expenditures as these staff may spend all or part of their time working on QIA. However, such costs may only be included up to the amount that reflects the percentage of the employees' time actual spent on QIA. Managed care plans that report these costs as QIA should take care to both document and retain records supporting the amount(s) reported and the determination of what portion of these costs are a direct QIA expense. This question was also addressed for health insurance issuers subject to the private market MLR requirements in the HHS Notice of Benefit and Payment Parameters for 2023 (87 FR 27351).

Comment: One commenter noted that some administrative costs related to QIA implementation should be allowed because disallowing these types of costs could make plans less likely to implement QIAs.

Response: We disagree that prohibiting indirect or administrative costs in QIA will make managed care plans less likely to implement QIAs. We note that the proposed and finalized regulation prohibits managed care plans from allocating fixed costs that would, for the most part, exist even if the managed care plan did not engage in any QIA. That is, many administrative costs such as office space, human resources, and computer use would exist even if the managed care plan did not undertake QIA.

Comment: One commenter noted that undertaking QIA unavoidably adds administrative costs to the business or service line. The commenter noted that disallowing costs that are reasonably related or incidental to QIA could lead to understating the portion of the capitation rate for QIA. The commenter noted they believe that the QIA portion of the capitation rate may be set too low if most administrative costs were excluded from QIA, and therefore, managed care plans may have less incentive to perform QIA.

Response: We disagree with the commenter that implementing QIA requires incurring unavoidable administrative costs as many indirect costs such as office space and human resources would be incurred even if the

managed care plan did not implement QIA. We disagree that prohibiting administrative costs such as office space or marketing, which do not provide direct benefit to enrollee health, in QIA would lead to incorrect QIA capitation rate setting. If costs that do not provide direct benefit to enrollee health are included in QIA rate setting, the portion of the capitation rate for QIA will be set too high and the resulting managed care capitation rates will be inappropriately inflated.

Comment: One commenter requested examples of computer software that would be considered indirect expenses, and therefore, would not qualify as QIA.

Response: Sections 438.8(e)(3)(iii) and 457.1203(c) provide that MCO, PIHP, or PAHP expenditures that meet the requirements related to Health Information Technology (HIT) in the private market MLR regulations at 45 CFR 158.151 would qualify as QIA expenditures. The proposed and finalized amendment to § 438.8(e)(2) does not modify the specification of HIT as outlined in 45 CFR 158.151. We affirm that HIT expenses that meet the applicable requirements in 45 CFR 158.151 are permissible costs that can be included as QIA expenses under §§ 438.8(e)(3)(iii) and 457.1203(c). For example, the cost of software designed and used primarily for QIA purposes such as Healthcare Effectiveness Data and Information Set (HEDIS) reporting, constitutes a direct expense related to activities that improve health care quality and can be included in QIA expenses for MLR reporting. In contrast, the costs of information technology infrastructure that primarily support regular business functions such as billing, enrollment, claims processing, financial analysis, and cost containment, do not constitute a direct expense related to activities that improve health care quality and cannot be included in QIA expenses for MLR reporting purposes. A similar comment was also addressed in the HHS Notice of Benefit and Payment Parameters for 2023 (87 FR 27351).

Comment: One commenter stated that the proposed QIA changes should not be finalized until CMS determines that the changes would not make VBP arrangements more difficult to implement in Medicaid managed care.

Response: The commenter did not provide any reasons as to why the proposed changes to QIA in the Medicaid MLR regulations would make VBP implementation more difficult. We do not believe that the proposed and finalized QIA change will make it more difficult for States and managed care plans to implement VBP. As one goal of

VBP is to reduce excessive health spending and growth by limiting administrative waste,¹⁷⁵ we believe that the changes finalized in this rule at §§ 438.3, and 457.1203 are very much aligned with the goals of VBP.

Comment: We received several comments related to including expenditures for activities related to social determinants of health (SDOH) and health-related social needs (HRSN) in the MLR. Commenters noted that these specific types of expenditures should be included in the numerator of the MLR, including community health worker quality improvement activities, activities related to SDOH, and managed care plan activities for the coordination of social services to address SDOH, as well as ILOSs at § 438.3(e)(2).

Response: We provided guidance related to the inclusion of expenses for activities to address SDOH in the MLR in a State Health Official Letter dated January 7, 2021,¹⁷⁶ that is also relevant for HRSN expenses. We provide a summary of the guidance here and encourage States and managed care plans to review the original guidance as it contains many examples of activities to address SDOH.

States may use incentive payments arrangements to reward managed care plans that make investments and/or improvements in SDOH. These payments must align with performance targets specified in the managed care plan contract, including implementation of a mandatory performance improvement project under § 438.330(d) that focuses on factors associated with SDOH, and comply with Federal requirements at § 438.6(b)(2). These incentive arrangements represent additional funds over and above the capitation rates. Managed care plan contract payments that incorporate incentive arrangements may not exceed 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement. In the 2016 managed care rule (81 FR 27530), we specified that incentive arrangements made to the managed care plan in accordance with § 438.6(b)(2) should not be included in the denominator of the MLR as such payments are in addition to the capitation payments received under the contract.¹⁷⁷

¹⁷⁵ Value-Based Payment As A Tool To Address Excess US Health Spending, "Health Affairs Research Brief, December 1, 2022.DOI: 10.1377/hpb20221014.526546.

¹⁷⁶ https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.

¹⁷⁷ https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.

In the 2016 final rule (81 FR 27537), we clarified that services approved under a waiver (for example, sections 1915(b)(3), 1915(c), or 1115 of the Act) are considered State plan services for purposes of MLR requirements and are encompassed in the reference to State plan services in § 438.3(c). Therefore, if services to address SDOH are approved under these waiver authorities for the State Medicaid program, and the services are included in the managed care contract, then the covered services must necessarily be incorporated in the numerator of a plan's MLR. Additionally, States may develop and implement specific managed care plan procurement and contracting strategies to incentivize care coordination across medical and nonmedical contexts, including to address SDOH. Per recently issued guidance, Medicaid-covered HRSN services must be integrated with existing social services and housing services.¹⁷⁸ If managed care plans implement SDOH activities that meet the requirements in 45 CFR 158.150(b) and are not excluded under 45 CFR 158.150(c), managed care plans may include the costs associated with these activities in the numerator of the MLR as activities that improve health care quality under § 438.8(e)(3).¹⁷⁹

Under the 2016 final rule (81 FR 27526), we also clarified that all services under § 438.3(e), including approved in lieu of services and settings, at § 438.3(e)(2), can be considered as incurred claims in the MLR numerator. Under § 438.3(e)(1), a managed care plan may voluntarily cover, for enrollees, services that are in addition to those covered under the State plan. These services are often referred to as value-added services, and the cost of these services may not be included in the capitation rate; however, as outlined in the 2016 final rule (81 FR 27526), value-added services can be considered as incurred claims in the numerator for the purposes of the MLR calculation if the services are activities that improve health care quality under 45 CFR 158.150 and are not excluded under 45 CFR 158.150(c).

After reviewing public comments, we are finalizing §§ 438.8(e)(3) and 457.1203(c) as proposed.

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 private market, 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.¹⁸⁰ 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 accurately reported or inappropriately inflated.

The private market MLR regulations at 45 CFR 158.170(b) require significantly more detail for expense allocation in issuer's MLR reports. 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 allocate these expenses. We proposed 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 in the MLR report that they submit to the State that reflects the same information required under private market requirements at § 158.170(b). Specifically, in § 438.8(k)(1)(vii), we proposed 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 proposed 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 also align with private market regulations and reduce administrative burden for managed care plans operating across multiple markets. We proposed 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. We sought comment on this proposal.

We summarize and respond to public comments received on Additional Requirements for Expense Allocation Methodology (§§ 438.8(k)(1)(vii) and 457.1203(f)) below.

Comment: Several commenters supported the proposed changes to expense allocation methodology reporting. Commenters noted that these changes will clarify the underlying elements of MLR calculations to address potentially inaccurate or inflationary MLR calculations and produce more reliable reports.

Response: Given that a recent state-level Medicaid MLR review¹⁸¹ found that many MLR reports from managed care health plans did not contain information about expense allocation methodologies, we believe the proposed and finalized changes to the regulation will improve expense allocation reporting from managed care plans.

Comment: One commenter noted that the proposed new reporting requirements imposed significant burdens on plans that serve dually

¹⁷⁸ https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.

¹⁷⁹ https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.

¹⁸⁰ See Completed MLR audit reports at: <https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reports-guidance>.

¹⁸¹ <https://www.cms.gov/files/document/oregon-medicaid-managed-care-medical-loss-ratio-report.pdf>.

eligible beneficiaries in fully integrated dual eligible special needs plans (FIDE SNPs).

Response: We do not believe that the proposed reporting requirements will impose new or significant burdens on managed care plans serving dually eligible beneficiaries as those types of managed care plans are currently required to allocate certain types of costs across lines of business as part of MLR reporting. The proposed change requires managed care plans to provide additional detail about how the plans allocate expenses across lines of business for MLR reporting; it does not require plans to report new types of expenses, nor does it change how costs should be allocated across lines of business.

Comment: One commenter noted that some managed care plans may have a “delegated model” where subcontractors are paid using capitated payment arrangements. The commenter noted they believe that managed care plans that use these types of arrangements will have significant difficulty with the proposed reporting requirements as medical and non-medical expenditures cannot be easily reported separately.

Response: We disagree that the proposed changes will burden managed care plans using a “delegated model” as Medicaid and CHIP requirements for delegation to subcontractors were finalized in the 2016 Managed Care rule at §§ 438.230(c)(1) and 457.1201(i) respectively and have been known to States and managed care plans since that time. We also published guidance in 2019 to assist States and managed care plans in MLR reporting when subcontractor arrangements were used by the managed care plan.¹⁸² In this guidance, we noted that “when a managed care plan subcontractors with a third-party vendor to administer, and potentially provide, a portion of Medicaid covered services to enrollees, the subcontractor must report to the managed care plan all of the underlying data needed for the Medicaid managed care plan to calculate and report the managed care plan’s MLR.” To correctly calculate the MLR, the required underlying data would need to separate medical and non-medical expenditures. Given that the subcontractor regulations and related guidance in this area have been available for several years, we would expect all managed care plans to be complying with MLR reporting

requirements for subcontractor arrangements.

Comment: Several commenters requested that we provide preferred expense allocation methodologies for income taxes and other types of expenditures to promote more consistency in MLR calculations. One commenter noted that the Medicare Advantage MLR reporting instructions provide detail on income tax expense allocation methods unlike those for issuers offering group or individual health insurance coverage and Medicaid managed care plans.

Response: We respectfully disagree with the commenter that the Medicare Advantage MLR reporting instructions provide detail on income tax expense allocation methods. Neither the private market nor the Medicare MLR regulations provide methodologies for the allocation of specific types of expenditures, including income taxes. The private market MLR instructions reference to the National Association of Insurance Commissioners (NAIC) Statements of Statutory Accounting Principles (SSAP) and Supplemental Health Care Exhibit (SHCE) in effect for the MLR reporting year.¹⁸³ The instructions note that “[t]hese references are solely for the convenience of the filer in identifying the information needed for this MLR form.”¹⁸⁴ Similarly, the Medicare Advantage 2013 final rule references the use of Statutory Accounting Principles to align with the commercial MLR expense allocation requirements but does not specify methods for expense allocation; the preamble notes that MA organizations should “allocate the expense to that particular activity” or use “a generally accepted accounting method that yields the most accurate results.” (78 FR 31293) We decline to provide recommendations for specific expense allocation methodologies in regulation as neither the private market nor the Medicare regulations specify this detail. As noted in the preamble of the proposed rule, we aim to remain aligned with the private market MLR regulations to the extent possible (88 FR 28154). Specifying a method of allocating income taxes is also complicated by the fact that many issuers and managed care plans are affiliated, and taxes are filed at the holding company or parent level pursuant to an inter-company tax allocation agreement. Thus, prescribing the most accurate tax expense allocation methodology in the Medicaid regulation would be nearly impossible. In addition,

as State Medicaid programs are unique, States are in the best position to develop oversight strategies and guidance for managed care plan financial reporting, including methods for income tax expense allocation.

Comment: One commenter stated that the proposed changes for expense allocation methodologies should not be finalized until CMS determines that the changes would not make VBP arrangements more difficult to implement in Medicaid managed care.

Response: The commenter did not provide any reasons as to why the proposed changes to the Medicaid MLR expense allocation regulations would make VBP implementation more difficult. We do not believe that the proposed and finalized changes for expense allocation will make it more difficult for States and managed care plans to implement VBP. As one goal of VBP is to reduce excessive health spending and growth by limiting administrative waste,¹⁸⁵ we believe that the changes finalized in this rule at §§ 438.8, and 457.1203 are very much aligned with the goals of VBP.

Comment: A few commenters requested additional time for implementation and suggested that CMS not require managed care plans to comply with §§ 438.8(k)(1)(vii) and 457.1203(f) until the rating period beginning on or after 60 days after the effective date of the final rule.

Response: Although providing this level of detail related to expense allocation methods may be new for some managed care plans, we do not believe that it is particularly burdensome or that managed care plans need additional time for implementation. We point out that the effective date of the rule will be 60 days after publication in the **Federal Register**.

After reviewing the public comments, we are finalizing §§ 438.8(k)(1)(vii) and 457.1203(f) as proposed.

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 calculation for the MLR applicable to the private market, and to address the special circumstances of smaller plans.

¹⁸² <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib051519.pdf>.

¹⁸³ See, for example, <https://www.cms.gov/files/document/2022-mlr-form-instructions.pdf>.

¹⁸⁴ *Ibid*.

¹⁸⁵ Value-Based Payment As A Tool To Address Excess US Health Spending, “Health Affairs Research Brief, December 1, 2022.DOI: 10.1377/hpb20221014.526546.

The NAIC model regulation allows smaller plans in the private market 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 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 proposed 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 will use the methodology specified at § 438.8(h)(4)(i) through (vi). We did not propose any revisions to § 438.8(h)(4)(i) through (vi) in this rule. We proposed that these changes will be effective 60 days after the effective date of this final rule as we believe this timeframe is reasonable. We sought comment on this proposal.

We summarize and respond to public comments received on Credibility Factor Adjustment to Publication Frequency (§§ 438.8(h)(4) and 457.1203(c)) below.

Comment: One commenter requested CMS to clarify if credibility factors will be reviewed on a regular basis even if they are not published annually.

Response: We understand the importance of credibility factors to smaller managed care plans’ MLR calculations and commit to review them on a regular basis and publish updates if the factors change. If we determine that the factors need to be updated, we will use the methodology specified at § 438.8(h)(4)(i) through (vi).

After reviewing the public comments, we are finalizing § 438.8(h)(4) as proposed.

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 will 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.

We proposed 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 will only be required to resubmit an MLR report to the State when the State makes a retroactive change to capitation rates. Specifically, we proposed to replace “payments” with “rates” and to insert “retroactive rate” before the word “change.” We proposed that these changes will be effective 60 days after the effective date of this final rule as we believe this timeframe was 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. We sought comment on this proposal.

We summarize and respond to public comments received on MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (§§ 438.8(m) and 457.1203(f)) below.

Comment: Several commenters opposed our proposal to modify § 438.8(m). These commenters opposed the proposed changes as they believed that retroactive eligibility determinations could have a significant impact on the MLR report calculation.

Response: After further consideration of these comments, as well as States’ restarting of the eligibility redetermination process, we believe that the retroactive eligibility process that adjusts the number of capitation payments to plans may involve many individuals and could significantly affect the accuracy of the MLR calculations. After consideration of public comments and reconsideration of the impact of the restarting of the Medicaid and CHIP eligibility redetermination process, we have determined that by restricting managed care plan MLR resubmissions to when States make capitation rate changes, the MLRs may not be accurate. Therefore, we will not finalize proposed § 438.8(m).

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 proposed 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 will have to be reported for each managed care plan, we proposed in § 438.74(a)(1) to replace “the” with “each” before “report(s).” In addition, in § 438.74(a)(2), we proposed 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 will specify that States must provide MLR information for each managed care plan in their annual summary reports to CMS. We proposed that States and managed care plans will 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. We sought comment on this proposal.

We summarize and respond to public comments received on Level of MLR Data Aggregation (§§ 438.74 and 457.1203(e)) below.

Comment: Numerous commenters supported the proposed requirement for States to provide MLR reports at the managed care plan level, and CMS received no comments opposing the proposal. One commenter supported the

proposed applicability date of 60 days after the effective date of the final rule, and we received no comments opposing the proposed timeline.

Response: We thank the commenters for their support of the proposed changes to specify the level of data aggregation required for State summary MLR reporting to CMS and the applicability date.

After reviewing the public comments, we are finalizing §§ 438.74 and 457.1203(e) as proposed.

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 a Medicaid managed care plan’s 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.

We proposed 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 will 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, managed care programs, and FFS.

CMS’s 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” will 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 proposed 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 believed 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 will be better equipped to: direct managed care plans to look for specific network provider issues, identify and recover managed care plan and FFS claims that are known to be unallowable, take corrective actions to correct erroneous billing practices, or consider a potential law enforcement referral.

We solicited public comments 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 proposed that States and managed care plans will 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. We sought comment on this proposal.

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

The overpayment reporting provisions in 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 will 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, in our May 3, 2023, proposed rule, we proposed 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 will 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 will be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the contract. We proposed that States and managed care plans will 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. We solicited comments on this proposal. We summarize and respond to public comments received on Contract Requirements for Overpayments (§§ 438.608(a)(2) and (d)(3), and 457.1285) below.

Comment: Several commenters opposed the proposal regarding the effective date of the proposed requirements at § 438.608(a)(2) and (d)(3). One commenter suggested delaying implementation of the rule to align with the next rate certification or contract submission date, instead of 60 days after the rule is finalized. Other commenters requested a minimum of 1 year, rather than 60 days.

Response: We considered these comments when finalizing the effective date of the new requirements for the prompt reporting of overpayments in § 438.608(a)(2) and (d)(3). We acknowledge that 60 days may not be long enough for CMS to provide any needed guidance to States, or for States to engage with managed care plans and update contract language. After considering the public comments, we are finalizing a revised effective date of the first rating period beginning on or after 1 year from the effective date of this final rule to provide States sufficient time to complete the necessary actions to come into compliance with these requirements.

Comment: One commenter supported our proposed 10 business days timeframe for “promptly” reporting overpayments under § 438.608(a)(2). However, many commenters recommended a longer timeframe for “promptly” reporting overpayments, indicating that 10 business days is not

enough time due to operational concerns. Several commenters suggested a 30-day or monthly cadence for “prompt” reporting to States, while other commenters suggested lengthier reporting timeframes, such as a 60-day, quarterly, or semi-annual cadence.

Response: We continue to believe that rapid reporting by managed care plans about identified or recovered overpayments is critical to enable 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. However, after considering the public comments, we acknowledge that a slightly longer timeframe to report can still provide States with prompt awareness of overpayments while providing managed care plans additional time to investigate overpayments and determine whether they are due to potential fraud or other causes, such as billing errors. Therefore, we are finalizing a revised proposal at § 438.608(a)(2) that States shall require managed care plans to report identified or recovered overpayments within 30 calendar days from the date of identification or recovery of an overpayment. We believe that 30 calendar days achieves the appropriate balance of addressing some commenters’ concerns and maintaining the intent of “prompt” reporting of identified or recovered overpayments. While we are finalizing “prompt” reporting as within 30 calendar days, States still retain the flexibility to require managed care plans to report overpayments within a shorter timeframe.

Comment: Several commenters suggested aggregated or batched reporting instead of reporting each identified or recovered overpayment to the State. One commenter recommended reporting this on a routine basis, such as monthly or bimonthly, to avoid excessive notifications, as well as establish a cadence in which State could expect to receive reports. Another commenter recommended that the reporting be part of the managed care plan’s and/or Risk Bearing Organization (RBO)’s normal quarterly financial reporting to the payer and/or regulator.

Response: We appreciate the comments on the allowable method of reporting. However, defining the method through which reporting of identified or recovered overpayment must be done, including the use of batched or other reporting mechanisms, is outside the scope of our proposal to define “prompt” reporting as within 10

business days. States maintain flexibility to determine the manner with which managed care plans report so long as it meets the finalized requirement that identified or recovered overpayment(s) be reported within 30 calendar days from the date it was identified or recovered.

Comment: One commenter suggested that while it might be reasonable to require reporting of an overpayment identified during an investigation to the State within 10 business days, it would not be feasible to require that investigation be completed within 10 days of identification.

Response: Our proposal does not include that an investigation must be completed in any amount of time. We stated in the proposed rule that our proposal of 10 business days would be sufficient time to begin an investigation and determine whether overpayments are due to potential fraud or other causes, such as billing errors. Also, as described above, after consideration of public comments, we are finalizing that States require managed care plans to report identified or recovered overpayments within 30 calendar days from the date of identification or recovery of an overpayment, specifying the overpayments due to potential fraud. This does not also require that an investigation be completed within that 30-calendar day timeframe.

Comment: Commenters sought clarification regarding the definition or interpretation of several terms within § 438.608(d)(3). Some commenters requested guidance to clearly define “identified overpayment” as compared to an allegation of fraud, waste, abuse, or other provider misconduct. Another commenter requested clarification about whether MCOs must separately report overpayments when they are both identified and when/if they are eventually recovered. One commenter supported the broad interpretation of “overpayments,” which may be the result of fraud, waste, abuse, or other billing errors, while other commenters suggested changes related to the reporting of any overpayments. One commenter suggested that an “overpayment” should not be considered “identified” until there is an actual claim paid and/or a final dollar value is determined. Another commenter suggested limiting reporting requirements to overpayments that rise above a de minimis percentage of the total claim amount to minimize administrative burden. Another commenter suggested either removing the word “all” from the language or allowing reporting of overpayments related to claim adjustments,

Coordination of Benefits/Third Party Liability, error, and retroactive member disenrollment on a less frequent basis. One commenter suggested that CMS should allow managed care plans to apply direct costs for identifying, mitigating, and recovering overpayments in the MLR numerator.

Response: With regard to the commenters’ request for clearly defined guidance on “identified overpayment” as compared to an allegation of fraud, waste, abuse, or other provider misconduct under revised § 438.608(d)(3), this is out of the scope of the proposed overpayment reporting requirements. States maintain flexibility to determine the scope of “identified overpayments,” and we encourage States to work with their managed care plans to ensure these terms are clearly and consistently defined in the contracts.

For the commenters’ request for clarification about whether a managed care plan must separately report overpayments when the payments are both identified and when/if they are eventually recovered, these overpayments must be separately reported. As stated in the proposed rule, the omission of the words “identified or” from § 438.608(d)(3) 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. 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. The 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 Medicaid capitation rates as required under § 438.608(d)(4). As such, our intent is that any overpayment (whether identified or recovered) must be separately reported by Medicaid or CHIP managed care plans to the State. Through this final rule, 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 of 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 managed care plan contract.

With regard to the commenter's suggestion about limiting the reporting of overpayments to overpayments that rise above a de minimis percentage of the total claim amount to reduce administrative burden, we believe this is outside the scope of our proposal, as we did not propose a threshold for which overpayments must be reported under § 438.608(d)(3). The previous regulation at § 438.608(d)(3) required managed care plans to report recovered overpayments to the State and did not establish a certain threshold for such reporting. While our proposal specifically added the term "all" when referring to reported overpayments, our proposal sought to clarify what was previously implied, that all overpayments should be reported. As stated in the 2016 final rule, a requirement to report all overpayments is important to ensure actuarial soundness. For the commenter's comment about either removing the word "all" from the language or allowing reporting of overpayments related to claim adjustments, Coordination of Benefits/Third Party Liability, error, and retroactive member disenrollment on a less frequent basis, we also believe this is outside the scope of this proposal, as described above. Similarly, with regard to the commenter's suggestion that CMS should allow managed care plans to apply direct costs for identifying, mitigating, and recovering overpayments in the MLR numerator, this is outside the scope of this proposal.

Comment: Commenters requested that CMS confirm whether NEMT PAHPs are excluded from reporting overpayments.

Response: We appreciate the commenters' request for clarification. Requirements at §§ 438.9 and 457.1206 outline the provisions of 42 CFR part 438 subpart H and part 457 subpart L, respectively, that apply to NEMT PAHPs. Because the reporting of overpayments requirements at § 438.608 are not included in the provisions that apply to NEMT PAHPs, these provisions do not apply to NEMT PAHPs, and we are removing reference to NEMT PAHPs from these provisions in this final rule.

Comment: One commenter requested that CMS provide guidance regarding situations where a third-party should review overpayments.

Response: We believe this proposed clarifying guidance is outside the scope this final rule. We encourage managed care plans to work closely with States to gain a clear understanding of expectations and contractual requirements around identifying overpayments.

After consideration of public comments, we are finalizing our proposals for overpayments in revised § 438.608(a)(2) and (d)(3). However, we are modifying our proposal that States require managed care plans to define "prompt" as within 10 business days of identifying or recovering an overpayment. We are instead finalizing in revised § 438.608(a)(2) that States require managed care plans to define "prompt" as within 30 calendar days of identifying or recovery an overpayment. This revision is also applicable to separate CHIP via an existing cross-reference at § 457.1285. We believe 30 calendar days will provide a managed care plan sufficient time to investigate an overpayment and determine whether the overpayment is due to potential fraud or other causes, such as billing errors, and provide States with awareness to mitigate other potential overpayments across its networks, managed care programs, and FFS. With a clear and consistent overpayment reporting requirement, States will be better equipped to direct managed care plans to look for specific network provider issues, identify and recover managed care plan and FFS claims that are known to be unallowable, take corrective actions to correct erroneous billing practices, or consider a potential law enforcement referral. We reiterated that nothing in this final rule would prohibit a State from setting a shorter timeframe than 30 calendar days for reporting of overpayments.

We are also finalizing our proposal in § 438.608(d)(3) for Medicaid and separate CHIP managed care programs (through an existing cross-reference at § 457.1285), to clarify that all overpayments (identified or recovered) must be reported by Medicaid or CHIP managed care plans annually to the State. We believe this change will provide managed care plans and States with more consistency in the overpayment reporting requirements at § 438.608(a)(2) and (d)(3) by requiring reporting of all overpayments, whether identified or recovered, to the States. By ensuring both identified and recovered overpayments are reported, States and CMS will be more assured that capitation rates account for only reasonable, appropriate, and attainable costs covered under the contract.

To address an error in the proposed rule, we are removing reference to the applicability of the overpayment reporting requirements at §§ 438.608(a)(2) and (d)(3) to NEMT PAHPs, as these plans are excluded from these regulatory provisions under existing §§ 438.9 and 457.1206.

Finally, we are modifying our proposals regarding the effective date of beginning on or after 60 days following the effective date of the final rule for both revisions to § 438.608(a)(2) and (d)(3). Instead, we are finalizing an effective date of the first rating period beginning on or after 1 year from the effective date of this final rule.

h. Reporting of SDPs in the Medical Loss Ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), 438.74, 457.1203(e) and 457.1203(f))

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 OIG, and GAO, and other interested parties including MACPAC, have authored reports focused on CMS oversight of SDPs.^{186 187 188 189} 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.2. of this final rule, CMS's 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 arrangements¹⁹⁰ nor do we review the

¹⁸⁶ 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>.

¹⁸⁷ 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>.

¹⁸⁸ U.S. Government Accountability Office, "Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency," December 14, 2023, available at <https://www.gao.gov/products/gao-24-106202>.

¹⁸⁹ 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>.

¹⁹⁰ As CMS does not routinely perform this review, the current requirements for separate payment terms outlined in the Medicaid managed care rate guide requires States to (1) submit documentation to CMS that includes the total

actual amounts that managed care plans pay to providers. CMS requires States to provide an estimated total dollar amount that will be included in the capitation rates for the SDP arrangement.¹⁹¹ However, States are not required to report to CMS on the actual expenditures associated with these arrangements in any separate or identifiable way after the rating period has closed and claims are adjudicated. On a limited basis, we perform in-depth State-level medical loss ratio (MLR) 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 proposed 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 proposed 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 proposed 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.

We believe these proposals and our responses to comments should be discussed in the context of the other proposed SDP reporting requirements to

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.

¹⁹¹ <https://www.medicaid.gov/medicaid/managed-care/downloads/sdp-4386c-preprint-template.pdf>.

support oversight (see section I.B.2.o. of this final rule for comments and our proposed revisions to §§ 438.8(e)(2)(iii)(C) and (f)(2)(vii), 457.1203(e), 438.8(k)(1)(xiv) through (xvi), 438.74(a)(3) through (4)).

4. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.7, 438.16, 438.66, 457.1201 and 457.1207)

a. Overview of ILOS Requirements (§§ 438.2, 438.3(e), 438.16, 457.10, 457.1201(c) and 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 proposed rule, 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 for 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, and CMS will not approve contracts in accordance with § 438.3(a) that include an ILOSs that does not meet standards in regulatory requirements.

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, 2021,¹⁹² January 4, 2023,¹⁹³ and November 16, 2023¹⁹⁴ respectively, ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address SDOH and HRSNs. The use of ILOSs can also improve population health, reduce health inequities, and lower overall health care costs in Medicaid and CHIP. 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 (less than 3 meals per day) as an ILOS may improve health outcomes and facilitate greater access to HCBS, thereby preventing or delaying enrollees' need for nursing facility care. We encouraged 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 expected 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 acknowledged 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 ILOSs which are alternative services and settings not covered in the State plan. Therefore, we proposed to revise the regulatory

¹⁹² <https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf>.

¹⁹³ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf>.

¹⁹⁴ <https://www.medicaid.gov/sites/default/files/2023-11/cib11162023.pdf>.

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 proposed 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 proposed 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 proposed several conforming changes in § 438.3(e)(2). We proposed 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 proposed 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 proposed 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 proposed 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 of this final rule. 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 made numerous proposals related to ILOSs, we believe adding a cross reference in § 438.3(e)(2)(v) to a new section will make it easier for readers to locate all of the provisions in one place and the designation flexibility of a new section will enable us to better organize the

provisions for readability. To do this, we proposed to create a new § 438.16 titled *ILOS requirements* for Medicaid, and we proposed to amend § 457.1201(c) and (e) to include cross-references to § 438.16 to adopt for separate CHIP. Our proposals in § 438.16 were based on several key principles, described in further detail in sections I.B.4.b. through I.B.4.h. of this final rule. These principles include that ILOSs would: (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 proposed 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. We proposed 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 in § 438.3(a) 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 acknowledged 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 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 proposed no 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 did 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 was excluded from the calculation for an ILOS cost percentage, described in further detail in section I.B.4.b. of this final 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 proposed 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 did 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 did 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 proposed to amend § 457.1201(e) to exclude references to IMDs in the cross-reference to § 438.3(e).

States and managed care plans 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.

We summarize and respond to public comments received in this section on ILOSs (§§ 438.2, 438.3(e), 457.10, 457.1201(c) and (e)) below.

Comment: Many commenters offered widespread support for our proposed ILOS policies as they believe the proposed policy direction and the flexibility to offer expanded ILOSs supported States and managed care plans in their efforts to strengthen access to care, improve enrollee's health care outcomes, and lower overall health care costs in Medicaid and CHIP. Many commenters also supported the proposed definition of an ILOS and stated that this definition appropriately accounted for immediate or longer-term substitutes for a covered service or setting under the State plan, noting that it supports efforts to address enrollees' physical, behavioral, and health-related social needs, improve population health, and advance health equity.

Response: We appreciate the support for the proposed ILOS policies, including the proposed definition of an ILOS. Our goal is to strike the right balance to place appropriate guardrails on the use of ILOSs, to establish clarity and transparency on the use of ILOSs, ensure ILOSs advance the objectives of the Medicaid program, are an appropriate and efficient use of Medicaid and CHIP resources, and are in the best interests of Medicaid and CHIP enrollees while also incentivizing States and plans to use them to improve health outcomes and reduce health care costs.

Comment: Some commenters raised concerns that the additional guardrails and reporting requirements could increase State and plan burden and disincentivize them from expanding ILOSs. A few of these commenters recommended that CMS not finalize the proposed provisions, but rather focus additional oversight only on more novel or non-traditional ILOSs and allow approved ILOSs to continue without additional guardrails.

A few commenters requested additional protections for FQHCs to ensure that ILOSs could not be substituted for FQHC benefits, thereby causing a reduction in an FQHC's

prospective payment system (PPS) or alternative payment methodology (APM) or otherwise reduce payment by other means such as restricting the definition of a billable encounter. Other commenters raised concerns that this definition could stifle managed care plans' ability to innovate and provide timely, person-centered, medically appropriate, and cost effective substitutes. One commenter raised concerns that the definition may require that the ILOS would need to be an immediate "offset" or substitute that reduces or prevents the use of the State plan-covered service or setting and recommended that CMS permit States and managed care plans additional latitude to expand ILOS coverage without a corresponding immediate offset in benefits elsewhere, such as if the plan demonstrates through documented experience or credible academic or other studies, a reasonable expectation that the ILOS will decrease cost and improve outcomes over time.

Response: While we recognize that defining an ILOS will add guardrails, we believe that finalizing a definition of ILOS is vital to ensuring clarity and transparency on the use of ILOSs to ensure appropriate and efficient use of Medicaid and CHIP resources, and that these investments advance the objectives of the Medicaid and CHIP programs. We also believe a definition will assist States in their efforts to determine that each ILOS is a medically appropriate and cost effective substitute for a covered service or setting under the State plan. The ILOS definition finalized in this rule provides flexibility to enable States to consider a longer-term substitute or when the ILOS is expected to reduce or prevent the future need for the State plan service or setting; therefore, an immediate offset or reduction in the State plan-covered service or setting would not always be necessary for a State to consider an ILOS to be medically appropriate and cost effective. We believe that the documentation of previous experience or credible academic studies could potentially be reasonable documentation for a State to consider as it makes its determination. We also do not believe specific protections are needed for FQHCs as the PPS rates are established in accordance with section 1902(bb) of the Act and approved in the State plan while ILOSs are substitutes for State plan-covered services and settings that are offered at the option of managed care plans and utilized by enrollees at their option. This inherent flexibility and unpredictability in the

use of ILOSs is not a factor in the PPS rates approved in the State plan.

Comment: Some commenters requested clarification on what types of services or settings would qualify under the definition of an ILOS. Another commenter requested clarification on whether States would be permitted to offer multiple ILOSs as substitutes for the same State-plan covered service or setting.

Response: We provided several examples of possible ILOSs in the proposed rule, including sobering centers, housing transition navigation services, and medically tailored meals (less than 3 meals per day) (88 FR 28167). Other potential examples could include respite services, asthma remediation, environmental accessibility adaptations (that is, home modifications), and day habilitation programs. Each ILOS must be determined by the State to be a medically appropriate and cost effective substitute for a covered service or setting under the State plan and comply with all applicable Federal requirements. We also direct commenters to section I.B.4.b. of this final rule which has related comments regarding our proposal in § 438.16(b) (cross-referenced at § 457.1201(e) for separate CHIP) that an ILOS be approvable in the State plan or waiver under section 1915(c) of the Act. We also acknowledge that it would be permissible for multiple ILOSs to be substitutes for the same State-plan covered service or setting so long as each ILOS is determined by the State to be a medically appropriate and cost effective substitute for a covered service or setting under the State plan for an appropriate target population.

Comment: One commenter recommended that CMS revise § 438.3(e)(2)(i) to define specific parameters around the scope, duration, and intensity of quality for ILOSs.

Response: We agree with the commenter that as States determine whether an ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan, the scope and duration of an ILOS is a factor States may consider. We also direct commenters to section I.B.4.d. of this final rule where we indicated that States could consider using additional criteria for ILOSs, such as including a limit on the amount of an ILOS to ensure it is medically appropriate and cost effective. We are unclear what the commenter was referring to when they referred to "intensity of quality." Generally, we agree that as States determine the medically appropriateness of an ILOS

that they consider whether an ILOS will improve quality of care and health outcomes. We decline to revise § 438.3(e)(2)(i) to define these specific terms as we believe States should have flexibility to make these determinations as they determine the ILOSs that are medically appropriate and cost effective substitutes for State plan-covered services and settings that best meet enrollees' needs and the target populations for ILOSs. ILOSs will also vary by managed care program given the differing populations and benefits offered, and the fact they are provided at plans' options. As such, we do not believe it is currently reasonable or appropriate for CMS to provide specific definitions for these terms to apply to all ILOSs.

Comment: Several commenters supported the proposed exclusion of 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 IMD from the proposed requirements in § 438.16. Commenters noted that this policy would lessen barriers for States to provide IMD coverage for those in need of these services, and in doing so, increase access to critical behavioral health care.

Response: We continue to believe, particularly with the support of commenters, that the exception of a short term stay in an IMD for inpatient mental health or substance use disorder treatment from the proposed requirements in § 438.16 is appropriate. As a reminder, this exclusion 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 as outlined in §§ 438.3(e)(2) and 438.6(e) respectively.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.2, 438.3(e), 457.10 and 457.1201(c) and (e) as proposed with minor modifications to §§ 438.3(e)(2), (e)(2)(ii) and (e)(2)(iii) to add a comma between "PIHP" and "or PAHP" for consistency with current regulatory text.

b. ILOS General Parameters (§§ 438.16(a) Through (d), 457.1201(c), and (e), and 457.1203(b))

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 proposed several key requirements in § 438.16.

We believe that a limitation on the types of substitute services or settings that could be offered as an ILOS was 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 final 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 proposed 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 the State determines it is a medically appropriate and cost effective substitute for a service or setting covered under the State plan.

For separate CHIP, we similarly proposed 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 proposed 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 reminded 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 final 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-centered 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 FFS 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 proposed 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 proposed 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 the proposed rule, we proposed requirements for State directed payments as a separate payment term, and proposed 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 proposed 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 did not believe it will be consistent with our intent to develop an ILOS cost percentage by aggregating data from more than one managed care program since that will 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 will 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 will 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 was necessary and appropriate for ILOSs. Therefore, we proposed, 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 proposed 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 proposed, in § 438.16(c)(1)(ii), that the State’s actuary will 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 proposed at § 438.16(c)(1)(iii) to require that the projected ILOS cost percentage and the final ILOS cost percentage would 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 will 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 proposed to amend § 457.1201(c) to exclude requirements for certification by an actuary. However, we reminded States that separate CHIP rates must be developed using “actuarially sound principles” in accordance with § 457.1203(a).

We proposed at § 438.16(c)(2), that the projected ILOS cost percentage would be calculated by dividing the portion of the total capitation payments that are 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 proposed, at § 438.16(c)(3), that the final ILOS cost percentage would be calculated by dividing the portion of the total capitation payments that are 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 proposed 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 proposed 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 was 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 acknowledged that the actual plan experience would inform prospective rate development in the future, but it was an inconsistent measure for limiting ILOS expenditures associated with FFP retroactively. We believe expenditures for short term stays in an IMD should 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 initially proposed at § 438.16(c)(1)(iii) that the actuary who certifies the projected ILOS cost percentage should 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.2.1. of the 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 proposed 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.

Under the proposed rule, the proposed denominator for the final ILOS cost percentage, in § 438.16(c)(3)(i), would have been based on the actual total capitation payments and the State directed payments paid as a separate payment term (see section I.B.2.1. of the proposed rule for details on this proposal for separate payment terms) paid by States to managed care plans. We recognized in the proposed rule that calculating the final ILOS cost percentage under this scenario 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 will 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 proposed, 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 CY 2024 rating period will be submitted to CMS with the CY 2027 rate certification. For separate CHIP, we do not require review of capitation rates by CMS and did 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 timelier 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 requested comment on whether our assumption that 1 year is inadequate is correct.

We also believe that it was 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 will enable CMS to review them concurrently. For these reasons, we proposed, 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 did 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 proposed, 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 final rule for developing the ILOS cost percentage for each managed care program. Therefore, in § 438.16(a), we proposed to define a “summary report for actual MCO, PIHP, and PAHP ILOS costs” and proposed that this summary report be calculated for each managed care program that includes ILOSs. We also proposed in § 438.16(c)(1)(ii) that this summary report be calculated on an annual basis and recalculated annually. We proposed 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 proposed 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 did 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 will 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 proposed that the ILOS documentation

States would submit to CMS, as well as an evaluation States would 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 proposed 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 proposed States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS. These parameters are noted further in sections I.B.4.d. and I.B.4.g. of this final 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 did not believe 5 percent was 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, was necessary for States that offer ILOSs representing 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 did not believe a similar rationale is appropriate or relevant for this proposal, and thus, we did 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, was 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 proposed 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 I.B.4.g. of this final rule. For separate CHIP, we proposed 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).

We summarize and respond to public comments received in this section on ILOSs (§§ 438.16(a) through (d), 457.1201(c) and (e), and 457.1203(b)) below.

Comment: Commenters generally supported the proposal that 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, as they believe it would implement ILOS guardrails and provide leeway under the proposed definition to include services

and supports to support SDOH and HRSN efforts.

Response: We appreciate comments in support of our proposal as we believe that ILOSs must be an appropriate and efficient use of Medicaid and CHIP resources and advance the objectives of these programs. We believe the proposal for an ILOS to be an approvable service or setting under the State plan or waiver under section 1915(c) of the Act will ensure an appropriate guardrail to meet these two aims.

Comment: Many commenters suggested revisions to the proposal that an ILOS must be approvable through another Medicaid authority or waiver. One commenter recommended revising § 438.16(b) to include services and settings approvable under Money Follows the Person while another commenter recommended using a similar set of eligibility criteria for Special Supplemental Benefits for the Chronically Ill (SSBCI) offered by Medicare Advantage plans. Some commenters stated that there should be no restriction on the types of services or settings that could be approved as an ILOS while another recommended creating an exception process for States that wanted to deviate from § 438.16(b). Another commenter recommended allowing room and board that is generally not allowed in Title XIX of the Act. Other commenters opposed this proposal and indicated it was too narrow, could limit States' use of ILOSs and chill innovation with one of these commenters indicating that any service or setting authorized in a demonstration under section 1115 of the Act should be allowable as an ILOS.

Response: We do not believe it is appropriate to include services and settings that are approvable in Money Follows the Person as it is a demonstration program with unique funding and eligibility criteria. SSBCI is a supplemental benefit option in Medicare Advantage specifically for the certain chronically ill SSBCI-eligible plan enrollees, so we do not believe it is relevant for ILOS policy as ILOSs are not limited to a target population of the chronically ill nor a supplemental benefit. We also do not believe authority under section 1115 of the Act is an adequate rationale to expand the scope of allowable ILOSs as this authority is utilized to approve experimental, pilot or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program, and this unique authority is separate and distinct from other traditional Medicaid authorities such as the State plan. We further believe that ensuring ILOSs comply

with applicable Federal requirements, such as the general prohibitions on payment for room and board under Title XIX of the Act, is necessary and appropriate (see section I.B.4.a. of this final rule for further details on short-term IMD stays for inpatient mental health or substance use disorder treatment). ILOSs are not to be used as a mechanism to evade compliance with Federal statute and regulations. Therefore, we decline to adopt any of these suggestions in the finalized definition.

We recognize that requiring an ILOS to be approvable as a service or setting under the State plan or waiver under section 1915(c) of the Act will place restrictions on allowable ILOSs, but we believe the proposal strikes the right balance to encourage innovation while ensuring appropriate use of Medicaid and CHIP resources. We do not believe it is appropriate to consider an exception process for existing ILOSs that do not meet the proposed definition in § 438.3(b) as this would create inequity in the use of ILOSs and fail to ensure compliance with proposed Federal requirements, and we decline to revise the proposal to adopt such a process. We also remind managed care plans that if a service or setting they wish to provide does not meet ILOS requirements, the plans may always choose to voluntarily provide additional services in accordance with § 438.3(e)(1) although the cost of these services cannot be included when determining payment rates under § 438.3(c).

Comment: One commenter requested clarification on whether a service or setting must be approved in a State's Medicaid or CHIP State plan or waiver under section 1915(c) of the Act to be allowed as an ILOS.

Response: As specified in § 438.16(b), an ILOS must be approvable as a service or setting under the State plan or waiver under section 1915(c) of the Act to be eligible as an ILOS; however, it does not need to be approved in the State plan or waiver. For example, yoga is not a service that is approvable in the Medicaid or CHIP State plan, and therefore, it would not be eligible to be an ILOS. Additionally, any limitations in the coverage of a service or setting in the State plan or waiver under section 1915(c) of the Act must also be adhered to if the service or setting is covered as an ILOS, such as the limitations on room and board including that meals must be less than 3 meals per day and other limitations on allowable housing supports.¹⁹⁵

¹⁹⁵ On November 16, 2023, CMS published a CMCS Informational Bulletin on coverage of

Comment: One commenter recommended that CMS require more uniformity on allowable ILOSs by providing States with a menu of approved ILOSs that they can choose to implement within their Medicaid programs, with the option for States to include other ILOSs at their discretion. The commenter noted they believe that this uniformity could make it easier to evaluate the effectiveness of each ILOS. Other commenters opposed the proposal in § 438.16(b) as they noted it required unnecessary uniformity and decreased innovation.

Response: As required in § 438.3(e)(2)(1), States are required to determine that an ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan, and States have flexibility in §§ 438.3(e) and 438.16 to identify the ILOSs that they believe best meet enrollees' needs and the target population for an ILOS. Appropriate ILOSs will also vary by managed care program given the differing populations and benefits offered. As such, we do not believe it is currently reasonable or appropriate for CMS to provide a menu of approved ILOSs.

Comment: Some commenters requested clarification on whether nutritional supports, services provided by community health workers, or services provided through telehealth are allowable ILOSs while another commenter recommended that chronic pain management not traditionally covered by Medicaid or CHIP be considered approvable as an ILOS. Another commenter requested clarification on whether transportation to underlying services being provided as an ILOS would also be considered as a component of the ILOS.

Response: We continue to believe it is not appropriate to cover services or settings as an ILOS that are not approvable through the State plan or waiver under section 1915(c) of the Act to ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources. As such, States must assess whether an ILOS being considered for inclusion in a managed care plan's contract is approvable in Medicaid and CHIP to evaluate if it is eligible as an ILOS. Similarly, transportation in conjunction with another service that is an ILOS could potentially be allowable as a component of that ILOS only if this is an allowable component of a service or setting that is approvable under the

services and supports to address HRSN needs in Medicaid and CHIP that included a table on allowable HRSN coverage and associated limitations: <https://www.medicaid.gov/sites/default/files/2023-11/cib11162023.pdf>.

State plan or waiver under section 1915(c) of the Act.

Comment: Generally, there was support for the proposed calculation and documentation of projected and final ILOS cost percentages, including the exclusion of short-term IMD stays that are ILOSs, and the summary report of managed care plans' ILOS costs. Many commenters also indicated that the definitions for the ILOS cost percentages were reasonable and appropriate. There were no specific comments on our proposals that these cost percentages be certified by State actuaries and reviewed by CMS. Another commenter supported our proposal to allow 2 years for submission of the final ILOS cost percentage as reasonable and indicated that the alternative of 1 year would be insufficient time for States to finalize this calculation. Some commenters supported the proposed 5 percent limit for the projected ILOS cost percentage and final ILOS cost percentage at § 438.16(c)(1), and indicated it was an appropriate upper threshold for ILOS expenditures as a component of total capitation payments.

Response: We believe these proposals are appropriate fiscal protections for Medicaid and CHIP investments in ILOSs. We also appreciate the feedback we received on the proposal in § 438.16(c)(5)(ii) regarding the timing to submit the final ILOS cost percentage. As the comments confirmed our concern that 1 year would be insufficient time for States and actuaries to develop this final calculation, we are finalizing this provision without revision.

Comment: Some commenters suggested revisions to the proposed calculations and documentation for ILOS cost percentages. One commenter recommended that CMS allow States with smaller programs to calculate the ILOS cost percentage across programs or require integrated programs to calculate ILOS cost percentages by major service types such as physical health, behavioral health, or LTSS within the single program (with a higher threshold limit for the ILOS cost percentage to offset the narrower denominator). Another commenter stated concern that the proposed definitions for the projected ILOS cost percentage and the final ILOS cost percentage were complex although no detail was provided by the commenter and indicated that the ILOS cost percentage calculations would create a new State administrative burden. Another commenter questioned the need for the calculation of both a projected ILOS cost percentage and a final ILOS cost

percentage as the numerator for these calculations is consistent and only the denominator varies. This commenter requested clarification on why the final ILOS cost percentage was necessary given the proposal in § 438.16(c)(4) for States to submit to CMS a summary report of the managed care plans' actual ILOS costs for delivering ILOSs based on the claims and encounter data.

Response: We acknowledge that the calculation of projected ILOS cost percentages and final ILOS cost percentages will be a new State administrative burden; however, we believe it is a necessary tool to ensure appropriate Federal oversight. We accounted for this burden in the associated Collection of Information for § 438.7 Rate Certifications (see section II.B.4. of this final rule for further details).

We continue to believe that an ILOS cost percentage should be calculated for each managed care program. We do not believe it is appropriate for this to be an aggregate calculation across multiple programs or broken down by major service category. This calculation should occur distinctly for each managed care program as ILOSs available may vary by program, each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types, and capitation rates are typically developed by program.

We agree that the numerator for the projected ILOS cost percentage and final ILOS cost percentage are identical, and it is the denominator that varies. As capitation rates are developed prospectively based on historical utilization and cost experience, the denominator for the projected ILOS cost percentage can only capture the projected total capitation payments. Conversely, the denominator of the final ILOS cost percentage captures the actual total capitation payments paid by the State to the managed care plans. As States claim FFP on these capitation payments and not managed care plans' actual expenditures, we believe it is necessary and appropriate to ensure compliance with the 5 percent limit proposed in § 438.16(c)(1) for both percentages. We also note that the final ILOS cost percentage is developed based on capitation payments while the summary report captures managed care plans' actual costs for delivering ILOSs based on claims and encounter data; these two are distinct reporting requirements to acknowledge the nature of risk-based rate development and how FFP is claimed for managed care expenditures.

Comment: One commenter recommended that CMS provide guidance on how costs associated with third party administrative management of ILOSs would be factored into the ILOS cost percentage. Another commenter recommended that CMS help States invest in infrastructure to support ILOS administration.

Response: We do not believe it is appropriate to include costs associated with third party management, operational costs, or infrastructure of ILOSs within any portion of ILOS costs. That is, these expenditures should not be included in any part of the ILOS cost percentage, ILOS benefit or non-benefit component, or any portion of Medicaid managed care capitation rates. For example, an ILOS cost percentage is focused on the portion of the total capitation payments that is attributable to the provision of ILOSs. In accordance with § 438.5(e), the non-benefit component of capitation rates includes reasonable, appropriate, and attainable expenses including those related to the managed care plan's operational costs associated with the provision of services identified in the § 438.3(c)(1)(ii) to the populations covered under the contract. While we are revising § 438.3(c)(1)(ii) to ensure that final capitation rates may be based on State plan, ILOSs and additional services deemed by the State to be necessary to comply with mental health parity, § 438.3(c)(1)(ii) also requires that this payment amount must be adequate to allow the managed care plan to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements. As ILOSs are substitutes for State plan-covered services and settings that are provided at the option of the managed care plan, and not a contractual requirement, we do not believe it is appropriate to include associated costs for managed care plan operational costs, the third party administrative management of ILOSs or associated plan or provider infrastructure needs in the benefit or non-benefit component of capitation rates, or the associated ILOS cost percentage that is calculated based on capitation payments.

Comment: One commenter stated concern regarding the additional ILOS reporting proposed at § 438.16(c)(5)(ii) and suggested that CMS leverage existing reporting structures like the MCPAR.

Response: We agree with the commenter that we should leverage existing reporting, including the MCPAR for ILOSs; accordingly, we revised the requirement to include ILOSs in reporting related to availability

and accessibility of covered services in the MCPAR at § 438.66(e)(2)(vi). However, we do not believe capturing information on ILOSs in the MCPAR alone is sufficient to appropriately monitor and oversee the fiscal impact of ILOSs on managed care expenditures. ILOSs are included in capitation rates and, as outlined in this section of the preamble as well as section I.B.4.e. of this final rule, we believe it is appropriate for us to review the ILOS cost percentage and the summary report of managed care plans' actual ILOS costs as a component of our review of rate certifications. This helps us to review the calculation for the projected ILOS cost percentage and determine if it was developed in a manner consistent with how associated ILOS costs would be included in rate development and that the historical experience garnered from the final ILOS cost percentage and summary report of managed care plans' actual ILOS costs informs prospective rate development as appropriate.

Comment: Many commenters recommended revisions to the proposed 5 percent limit for the ILOS cost percentage or were in opposition to the limit. One commenter supported this limit, but raised concerns that the cost of a service should not be the principal or determinative criterion in findings of medical necessity for Medicaid coverage. Other commenters supported a 5 percent limit on ILOS expenditures but recommended other exceptions to this limit which varied by commenter or to focus the limit on novel ILOSs. Recommended exceptions included all approved ILOSs, ILOSs focused on HCBS, or ILOSs needed to ensure access to quality care such as HCBS and behavioral health. One commenter recommended that the proposed 5 percent limit be a general guideline while allowing States the flexibility to propose a modification to this limit by means of a waiver or exception process while another commenter recommended a process by which the 5 percent limit would be removed if a State met a pre-defined set of quality or cost outcomes. One commenter recommended that States should have the flexibility to set their own limit. Another commenter recommended this limit be increased to 10 to 15 percent for some programs, such as smaller behavioral health programs.

Other commenters opposed any limit of the projected ILOS cost percentage or final ILOS cost percentage. These commenters raised concerns that a fiscal limit could discourage utilization of ILOSs, reduce the use of existing ILOSs, remove State flexibility and create inequities in the ILOSs offered across

States. One commenter stated concern that any fiscal limit could create hardships for smaller, limited benefit managed care programs while another stated similar concerns for nonintegrated programs. One commenter noted that the proposed CMS review of ILOSs and evaluation, as applicable, as well as the documentation of a projected ILOS cost percentage should be sufficient for demonstrating the reasonableness and appropriateness of ILOSs instead of requiring an overall fiscal limit. Another commenter noted that the cost effectiveness test for section 1915(b)(3) of the Act services should be sufficient and did not believe an additional limit was necessary for ILOSs. A few commenters requested clarification for CMS's rationale for selecting 5 percent and some of those commenters raised concerns that 5 percent was arbitrary. One commenter who opposed any fiscal limit did acknowledge that they were unaware of any States that actually spent more than 5 percent of total capitation payments on ILOSs.

Response: We believe that there must be appropriate and consistent fiscal guardrails on the use of ILOSs in every managed care program to ensure proper and efficient operations in Medicaid, and efficient and effective health assistance in CHIP. While we recognize that any limit imposed on ILOS expenditures in comparison to overall program expenditures will limit State and managed care plan use of ILOSs to some degree, we believe that we have an obligation to implement appropriate fiscal constraints for Medicaid and CHIP investments in ILOSs, and it is appropriate to set a limit for each managed care program so that ILOS expenditures do not grow unfettered. We continue to believe a fiscal limit would increase accountability, reduce inequities in the services and settings available to beneficiaries across managed care and FFS delivery systems, and ensure that enrollees receive State plan-covered services and settings. We believe a 5 percent limit on ILOS expenditures in comparison to total program expenditures is a reasonable limit for every managed care program, including smaller, limited benefit programs, because it is high enough to encourage the use of ILOSs, at the plan and enrollee option, but still low enough to maintain appropriate fiscal safeguards.

We do not believe it is reasonable or appropriate to include additional exceptions to the proposed fiscal limit as we believe this would exacerbate inequities in the coverage of ILOSs in State programs as well as create

operational and oversight challenges. ILOSs are substitute services and settings provided in lieu of services or settings covered under the State plan. States have an obligation to ensure that all services covered under the State plan are available and accessible to managed care enrollees in a timely manner as required at §§ 438.206 and 457.1230(a) for Medicaid and separate CHIP, respectively, and that there is adequate capacity to serve the expected enrollment as required at §§ 438.207 and 457.1230(b), respectively. Therefore, we do not believe an exception process is reasonable based on access concerns. If States have concerns about compliance with this fiscal limit, States should explore transitioning to cover the services as Medicaid benefits through other pathways for coverage such as the State plan authority in section 1905(a), 1915(i) and 1915(k) or a waiver under section 1915(c) of the Act. For example, we are aware of one State that recently undertook an assessment of its historical ILOSs and determined that some historical ILOSs, or a component of an ILOS, were duplicative of services authorized in the Medicaid State plan. Once this State terminated these historical ILOSs prospectively, this eliminated the State's concern of exceeding the projected ILOS cost percentage for its applicable managed care program as the numerator of the ILOS cost percentage is the portion of the total capitation payments that is attributable to the provision of ILOSs and not services authorized in the Medicaid State plan as benefits.

The final rule does not stipulate that ILOS cost is the principal or determinative criterion in findings of medical necessity for Medicaid or CHIP coverage. In accordance with existing Federal requirements at § 438.3(e)(2)(i), States must determine each ILOS to be a medically appropriate and cost effective substitute for the covered service or setting under the State plan. Cost effectiveness of an ILOS is one factor in a State's determination, and medical appropriateness is an additional factor. CMS proposes to ensure clarity in the managed care plan contracts on the target population(s) for which each ILOS is determined to be medically appropriate and cost effective substitute for a State plan-covered service or setting (see section I.B.4.d. of this final rule for further details). We continue to believe that there should be an overall fiscal limit on ILOS expenditures to ensure appropriate use of ILOSs and to avoid creating a perverse incentive for States and plans

not to provide State plan-covered services and settings. For the reasons outlined above, we decline to revise the proposed 5 percent limit at § 438.16(c)(1).

We also remind commenters that section 1915(b)(3) of the Act services are separate and distinct services from ILOSs and have a separate and distinct cost effectiveness requirement. Under section 1915(b)(3) of the Act, States share cost savings resulting from the use of more cost effective medical care with enrollees by providing them with additional services, known as section 1915(b)(3) services. There is a specific cost effectiveness test that States must prospectively meet to request approval from CMS for section 1915(b)(3) services as a component of a section 1915(b) waiver application as well as retrospective cost effectiveness reporting.

Comment: One commenter stated concern about the administrative burden that the proposed ILOS rules will pose for smaller, more specialized CHIP managed care programs. In particular, the 5 percent limitation on ILOS as a proportion of overall capitated payments has a disproportionate impact on CHIP programs with a smaller enrollment population. The commenter stated the increased limitations on managed care programs do not align with the overall intent of managed care and restrict the flexibilities that make managed care a desirable model for children's services.

Response: We appreciate the commenter's concerns for the potential impact of new ILOS requirements on managed care programs that serve smaller separate CHIP populations. In our determinations throughout this final rule for which provisions would align separate CHIP with Medicaid, we sought to balance the burden on CHIP State agencies and separate CHIP managed care programs with the need for responsible Federal oversight and protections to CHIP beneficiaries. We believe requiring a 5 percent limit on ILOS expenditures in comparison to total program expenditures remains a reasonable limit even for managed care programs serving smaller populations. The 5 percent limit on ILOS expenditures ensures fiscal responsibility and additional transparency for State and Federal oversight of managed care programs. If separate CHIP managed care programs have concerns about exceeding this 5 percent limit for the ILOS cost percentage, we encourage States to evaluate services currently being provided as ILOSs that might alternately be coverable under the CHIP State plan

through the service definitions at § 457.402—specifically “home and community-based health care services and related supportive services.” States also have the flexibility to cover SDOH and HRSN services through CHIP Health Services Initiatives.

Comment: One commenter requested that if CMS finalizes the 5 percent limit, that CMS should identify the affected States so interested parties can meaningfully understand the impacts of the proposed limits.

Response: We agree that States should engage with interested parties to ensure clarity on how the ILOS fiscal limit may impact particular managed care programs and we encourage the engagement of interested parties more broadly such as on ILOS development, evaluation and any necessary transition planning. We are unable to currently identify potentially affected States as ILOS offerings and enrollee utilization may vary year to year, and this will impact State calculations for the ILOS cost percentage. We encourage interested parties to engage directly with States.

Comment: One commenter recommended that CMS closely monitor this 5 percent limit after implementation to assess if the limit should be revisited in future rulemaking.

Response: We agree that it is imperative that CMS and States closely monitor implementation of this required limit to ensure compliance.

Comment: Several commenters supported the annual reporting of managed care plans' ILOS costs. One commenter indicated that ILOSs and the amounts paid by managed care plans should continue to be monitored at the State and national levels to drive Federal policy changes to the Medicaid program. Another commenter recommended that this spending data be made publicly available.

Response: We appreciate the support for this proposal to require annual reporting on managed care plans' actual ILOS costs and we believe this data should inform rate development and could be utilized to inform other policy changes. Managed care plans are required to provide all encounter data, including allowed and paid amounts, to the State per §§ 438.242(c)(3) and 457.1233(d) for Medicaid and separate CHIP respectively, and the State is required to submit this data to T-MSIS per §§ 438.818 and 457.1233(d), respectively. As encounter data will be generated when an ILOS is rendered, the data will be captured in T-MSIS and treated as other encounter data in the

production of T-MSIS analytic files.¹⁹⁶ At this time, CMS does not plan to publicly release the annual reporting by managed care plans on actual ILOS costs, but we will take this into consideration in the future.

Comment: Some commenters supported the use of a risk-based approach for States' ILOS documentation and evaluation requirements as they believe the proposals struck the right balance between Federal oversight and State administrative burden.

Response: We appreciate the support for these proposals, and for the feedback that our proposals appropriately balanced States' administrative burden with ensuring fiscal safeguards and enrollee protections related to ILOSs.

Comment: One commenter requested clarification on whether the proposed 1.5 percent threshold applied to each managed care plan contract or each individual ILOS.

Response: The threshold for the risk-based approach is by managed care program. The definitions for a projected ILOS cost percentage and final ILOS cost percentage proposed in § 438.16(a) indicate that these percentages are calculated for each managed care program that includes ILOSs, and these percentages are based on calculations proposed in §§ 438.16(c)(2) and (c)(3) which include all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e). See this section of the preamble, as well as sections I.B.4.d. and I.B.4.g. of this final rule for further details.

Comment: Other commenters were concerned with the State administrative burden associated with the proposed documentation and evaluation requirements, and either opposed any new requirements or recommended alternatives.

Response: As required in existing Federal requirements at § 438.3(e)(2)(1), States must determine each ILOS to be a medically appropriate and cost effective substitute for a State plan-covered service or setting. We expect that whenever a State is making such a determination that it has a clear process and protocol, and that it adequately maintains documentation of its decisions. Therefore, we do not believe the documentation requirements proposed in § 438.16(d)(2) should create substantially new burden for States as States should be readily able to provide a description of their evaluative

¹⁹⁶ <https://www.medicaid.gov/medicaid/data-systems/machbis/transformed-medicaid-statistical-information-system-t-msis/t-msis-analytic-files/index.html>.

processes as these should already be maintained in States' records. The goal of this proposal was to reduce State administrative burden by only requiring that this documentation be submitted to CMS when the projected ILOS cost percentage exceeded a 1.5 percent as opposed to always providing it.

We recognize that the proposed evaluation requirement outlined in § 438.16(e)(1) is a new State requirement and will increase administrative burden. We believe this is a necessary requirement to ensure that States appropriately evaluate whether ILOSs meet their intended purposes and truly are medically appropriate and cost effective, and for CMS to receive these evaluations to inform our determination of continued approval of these ILOSs in managed care plan contracts or to consider termination as appropriate. We did account for this burden in the associated Collection of Information for § 438.16 (see section II.B.7. of this final rule for further details).

Comment: A few commenters recommended alternatives to the 1.5 percent threshold. The recommended alternative varied by commenter and included utilizing a 2.5 or 3 percent threshold, allowing the State's actuary to determine a threshold, and only requiring these requirements when the ILOS cost percentage had shifted noticeably. Some commenters also recommended exempting currently approved ILOSs from any additional documentation and evaluation requirements. Other commenters recommended CMS consider setting a minimum threshold for each ILOS so that the documentation and/or evaluation requirements only apply to individual ILOSs of material size. A few commenters recommended using the 1.5 percent threshold for each ILOS while several of the commenters indicated they thought a threshold of 0.1 percent of the capitation rates for each ILOS was a reasonable threshold.

Response: Commenters provided several alternatives to the proposed 1.5 percent threshold which we have reviewed and considered. We do not believe the alternative to consider an ILOS cost percentage threshold that exceeds 3 percent for additional documentation and evaluation requirements is appropriate to consider for this risk-based approach. We believe that this alternative, which is twice as high as the 1.5 percent threshold proposed, is not sufficient to appropriately ensure appropriate Federal oversight that ILOSs are medically appropriate and cost effective substitutes for State-plan covered services and settings and in the best

interests of the Medicaid and CHIP programs.

We continue to believe that there should be a consistent Federal standard utilized across all managed care programs that include ILOSs to appropriately monitor and oversee the use of ILOSs, and therefore, we do not believe it is reasonable and appropriate to consider allowing a State's actuary to have the discretion to determine a varying threshold for each program or to allow currently approved ILOSs to be excluded from this risk-based approach. We also note that the commenters who recommended the alternative to allow a State's actuary to have the discretion to determine a threshold for this risk-based approach did not provide a rationale for this alternative for us to reconsider our position. Therefore, at this time, we do not believe allowing States and their actuaries to identify a reasonable threshold for submitting to CMS additional documentation and evaluation requirements is a reasonable alternative to consider further.

We are also concerned that applying a risk-based approach threshold for documentation and evaluation requirements by each ILOS, rather than for all non-IMD ILOSs across a given managed care program, could actually increase State administrative burden based on the potential volume of ILOSs that could exceed the proposed 1.5 percent ILOS cost percentage threshold. We also have concerns that the proposed alternative to consider a threshold of 0.1 percent would be far too low to meaningfully ensure appropriate Federal oversight of ILOSs. We are also concerned that any threshold that is required for each ILOS, rather than at the aggregate across a managed care program, could increase administrative burden and the complexity for States and CMS to operationally implement and oversee this proposed requirement as some States have a significant volume of ILOSs.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(a) through (d), 457.1201(c) and (e) and 457.1203(b) as proposed with the following modifications. As outlined in section I.B.2. of this final rule, we are prohibiting the use of separate payment terms for State directed payments. We will modify § 438.16(c)(2)(ii) to remove the word "including" before "all State directed payments," and the following language: "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)" and the comma that

preceded this statement as well as add a comma before "and pass-through payments." We will also modify § 438.16(c)(3)(ii) to remove the word "including" before "all State directed payments," and the following language: "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)" and the comma that preceded this statement as well as add a comma before "and pass-through payments." We will also modify §§ 438.16(c)(4) and (c)(5) to add a comma before "and PAHP" for consistency.

c. Enrollee Rights and Protections (§§ 438.3(e), 438.10(g), 457.1201(e) and 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 proposed 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 will 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 proposed to specify, in § 438.3(e)(2)(ii)(A), that an enrollee who is offered or utilizes an ILOS will retain all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they will retain their right to receive the service or setting covered under the State plan on the same terms as will 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 proposed 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 proposed 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 wanted 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 proposed 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 could 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 wanted 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 proposed 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 proposed 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 could 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 proposed this documentation requirement in § 438.16(d)(1)(v). For separate CHIP, we proposed 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).

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.3(e), 438.10(g), 457.1201(e), 457.1207) below.

Comment: Many commenters supported the proposed enrollee rights and protections and the inclusion of these in managed care plan contracts and enrollee handbooks if ILOSs are authorized and identified in managed care plan contracts as commenters noted

they believe these were reasonable and appropriate guardrails.

Response: We appreciate the support for these proposals, and we continue to believe that outlining the existing enrollee rights and protections in regulation is a critical safeguard to ensure that the delivery of ILOSs is in the best interest of beneficiaries and advances the objectives of the Medicaid and CHIP programs.

Comment: A few commenters recommended that CMS require States to develop a public list of available ILOSs, related targeting criteria and the managed care plans who offer them, and to conduct outreach to providers and enrollees, so that providers and enrollees understand what ILOS options may be available.

Response: Information on ILOSs authorized by the State that their managed care plans may elect to offer and that enrollee may choose at their option to utilize will be in the managed care plan contracts which, as required in §§ 438.602(g)(1) and 457.1285 for Medicaid and separate CHIP respectively, must be posted on their websites. We are aware that many States conduct education and outreach efforts to raise awareness of authorized ILOSs, including web postings, provider outreach, enrollee handbooks, and other interested parties engagement. We do not believe it is necessary for CMS to further mandate the use of specific education and outreach mechanisms as States are in the best position to determine what efforts are appropriate for the target population for each ILOS.

Comment: One commenter recommended that CMS implement an appeals process, using existing State and managed care plan infrastructure, for ILOSs.

Response: We appreciate these comments as they allow CMS to clarify existing policy guidance. On January 4, 2023, we published ILOS guidance¹⁹⁷ which clarified 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 any ILOS." Enrollees retain all rights afforded to them in part 438. As we further noted in this ILOS guidance published on January 4, 2023, managed care plans' contracts must, pursuant to § 438.228, require each managed care plan to have a grievance and appeal system in place that meets the requirements of subpart F of part 438. States are required to provide State fair hearings, as described in subpart E

¹⁹⁷ <https://www.medicaid.gov/sites/default/files/2023-12/smd23001.pdf>.

of part 431, to enrollees who request one after an adverse benefit determination is upheld on appeal (see § 438.402(c)(1)(i)). The grievance, appeal, and State fair hearing provisions in part 438, subpart F, apply to enrollees and ILOSs to the same extent and in the same manner as all other services covered by the managed care plans' contracts. As with all services in managed care, enrollees can request a State fair hearing before the Medicaid agency in accordance with § 431.220(a)(4). As further noted in the January 4, 2023, guidance, "The offer or coverage of ILOS(s) by a managed care plan in no way alters or diminishes an enrollee's rights under subpart F of part 438. For example, at § 438.404, managed care plans are expected to provide notice of an adverse determination to enrollees if ILOS(s) offered by their Medicaid managed care plan are not authorized for an enrollee because of a determination that it was not medically appropriate. Additionally, consistent with § 438.402, Medicaid enrollees also retain the right to file appeals and/or grievances with regard to the denial or receipt of an ILOS." For separate CHIP, we amended § 457.1201(e) to apply separate CHIP enrollee rights and protections at subparts K and L of part 457 for ILOSs. Subpart L of part 457 applies separate CHIP managed care grievance system requirements to ILOSs and subpart K of part 457 applies all separate CHIP external review requirements to ILOSs. We are finalizing the proposal to clarify this existing guidance in §§ 438.3(e)(2)(ii)(A) and 457.1201(e) for Medicaid and separate CHIP, respectively.

Comment: One commenter requested clarification on whether ILOSs could be offered retroactively, and if so, how the managed care plan would ensure enrollee rights and protections.

Response: ILOSs must be provided at the option of the enrollee and the managed care plan, as well as authorized and identified in the managed care contract as required in § 438.3(e)(2). As such, it is not appropriate to retroactively implement an ILOS. For example, it is not possible to retroactively offer an enrollee the option to receive an ILOS rather than the State plan service.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.3(e), 438.10(g), 457.1201(e) and 457.1207 as proposed with a minor modification to § 438.3(e)(2)(B) to add a comma between "PIHP" and "or PAHP" for consistency.

d. Medically Appropriate and Cost Effective (§§ 438.16(d) and 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 interpreted 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 was a reasonable interpretation in acknowledgement that health outcomes from any health care services and settings may also not be immediate. We offered 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 could 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 could 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 could 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 were 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 within the allowable limit of less than 3 meals per day. 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 was 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 proposed to expand the documentation requirements for ILOSs through the addition of requirements in § 438.16. Specifically, we proposed 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 was 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 was needed to ensure accountability and transparency in managed care plan contracts. Therefore, we proposed § 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 was determined to be a medically appropriate and cost effective substitute by the State. For separate CHIP, we proposed 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 final rule, we proposed 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 will have to identify the target populations for each ILOS using clear clinical criteria. Prospective identification of the target population for an ILOS is 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 proposed 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 proposed to adopt the new documentation requirements at § 438.16(d)(1)(iii) by amending § 457.1201(e) to include the cross-reference. We proposed the phrase "clinically defined target populations" as we believe that States would have to identify a target population for each ILOS that would 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 proposed, 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 determine that an ILOS is medically appropriate for a specific enrollee before it was provided. 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 proposed 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 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 include how each ILOS is expected to address those needs.

As discussed in section I.B.4.b. of this final rule, we proposed 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 will 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 proposed, 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 proposed that the State submit 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 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 expected States 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 proposed 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 clinically defined target population(s), consistent with the proposed § 438.16(d)(1)(iii). CMS has the authority in § 438.3(a) 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 proposed 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 proposed 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 determined that the requested information was pertinent to the review and approval of a contract that includes ILOS(s). For separate CHIP, we proposed 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.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(d), 457.1201(e)) below.

Comment: Many commenters supported our documentation requirements proposed in this section of the preamble and indicated the proposals were reasonable to ensure that ILOSs are an appropriate Medicaid investment and serve to meet beneficiaries' health care needs and ensure enrollees' health and safety.

Response: We appreciate the support we received for these documentation proposals to ensure proper and efficient operations for the use of ILOSs in Medicaid and CHIP managed care.

Comment: Some commenters recommended allowing States flexibility to only update managed care plan contracts every 3 to 5 years rather than when the level of detail on ILOSs changes as the commenters indicated that the level of detail rarely changes. Other commenters recommended to grandfather in existing ILOSs and not require additional contract documentation for these existing ILOSs. A few of these commenters raised concerns that the proposed documentation requirements could

create administrative burden, inhibit use of these ILOSs in the future or not allow flexibility including individualized planning to meet enrollees' needs. A few of these commenters requested flexibility to revise the ILOSs outside the managed care contracts when such care otherwise meets the criteria for ILOSs, and one such commenter recommended all the necessary detail be included in the rate certification rather than the contract.

Response: As managed care plan contracts are the critical vehicle by which States outline their expectations to the managed care plans and are used to enforce plans' contractual obligations, we have historically believed and continue to believe that the contracts are the appropriate mechanism to document the ILOSs that the State had determined to be medically appropriate and cost effective substitutes for State plan-covered services and settings, as well as the administrative and operational processes necessary to monitor these ILOSs. The proposals in § 438.16(d) also build upon existing Federal requirements in § 438.3(e)(2)(iii) that the ILOSs approved by the State are identified in the managed care plan contracts. In alignment with this existing requirement, as well as the new proposed requirements, we expect States to revise managed care plan contracts anytime the ILOSs that the State has determined to be medically appropriate and cost effective substitutes change, as well as any time the associated administrative and operational processes for these ILOS change. We do not believe it would be appropriate to outline the proposed documentation outlined in § 438.16(d) within a rate certification in lieu of a managed care plan contract as a rate certification is the documentation a State's actuary develops as it certifies actuarially sound Medicaid capitation rates. States may find it administratively less burdensome to revise an appendix to the managed care contract, though we remind States that any appendix to the contract or other document included as reference in the contract is a component of the contract that requires CMS review and approval. We also remind commenters that ILOSs are required to be medically appropriate and cost effective substitute services for clinically defined target populations. We remind managed care plans that if a service or setting they wish to provide does not meet ILOS requirements, the plans may always choose to voluntarily provide additional services in accordance with § 438.3(e)(1) although the cost of these services cannot be

included when determining payment rates under § 438.3(c).

Comment: Some commenters sought revisions or clarifications on the processes in § 438.16(d)(iii) and (iv). One commenter recommended revising the term "clinically defined target population" to include functional and HRSNs of enrollees in addition to medically appropriateness of an ILOS. Another commenter requested confirmation that the State should identify the clinically defined target populations for ILOSs and not managed care plans. Other commenters recommended that CMS require States and managed care plans to document the safety and efficacy of each ILOS in the enrollee's records or require that only the enrollee's primary care provider be allowed to make the determination that an ILOS is medically appropriate.

Response: We agree that States should consider the safety and efficacy of an ILOS when they are determining a potential ILOS is medically appropriate, as well as when a network provider or staff provider for the managed care plan determines and documents in the enrollee's records that an ILOS is medically appropriate for a specific enrollee.

We are not entirely clear what the commenter meant by functional need, but we believe the commenter may be referring to functional assessment tools that collect information on an individual's health conditions and functional needs. We agree that evaluating the functional needs and HRSNs of enrollees can be critical components for care coordination and determining medically appropriate services; however, these factors cannot be the sole rationale for the determination that an ILOS is medically appropriate, as an ILOS is a substitute for a State plan-covered service or setting.

We appreciate the commenter who requested confirmation that the State should identify the clinically defined target populations for ILOSs and not managed care plans. As States are required to determine, subject to CMS review, each ILOS is a medically appropriate and cost effective substitute for a State plan-covered service or setting as required in § 438.3(e)(2)(i), the State is also responsible for determining the clinically defined target population for which each ILOS is determined to be a medically appropriate and cost effective substitute. We are finalizing § 438.16(d)(1)(iii) with a modification to add language after "medically appropriate and cost effective" to add

“substitute by the State” to ensure clarity on this issue.

As a reminder, when authorizing an ILOS, a State is required to determine the clinically defined target population(s) for which each ILOS is determined to be a medically appropriate and cost effective substitute for a State plan covered service or setting, and the State must document this clinically defined target population(s) in the managed care plan contract in accordance with § 438.16(d)(iii). For example, it would not be sufficient to indicate that the target population is any individual at risk for any chronic condition as clinical criteria must be utilized to document a specific clinical condition that is predictive of adverse health outcomes, and that is not itself a social determinant of health. For example, a State may determine that asthma remediation (e.g., air filters) is a medically appropriate and cost effective substitute in lieu of the covered State plan services of emergency department services, inpatient services, and outpatient services for a target population of individuals with poorly controlled asthma (as determined by a score of 25 or lower on the Asthma Control Test).

Additionally, in accordance with § 438.16(d)(iv), the State must ensure that there is the process by which a licensed network or plan staff provider determines and documents in the enrollee’s records that an identified ILOS is medically appropriate for a specific enrollee, and this process must be documented in the State’s contracts with its managed care plans. We agree that an enrollee’s primary care provider may be an appropriate provider to determine and document that an ILOS is medically appropriate for a specific enrollee; however, we believe States should have flexibility to allow other licensed network or staff providers to make this determination, as they deem appropriate.

Comment: One commenter recommended that managed care plans be able to provide ILOSs without State and provider determination that the ILOS is medically appropriate. One additional commenter requested that CMS remove managed care plans’ control over access to ILOSs and require standardized availability of ILOSs across managed care plans.

Response: ILOSs must be determined by States to be medically appropriate and cost effective substitutes for State plan-covered services and settings in accordance with § 438.3(e)(2)(i). We continue to believe that there must be appropriate documentation in managed

care plan contracts to ensure managed care plans appropriately offer ILOSs consistent with the State’s determination. We also remind commenters that in accordance with existing Federal requirements at § 438.3(e)(2)(iii), an ILOS is always provided at the option of a managed care plan as an ILOS is a substitute for a State plan-covered service or setting. An ILOS is not a Medicaid benefit, but rather a medically appropriate and cost effective substitute for one. CMS or States cannot remove managed care plans’ option to provide ILOSs; however, States must ensure standardization in the name, definition, clinically defined target population, and other critical components necessary to properly oversee that ILOSs are medically appropriate and cost effective substitutes for specific State plan-covered services and settings that also comply with all applicable Federal requirements.

Comment: One commenter requested clarification on whether a licensed social worker could be an allowable provider under the proposed requirement at § 438.16(d)(1)(iv).

Response: We agree that a licensed social worker could potentially be a provider that States and managed care plans consider as they develop the process outlined in § 438.16(d)(1)(iv).

Comment: A few commenters recommended that the ILOS documentation requirements be posted on the State’s website or otherwise made publicly available in addition to documented in the managed care plan contracts.

Response: We remind commenters that information on ILOSs authorized by the State that their managed care plans may elect to provide, and that enrollee may choose at their option to utilize will be in the managed care plan contracts, and these contracts are required in § 438.602(g)(1) to be posted on States’ websites.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(d) and 457.1201(e) as proposed with four minor corrections to replace “cost-effective” with “cost effective” in §§ 438.16(d)(1)(ii) and 438.16(d)(2)(ii) to utilize consistent language with existing regulatory terminology in § 438.3(e)(2)(i), modify § 438.16(d)(1)(iii) to add “substitute by the State” after “medically appropriate and cost effective,” and add a comma before “or PAHP” for consistency.

e. Payment and Rate Development (§§ 438.3(c), 438.7 and 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 subpart K of part 438 (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 will not be included within the requirement in § 438.3(c)(2)(ii) related to contractual requirements. We proposed 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).

Additionally, we proposed to revise § 438.7(b)(6) and the proposed § 438.7(c)(4) (see section I.B.2.l. of this final 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 (5)(i), described in section I.B.4.b. of this final 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 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 signaled our intent 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 did 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 would 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 ILOSs and enrollees utilize these ILOSs. States' actuaries should assess if adjustments to the actuarially sound capitation rates are necessary in accordance with §§ 438.4 and 438.7(a) and (c)(2). For example, a rate adjustment may be necessary if a managed care plan's actual uptake of ILOSs varies from what is initially assumed for rate development and results in an impact to actuarial soundness.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.3(c), 438.7 and 457.1201(c)) below.

Comment: Many commenters supported the proposed changes to § 438.3(c) and 438.7 to clarify that ILOSs, when authorized by a State and offered by a managed care plan(s), should be appropriately included in the final capitation rates and rate certifications.

Response: We appreciate the confirmation that these proposals provide clarity to States and their actuaries on how ILOS costs can be incorporated into managed care capitation rates and should be appropriately documented in rate certifications.

Comment: Some commenters requested that CMS clarify that capitation rates must be sufficient to account for ILOSs and State plan services, and one commenter raised concerns that this is not occurring today in a particular State.

Response: As required at § 438.5(b), when setting actuarially sound capitation rates, States and their actuaries must identify and develop base utilization and price data and make appropriate and reasonable adjustments to account for programmatic changes. The base data should include historical utilization and costs for State plan-covered services and settings, as well as associated ILOSs as applicable, and actuaries should make adjustments for programmatic changes to ILOSs and State plan services. Additionally, as required at § 438.4(b)(6), States' actuaries must certify that Medicaid capitation rates were developed in accordance with the ILOS requirements outlined in § 438.3(e). We believe these existing Federal requirements ensure that State plan services and settings and associated ILOSs are accounted for in the development of actuarially sound capitation rates; and we believe the proposed change at § 438.3(c) will clarify that ILOSs should be included in the final capitation rates and related capitation payments when ILOSs are offered by managed care plans. We also direct commenters to section I.B.4.b. of this final rule for our response to a commenter's inquiry on the inclusion of costs associated for managed care plan operational costs, the third party management of ILOSs, or associated plan or provider infrastructure needs for ILOSs within the ILOS cost percentage and the benefit or non-benefit components of Medicaid managed care capitation rates.

Comment: One commenter requested that CMS outline specific Federal guidelines for actuarial rate setting for ILOSs that are longer-term substitutes for State plan-covered services and settings under the State plan.

Response: We believe that States and their actuaries have responsibility under § 438.5(b)(4) to include appropriate and reasonable adjustments to account for ILOSs that are longer-term substitutes for State plan-covered services and settings in rate development. We encourage States to work with their actuaries on how best to incorporate ILOSs into capitation rates which may vary based on States' determinations on the medically appropriateness and cost effectiveness of the ILOS and the clinically defined target population(s). At this time, we do not believe additional Federal guidelines are necessary on this matter. CMS will continue to monitor this issue and may consider guidance within the annual Medicaid Managed Care Rate Development Guide in accordance with § 438.7(e) if deemed necessary.

Comment: One commenter requested that CMS consider revising its proposal at § 438.7(c)(4). The commenter opposed this proposal as they believe the proposal would increase State administrative expenses and not result in any improved oversight.

Response: We disagree with the commenter that the proposal at § 438.7(c)(4) would not improve oversight. As described in section I.B.4.b. of this final rule, we proposed in § 438.16(c)(2) and (c)(3) to require the calculation of a projected and final ILOS cost percentage based on capitation payments, and we proposed in § 438.16(c)(1) that this percentage, on both a projected and final basis, may not exceed 5 percent. We also proposed in § 438.16(c)(5)(i) to require that documentation for the projected ILOS cost percentage should be included in the rate certification. When States amend capitation rates, we believe this should require the calculation of a revised projected ILOS cost percentage, and this revised calculation should be accurately accounted for in the revised rate certification to ensure continued compliance with the proposed regulatory requirements in § 438.16, including the 5 percent limit for the projected ILOS cost percentage. We agree with the commenter that this proposal could increase State administrative burden, and we accordingly have revised the associated Collection of Information for § 438.7 Rate Certifications (see section II.B.4. of this final rule for further details).

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.3(c), 438.7 and 457.1201(c) as proposed.

f. State Monitoring (§§ 438.16(d) and (e), 438.66(e) and 457.1201(e))

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 proposed rule, 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 strengthened 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 will also support the evaluation and oversight of ILOS proposals described in sections I.B.4.g. and section I.B.4.h. of this final rule, and ensure appropriate rate development, as described in section I.B.4.e. of this final 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 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 proposed 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 encouraged States to work towards the development of standard CPT® and HCPCS codes for ILOSs, and we noted that States may wish to collaborate with appropriate interested groups. For separate CHIP, while the provisions at § 438.66 are not applicable, we proposed to adopt the new coding requirements at § 438.16(d)(1)(vi) by amending § 457.1201(e) 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 for ILOSs 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 final 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 proposed to add an explicit reference. Therefore, we proposed 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 will be an efficient way for States to report their activities.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(d), 438.66(e), 457.1201(e)) below.

Comment: Commenters generally supported the proposal to require States to identify and document in managed care plan contracts the specific codes and modifiers for ILOSs to utilize for encounter data. Commenters indicated that this proposal would make ILOS data more easily available in T-MSIS, support program integrity and provide transparency. One commenter also indicated that this proposal would provide plans, States and researchers more opportunities to assess and build the evidence base about which specific interventions work best as ILOSs and are medically appropriate and cost effective for specific clinically defined target populations.

Response: We agree that including ILOSs in encounter data is a critical component for appropriate program operations, oversight, and evaluation.

Comment: A few commenters suggested that CMS define and require specific ILOS codes for States to use for ILOS services to ensure uniformity and comparability of services across States, and one of those commenters also recommended that CMS provide States, managed care plans and providers with resources and technical assistance to educate providers on ILOS coding practices. Similarly, another commenter stated concerns that some ILOS providers, such as community-based organizations, have limited billing and coding experience and will need to build expertise and could benefit from necessary training and support. One commenter encouraged the use of Z codes to help identify SDOH factors.

Response: We encourage States to collaboratively work towards the development of standard CPT® and

HCPCS codes and modifiers for ILOSs, and we noted that States may wish to collaborate with appropriate interested groups in this section of the preamble. As the ILOSs utilized in States may vary and we do not want to stifle State innovation, at this time, we believe that States should continue to lead efforts to identify ILOS codes and modifiers that work best in their programs and provide necessary resources, training, and technical assistance to providers (although we remind States costs associated with these activities cannot be included within the capitation rates or ILOS cost percentage). CMS will continue to monitor States ILOS encounter data requirements to identify best practices and evaluate if CMS should consider further standardization in the future.

Comment: Commenters supported the proposal at § 438.66(e)(2)(vi) to include ILOSs in the MCPAR when States report on the availability and accessibility of covered services. One commenter noted it is unclear how ILOSs should be reported in the MCPAR.

Response: We appreciate the comments supporting our proposal to clarify that ILOSs are reported in the MCPAR in § 438.66(e)(2)(vi). As ILOSs are substitutes for State-plan covered services and settings, we believe States should already be reporting ILOSs in the MCPAR and we appreciate the support to clarify this issue. We intend to update the MCPAR template to enable States to easily, clearly, and separately include ILOS data in the report from State plan-covered services and settings. We also clarify that for separate CHIP, the provisions at § 438.66 are not applicable so we did not propose to adopt the additional reporting requirements through MCPAR.

Comment: One commenter requested clarification on how network adequacy standards will be applied to ILOSs given that MCOs provide ILOSs on an optional basis.

Response: We encourage States and managed care plans ensure appropriate access to ILOSs that States authorize, and managed care plans choose to offer so that enrollees have appropriate access to those ILOSs if they choose. As ILOSs are substitutes for State plan-covered services and settings, the access standards, such as the network adequacy standards outlined in § 438.68, are not required for ILOSs.

Comment: One commenter requested CMS provide additional guidance and discussion related to monitoring and reporting for ILOSs versus the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.

Response: We are unsure what specific guidance the commenter requires as they did not provide additional detail in their comment. Medicaid's EPSDT benefit for children and youth under age 21 provides a comprehensive array of preventive, diagnostic, and treatment services, as specified in section 1905(r) of the Act. Through EPSDT, States are required to provide comprehensive services and furnish all medically necessary services listed in section 1905(a) of the Act that are needed to correct or ameliorate health conditions, based on certain Federal guidelines. We direct the commenter to *Medicaid.gov* which provides more details on EPSDT requirements and related monitoring and reporting, including the annual EPSDT performance information required annually on Form CMS-416.¹⁹⁸ On the other hand, ILOSs are substitutes for State-plan covered services and settings that a managed care plan may provide at their option, and the related monitoring and reporting is outlined in the preamble of this final rule. We encourage States to request technical assistance from CMS if they have further questions on the monitoring and reporting for the EPSDT benefit and ILOSs.

After reviewing the public comments, we are finalizing the provisions outlined in this section at (§§ 438.16(d), 438.66(e), 457.1201(e) as proposed.

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 SMDL¹⁹⁹ 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, access to care, cost effectiveness, and impact on the State's Medicaid program 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 improving the quality of health care and services

¹⁹⁸ <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>.

¹⁹⁹ <https://www.medicaid.gov/federal-policy-guidance/downloads/smd122298.pdf>.

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 will be consistent with those existing requirements and the proposals outlined in sections I.B.4. of this final 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 require 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 proposed a risk-based approach to the State documentation requirement that will be proportional to a State's ILOS cost percentage. We proposed, 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 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 proposed 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

will likely impact evaluation rigor and could dilute or even alter evaluation results due to the variability among managed care programs. As States will 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 sought 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 will 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 NAAAR in §§ 438.207(d) and 457.1230(b) for Medicaid and separate CHIP, respectively. We considered requiring an annual submission for the report required in § 438.16(e)(1) but believe 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 will provide sufficient time to collect complete data. Therefore, we proposed 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 use the 5 most recent years of accurate and validated data for the ILOSs. We believe the 5-year period will 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 will be sufficient to permit robust data collection for cost effectiveness and medical appropriateness. We requested comment

on the appropriate length of the evaluation period. As described in section I.B.4.h. of this final rule, we also proposed in § 438.16(e)(2)(ii) that CMS may require the State to terminate the use of an ILOS if it determines the State is out of compliance with any ILOS requirement which includes if the evaluation does not show favorable results such as those consistent with those proposed in § 438.16(e)(1).

By proposing that retrospective evaluations be completed using the five most recent years of accurate and validated data for the ILOS(s), we recognized we needed 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 final 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 proposed 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 encouraged 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 requested 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 proposed 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 expanded upon these elements in § 438.16(e)(1)(iii) wherein we proposed the minimum elements that a State, if required to conduct an evaluation, would evaluate and include in an ILOS retrospective evaluation. We proposed, 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 will be appropriate for a State to evaluate any cost savings related to utilization of ILOSs in place of State plan-covered services and settings. CMS will monitor the results of the evaluations to ensure the results are reasonable and CMS may request additional evaluations per § 438.16(e)(1)(v) as necessary. As described in section I.B.4.h. of this final rule, we also proposed in § 438.16(e)(2)(ii) that CMS may require the State to terminate the use of an ILOS if it determines the State is out of compliance with any ILOS requirement which includes if the evaluation does not show favorable results such as those consistent with those proposed in § 438.16(e)(1).

Similarly, we proposed 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 for the clinically defined target population. To achieve this, we proposed § 438.16(e)(1)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which will require that States use encounter data to evaluate if each ILOS is a medically appropriate and cost effective substitute for the identified covered service or setting under the State plan or a medically appropriate and 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 and cost effectiveness of an ILOS. A State may initially determine that the provision of air filters as an ILOS is a medically appropriate and cost effective substitute service for a target population of individuals with poorly controlled asthma (as determined by a score of 25 or lower on the Asthma Control Test) in lieu of the covered State plan services of emergency department services, inpatient services and outpatient services. After analyzing the actual encounter data, the State may discover that the provision of air filters to this clinically defined target population did not result in decreased utilization of a State plan service such as emergency department services, inpatient services and outpatient services. In this instance, the evaluation results would demonstrate that the ILOS as currently defined was not a medically appropriate and cost effective substitute 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) CAHPS survey, and 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 proposed 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 did not propose 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 final rule, we weighed the value of independent evaluation with increased State burden. We were 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 final rule, we proposed that the final ILOS cost percentage be submitted 2 years following completion of the applicable rating period, and we proposed 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 solicited 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. of this final 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 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 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 was important to the completeness of the retrospective evaluation, that all final ILOS cost percentages available be included. Therefore, we proposed 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 final 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 document in the evaluation alongside the other data we 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 final 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 final 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 proposed 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 will be important to evaluate appeals, grievances, and State fair hearing trends to ensure that enrollees' experience with ILOSs was not inconsistent or inequitable compared to the provision of State plan services and settings. We acknowledged 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 proposed that States submit with the ILOS retrospective evaluation was 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 was critical to measure their impact on improving population health and reducing health disparities. We proposed 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 reminded

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 proposed 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 proposed 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 recognized 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 separate CHIP ILOS retrospective evaluation into CARTS rather than as a stand-alone report. We sought public comment on whether or not the proposed retrospective evaluation should be incorporated into CARTS for separate CHIP ILOSs.

We summarize and respond to public comments received in this section

related to ILOSs (§§ 438.16(e) and 457.1201(e)) below.

Comment: Many commenters supported the proposed ILOS evaluations in §§ 438.16(e) and 457.1201(e) as they stated it was an appropriate guardrail to ensure ILOSs are in the best interests of the Medicaid and CHIP programs and would ensure appropriate assessment of whether ILOS are medically appropriate, cost effective, as well as improve access to care, ensure enrollee rights and protections, and advance health equity efforts. Commenters stated support for requiring these evaluations be conducted for each applicable managed care program, and all ILOSs in that program as they believe it would ensure robust evaluations. Commenters also supported the evaluation elements, as they believe this would ensure a fulsome, broad-based evaluation.

Response: We believe an evaluation of ILOSs is a reasonable component of a State's monitoring and oversight activities. States should be actively monitoring their ILOSs on a continual basis to ensure that each ILOS is an appropriate substitute for a State-plan covered service or setting that an enrollee is entitled to, including monitoring trends in the utilization of ILOSs, data related to appeals, grievances, and State fair hearings for each ILOS to ensure there are no concerns with beneficiary rights and protections, and that each ILOS continues to be medically appropriate and cost effective.

As we reviewed these comments, we recognized a revision to the technical text in § 438.16(e)(1)(i) was needed. In the proposed rule, we outlined our intent to require that a retrospective evaluation, when required, must include all ILOSs in that managed care program (see 88 FR 28171). Therefore, we are revising § 438.16(e)(1)(i) to include "and include all ILOSs in that managed care program" after "be completed separately for each managed care program that includes an ILOS." The finalized revision to § 438.16(e)(1)(i) is also applicable to separate CHIP through a cross-reference at § 457.1201(e).

Comment: Some commenters supported revisions to the ILOS evaluation proposals. One commenter recommended that rather than requiring States conduct ILOS evaluations that CMS should assume this responsibility to reduce State administrative burden. Other commenters indicated the CMS should require States to conduct ILOS evaluations from all managed care programs to ensure that clinical learning and improvement can be derived from

those programs going forward. One commenter recommended that an evaluation be done for each managed care plan contract rather than by program though the commenter did not provide a substantive rationale for this alternative. Some commenters opposed this proposed evaluation requirement and raised concerns regarding the associated State administrative burden, possibility that it may inhibit State and managed care plan use of ILOSs, and/or did not find the evaluation necessary.

Response: We continue to believe that ILOSs evaluations are a reasonable and appropriate oversight mechanism to ensure ILOSs are an appropriate and efficient use of Medicaid and CHIP resources. We also believe it is appropriate for States rather than CMS to conduct ILOS evaluations at this time. We also believe that evaluations should be done for each managed care program rather than across managed care programs or by managed care plan contract, as in our experience, the ILOSs in managed care programs may have differing enrollee eligibility criteria, populations, covered benefits, managed care plan types, delivery models, and geographic regions. While we encourage States to evaluate all ILOSs, we will maintain our proposed risk-based approach for providing evaluations to CMS to balance State administrative burden.

Comment: One commenter requested clarification on whether CMS's intent is for States to continuously submit a rolling 5-year evaluation. This commenter also suggested CMS consider requiring that States update ILOS evaluations within a certain number of years, similar to CMS's proposal for evaluations of State directed payments described in section I.B.2.j. of the proposed rule. Another commenter noted their belief that clarity was needed on the timing for when ILOS evaluations would first be expected.

Response: We appreciate these comments. Upon further review, we acknowledge that the preamble was inconsistent for this proposal as to when an evaluation would be required and for what 5-year period. We utilized both "5 most recent years of accurate and validated data for ILOS" in preamble (85 FR 28171) and proposed regulatory text at § 438.16(e)(1)(ii) (85 FR 28242), as well as "the first 5 rating periods that included the ILOS" in preamble (85 FR 28173) and proposed regulatory text at § 438.16(e)(1)(iv) (see 85 FR 28242).

We believe an evaluation is a helpful tool to ensure that ILOSs that have been in place for some time, as well as new ILOSs, such as those to address HRSNs,

are reasonable and appropriate for Medicaid and CHIP enrollees. However, we also strive to balance State administrative burden; therefore, we are utilizing a risk-based approach to only require States submit an evaluation when the final ILOS cost percentage exceeds 1.5 percent as outlined in section I.B.2.b. of this final rule. Additionally, we do not believe it is necessary to have a "rolling" evaluation requirement as there are other monitoring and oversight tools that will continue to evaluate ILOSs, including the MCPAR required in § 438.66(e)(2), ILOS cost percentage and required State notification for identified issues at § 438.16(e)(2)(i) (see sections I.B.4.f., I.B.4.b. and I.B.4.h. of this final rule respectively). CMS also has the option to request an additional evaluation in § 438.16(e)(2)(v), such as if the ILOS is a longer term substitute and additional evaluation time is needed to determine whether an ILOS is a cost effective and medically appropriate substitute for a covered State plan service or setting (see 85 FR 28173).

As such, our intent was to require a retrospective evaluation of existing ILOSs typically only for a specified period of time (that is, 5 years) following the publication of the final rule unless new ILOSs are authorized by the State and offered by the plans. We also intend to utilize a risk-based approach to require States submit this evaluation to CMS if the final ILOS cost percentage for one of these 5 years exceeds 1.5 percent, unless CMS determines another evaluation is warranted. This intent is also consistent with the SMDL published on January 4, 2023,²⁰⁰ which indicated that the evaluation would be completed for "the first five contract years that include ILOS(s)" following the effective date of the guidance.

We also recognize that some ILOSs have been used for many years and other ILOSs will begin to be new, and we acknowledge both circumstances as we determine an appropriate timeframe for States to submit the evaluation to CMS. Therefore, we intend to require this evaluation be submitted to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that include ILOSs or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent. We believe 2 years is a sufficient period of time as all States are encouraged to develop 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 (88 FR 28171), and States should actively be monitoring their ILOSs to ensure they are medically appropriate, cost effective and in compliance with other Federal requirements. States will also project an ILOS cost percentage each year, should be closely monitoring this percentage throughout the rating period and will reasonably know if the final ILOS cost percentage will exceed 1.5 percent during the rating period and 6 months following the rating period when most claims data are finalized. Therefore, we believe it is unnecessary to require the evaluation to be submitted 2 years after the State submits this final ILOS cost percentage to CMS as we believe this would create unnecessary delays.

Therefore, we replace the proposed language in the first sentence at § 438.16(e)(1) after the section title of "Retrospective evaluation" of "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" with "A State is required to submit at least one retrospective evaluation of all ILOSs to CMS when the final ILOS cost percentage exceeds 1.5 percent in any of the first 5 rating periods that each ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) following the applicability date in paragraph (f), or as required in paragraph (v)." And finalize the second sentence in this subsection as proposed. Additionally, we replace language at § 438.16(e)(1)(iv) of "The State must submit the retrospective evaluation to CMS no later than 2 years after the first 5 rating periods that included ILOS" with "The State must submit the retrospective evaluation to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent." The revisions to §§ 438.16(e)(1) and (1)(iv) are equally applicable to separate CHIP through the cross-reference at § 457.1201(e).

We believe it would be helpful to provide a few illustrative examples of when an evaluation would be required, as well as the timeframe to be evaluated and the required timeline for submission of the ILOS evaluation to CMS. As one illustrative example, a State's managed care program that has 3 ILOSs that were first authorized by the State and documented in the managed care plan contracts for the CY 2027

²⁰⁰ <https://www.medicaid.gov/sites/default/files/2023-12/smd23001.pdf>.

rating period would be required to submit an evaluation of all 3 ILOSs to CMS if the final ILOS cost percentage for CYs 2027, 2028, 2029, 2030, or 2031 exceeds 1.5 percent. CMS also reserves the right to require the State to submit additional retrospective evaluations to CMS at § 438.16(e)(1)(v). If the final ILOS cost percentage for any of these 5 rating periods exceeds 1.5 percent, the State must submit an evaluation to CMS no later than 2 years after the completion of this 5-year period which in this example would be December 31, 2033, as this is 2 years following the completion of the first five rating periods that include the ILOSs. As a second illustrative example, a State's managed care program has 5 ILOSs that were first authorized by the State and documented in the managed care plan contracts in CY 2022. In CY 2027, the final ILOS cost percentage is 2 percent. The State is required to conduct an evaluation as the final ILOS cost percentage exceeds 1.5 percent. And this evaluation would be due to CMS by December 31, 2029, as this is 2 years following the completion of the CY 2027 rating period that had a final ILOS cost percentage that exceeded 1.5 percent. As a third illustrative example, a State's managed care program has 2 ILOSs that were first authorized by the State and documented in the managed care plan contracts in CY 2026. In CY 2040, the final ILOS cost percentage is 1.7 percent. Since CY 2040 is not the first 5 years following the applicability date in § 438.16(f), CMS would make a determination as to whether the State would be required to submit a retrospective evaluation per § 438.16(e)(1)(v).

Comment: Some commenters stated the 5-year evaluation period was appropriate while others recommended that CMS reconsider the 5-year look back period for evaluations and these commenters varied in their recommended timeframe, including 3 years or a longer evaluation period than 5 years. One commenter recommended 7 years while another commenter just indicated a timeframe greater than 5 years without specifying a specific timeframe. A few commenters indicated that many ILOSs are cost effective in the first year they are offered and indicated that in those circumstances reporting 5 years of data would be an unnecessary burden to apply unilaterally. One of these commenters recommended that CMS revise § 438.16(e)(1)(ii) to acknowledge that the evaluation would “be completed using either the most recent year or 5 most recent years” of accurate and validated data for the

ILOS, and the commenter noted they believe this flexibility would allow States to evaluate the ILOS using data for either one or 5 years of data and that this constraint, as opposed to a revision of “5 or fewer years” would preclude States from cherry-picking the most favorable set of years.

Response: We continue to believe that 5 years of ILOS data is an appropriate time period as it 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 to evaluate. The commenters who recommended 3 years did not provide a substantive rationale for us to evaluate this recommendation further. We also agree with commenters that a longer evaluation period than 5 years may be needed in some circumstances which is why CMS will finalize § 438.16(e)(v) which allows CMS to require the State to submit additional retrospective evaluations to CMS when warranted.

In line with the revisions at § 438.16(e)(1) and (e)(1)(iv) that we are finalizing, we are also replacing the first sentence proposed at § 438.16(e)(1)(ii) of “Be completed using the 5 most recent years of accurate and validated data for the ILOS” with “Be completed using 5 years of accurate and validated data for the ILOS with the basis of the data being the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii).” In addition, we are finalizing the second sentence in this subsection as proposed. The revision to § 438.16(e)(1)(ii) is equally applicable to separate CHIP through the cross-reference at § 457.1201(e). Given inconsistency in the proposed rule discussed in the previous comment and response, this revision clarifies our intent, which is that the ILOS evaluation be completed using ILOS data from the first 5 rating periods that the ILOS is authorized by the State and offered by the managed care plan. Using the first illustrative example described in the previous comment, the ILOS evaluation would be required to utilize ILOS data from CYs 2027, 2028, 2029, 2030, and 2031. Additionally, using the second illustrative example described above, the evaluation would be required to utilize ILOS data from CYs 2022, 2023, 2024, 2025, and 2026.

Comment: We received some comments on ILOS data and its use in evaluations. A few commenters requested flexibility on data used for ILOS evaluations and raised concerns with requiring ILOS encounter data to be utilized for evaluations. Another commenter stated concern that States

and plans would not utilize standard codes for ILOSs and there would then be little insight into the exact service provided. Other commenters recommended that CMS require specific data frameworks be utilized by States and plans for the ILOS evaluation, such as standardized social care data frameworks to report ILOS impact on health equity. A few commenters recommended that States work with managed care plans to encourage that ILOS data be stratified by various factors, including pregnancy status, as this provides useful insights in addressing health disparities and advancing health equity. One commenter also recommended the evaluation elements outlined in 438.16(e)(1)(ii) be expanded to include how many ILOSs were utilized with demographic data on age, disability, race, and ethnicity.

Response: As we further outline in section I.B.4.f. of this final rule, we believe that requiring managed care plans and their providers to utilize specific codes established by the State to identify each ILOS in encounter data is critical for appropriate monitoring, oversight, and evaluation; as such, we will not grant flexibility on this matter. The ILOS evaluation will include data on ILOS utilization as specified in § 438.16(e)(1)(iii)(A). Additionally, we continue to believe encounter data, when possible, must include data necessary for the State to stratify ILOS utilization by sex (including sexual orientation and gender identity), race, ethnicity, disability status, and language spoken to inform health equity initiatives and efforts to mitigate health disparities; and this type of data stratification can be utilized by States in many contexts beyond ILOSs. While we encourage States to stratify encounter data, when possible, we are not requiring it at this time given the data limitations that we recognize some States have, such as the data that enrollees choose to share. We are unclear what specific data the commenter is referring to when they indicated that data stratification by pregnancy status may also be useful. We agree that, when possible, States, plans and evaluators should stratify applicable data by pregnancy status to inform program development, oversight, and evaluation efforts. To aid these efforts, we remind commenters that we released a previous resource that may be helpful. As pregnant women are a critical subgroup of Medicaid beneficiaries and their identification in many administrative data files, such as the T-MSIS Analytic Files (TAF), is not

straightforward, CMS previously developed a set of specifications and programming code to help researchers who wish to use administrative data to analyze this population.²⁰¹ At this time, we are not requiring States to use a standardized social care data framework to evaluate the impact of the ILOS. As we monitor the use of ILOSs and State evaluations of ILOSs, we will continue to assess how various frameworks and standardization may be useful to States, managed care plans and CMS.

Comment: One commenter requested clarification on whether for purposes of the evaluation, the ILOS cost percentage will be calculated annually or as an average of the 5-year period of the evaluation.

Response: An ILOS evaluation will document the final ILOS cost percentage for each year of the respective evaluation as this percentage is an annual calculation. See section I.B.4.b. of this final rule for further details on the final ILOS cost percentage.

Comment: One commenter urged CMS to clarify how the proposed evaluation requirements would apply to MCOs serving dually eligible enrollees and account for data limitations on Medicare cost data.

Response: The evaluation proposed in § 438.16(e)(1) is critical to ensuring that ILOSs are used in an effective and efficient manner and achieve their intended purpose. CMS makes available a variety of Medicare claims data to States for dually eligible beneficiaries. As such, we believe States have sufficient relevant data on dually eligible enrollees to produce a robust evaluation.

Comment: A few commenters recommended that CMS create additional guidance or standardized templates for data collection and reporting associated with evaluations to make it easier for States to evaluate the effectiveness of ILOSs, and another recommended that CMS have final approval of the quality measures a State utilizes in an evaluation if it is not a validated measure set.

Response: We appreciate the recommendation regarding associated templates for data collection and reporting, and we will take this under advisement as we consider developing subregulatory guidance on ILOS evaluations. We recommend that States use validated measure sets, when possible, to evaluate the quality of care of ILOSs. At this time, we will not

require CMS to approve States' measure sets as we do not want to stifle States' evaluation efforts including those of novel ILOSs. We will take this into consideration for future rulemaking as needed.

Comment: One commenter recommended that CMS consider tracking mechanisms to ensure States are on track to submit necessary evaluations while another recommended that ILOSs and associated costs be monitored at the State and national levels to inform future policymaking. One additional commenter also encouraged CMS to require that ILOS evaluations be publicly available.

Response: We agree with commenters that CMS and States should closely monitor the evaluation efforts for ILOSs, and that these efforts may inform future policy efforts. States should 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 to ensure they are adequately prepared to conduct an ILOS evaluation when required. We also encourage States to post publicly on their websites all ILOS evaluations that they conduct, including those not required by CMS; however, we are not requiring this in Federal regulation at this time as this would cause additional State administrative burden than initially proposed in the proposed rule.

Comment: One commenter requested clarification on whether the proposed ILOS evaluation requirements would supersede any prior written requirements for an ILOS evaluation included in approved Standard Terms and Conditions for existing waivers and demonstrations under section 1915(b) and section 1115 respectively.

Response: Any approved Special Terms and Conditions in an approved waiver or demonstration, such as those under section 1915(b) or section 1115 of the Act, are additional requirements that are conditions of CMS's approval of the associated Medicaid authority.

Comment: We received some comments regarding our proposal to encourage, but not require States to utilize an independent evaluator for ILOS evaluations. Most commenters supported not requiring the use of an independent evaluator. One of these commenters indicated that an independent evaluator would be costly and administrative burdensome. A few commenters recommended that CMS require States use an independent evaluator.

Response: We appreciate this feedback from commenters. Given the

majority of commenters supported our proposal, we plan to move forward with our proposal to encourage, but not require an independent evaluator for ILOSs.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(e) and 457.1201(e) as proposed with a few changes. First, as discussed in this section, we will modify the text of § 438.16(e)(1), (1)(i), (1)(ii), and (1)(iv). Additionally, we will replace "cost-effective" with "cost effective" in § 438.16(e)(1)(iii)(C) to utilize consistent language with existing regulatory terminology in § 438.3(e)(2)(i).

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 proposed, in § 438.16(e)(2) 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 proposed 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 included, but was 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 was 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

²⁰¹ <https://www.medicaid.gov/medicaid/data-systems/macbis/medicaid-chip-research-files/transformed-medicaid-statistical-information-system-t-msis-analytic-files-taf/index.html>.

expeditious manner so that CMS may assess and swiftly remediate issues of noncompliance that might cause harm to enrollees. We sought comment on the time period for State notification to CMS to ensure it is reasonable and appropriate.

We believe a termination process for ILOSs was critical to properly safeguard the health and safety of Medicaid and CHIP enrollees. Therefore, we proposed 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 determined 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 proposed a process for termination of an ILOS that will 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 proposed that the State will 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 proposed 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 proposed to require that States establish a process to notify enrollees that the ILOS they are currently receiving will be terminated as expeditiously as the enrollee's health condition requires. We also proposed, 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 will 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 proposed 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 was 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 proposed, 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 permitted 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 required otherwise. As part of the transition plan, States would be required to provide an assurance that it will 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, would 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 will 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 proposed 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 will 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 separate 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 proposed 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 part 457.

We summarize and respond to public comments received in this section related to ILOSs (§§ 438.16(e) and 457.1201(e)) below.

Comment: Some commenters supported the proposed State notification requirements when a 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. The commenters stated the proposal ensured adequate notice and transparency. Many commenters also supported a required transition plan for terminated ILOS and prompt enrollee notification when an ILOS is terminated, and indicated it was appropriate oversight and transparency.

Response: We appreciate the support for these provisions which we believe are critical to ensure appropriate Federal oversight of ILOSs to ensure they advance the objectives of the Medicaid and CHIP programs, and properly safeguard the health and safety of Medicaid and CHIP enrollees. We take this opportunity to note that both States and CMS can determine that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting. Further, both States and CMS can identify other areas of noncompliance.

Comment: One commenter supported a 60-day time period for this notification rather than our proposed 30-day timeframe as the commenter indicated that additional time was necessary to provide this notification to CMS. This commenter also requested clarification on the format and process for this proposed notification. Another commenter opposed the State notification requirement.

Response: We continue to believe that requiring States to notify CMS within 30 calendar days is necessary to ensure appropriate oversight. We believe this is critically important in circumstances where enrollee's health or well-being may be impacted. We are concerned that 60 calendar days is not an adequate timeframe to ensure CMS can assess and swiftly remediate issues of noncompliance that might cause harm to enrollees. We also believe that States have existing experience on required notifications to CMS such as those required in § 438.610(d)(1) for prohibited affiliations and in § 438.742 for sanctions, as well as notifications related to the termination of waivers under section 1915(b) of the Act. Therefore, we do not believe additional guidance on the notification process is necessary, but we will provide technical assistance to States as necessary, and continue to evaluate if further guidance is necessary on this process for State notification.

As we reviewed these comments, we recognized a technical correction to the regulatory text in § 438.16. As outlined in this section of the preamble for the proposed rule (88 FR 28174), our intent was to require State notification of noncompliance with part 438 as evident by the examples to contravening statutory requirements (such as the provision of room and board), failure to safeguard the enrollee rights and protections enumerated under part 438, etc. The proposed regulatory text utilized the term "in this section" which could be construed to reference only § 438.16. Therefore, we believe a technical correction is needed. While we are finalizing the notification timeframe as proposed, we are revising § 438.16(e)(2)(i)(B) to acknowledge that identified noncompliance relates to part 438, and not just § 438.16. The revision to § 438.16(e)(2)(i)(B) is equally applicable to separate CHIP through the cross-reference at § 457.1201(e).

Comment: Some commenters raised concerns with our proposal that States must submit a transition plan to CMS within 15 calendar days. Several commenters indicated that 15 calendar days is not a reasonable timeframe to develop and submit a transition plan because States would struggle to collect necessary data from their managed plans, and analyze it quickly enough to develop a meaningful transition plan for the specific ILOS. Commenters stated that transition plans should ensure that enrollees experience minimal disruption to services when an ILOS is no longer available to them and developing a robust plan specific to each ILOS takes time and should include input from interested parties. These commenters noted they believe this is likely not feasible within 15 calendar days and recommended alternative timeframes of 45 days, 60 days, and 12 months. Further, commenters pointed out that this 15-day timeframe does not align with the 30-day timeframe for a State to notify CMS as proposed in § 438.16(e)(2)(i)(A) and (B). These commenters stated that this misalignment makes the requirements on States unclear which could lead to confusion and disruption for enrollees. One commenter also noted that in some instances, States may choose to terminate ILOSs at a future date, but the requirement to submit a transition plan is based on the decision to terminate and not the termination date; the commenter requested clarification on the which action the timeframe is tied to.

Response: We concur with commenters that smooth transitions with minimal disruption for enrollees is

our goal. We proposed that an ILOS transition plan be submitted within 15 calendar days of the decision by a State, managed care plan or CMS to terminate an ILOS believing that to be the most appropriate timeframe to address potential health and safety concerns. However, we realize that monitoring for and addressing health and safety concerns is a routine part of managed care plan operations and is done through multiple methods such as grievance monitoring, encounter data analysis, and utilization management. While identifying these issues must inform the development of a transition plan, we know that managed care plans will continue to prioritize addressing health and safety issues as expeditiously as necessary. We acknowledge that we may have focused on those issues too narrowly leading us to propose 15 calendar days, but we agree with commenters that transition plans have to be meaningful and address many aspects in order to be effective. After consideration of the comments, we are finalizing § 438.16(e)(2)(iii) to allow States up to 30 calendar days to submit an ILOS transition plan to CMS for review and approval to align with the State notification process so both of these activities, when pertinent, could occur concurrently within the same 30-day timeframe. The revision to § 438.16(e)(2)(iii) is equally applicable to separate CHIP through the cross-reference at § 457.1201(e). We remind States that this 30-day timeframe to submit an ILOS transition plan is a maximum time period and States must always ensure that any health and safety issues for enrollees are mitigated as expeditiously as possible. We also continue to believe that the submission of a transition plan should be tied to the decision date and not the termination date to ensure adequate timing for enrollee notification and operational planning, as well as allow CMS time to review and approve the transition plan.

Additionally, as we reviewed these comments, we recognized that our intent in § 438.16(e)(2)(iii) would be clearer if we restructured the proposed language. In response to commenters' requests, we believe it would be helpful to clarify the specific actions that require an ILOS transition plan to be submitted to CMS as the term "decision" appears to have caused confusion. Consistent with the intent outlined in this section of the proposed rule preamble, upon receipt of a notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS, an MCO, PIHP, or PAHP provides to the State of its decision to cease

offering an ILOS to its enrollees, or CMS provides to the State of its decision to require the State to terminate an ILOS, the State must submit an ILOS transition plan to CMS for review and approval. Therefore, we are finalizing § 438.16(e)(2)(iii) by replacing “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” with “Within 30 calendar days of receipt of a notice described in paragraph(e)(2)(iii)(A), (B) or (C) of this section, the State must submit an ILOS transition plan to CMS for review and approval: (A) The notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS; (B) The notice an MCO, PIHP, or PAHP provides to the State of its decision to cease offering an ILOS to its enrollees; or (C) The notice CMS provides to the State of its decision to require the State to terminate an ILOS.” Additionally, we are redesignating requirements for an ILOS transition plan originally proposed in § 438.16(e)(2)(iii) to § 438.16(e)(2)(iv). The revisions to § 438.16(e)(2)(iii) and (iv) are equally applicable to separate CHIP through the cross-reference at § 457.1201(e).

Comment: Some commenters recommended revisions to § 438.16(e)(iii) to require a termination process for ILOSs. One commenter requested that CMS outline a specific process, including timelines and parameters for notifying enrollees about the termination of an ILOS while another commenter requested that CMS outline the requirements for the termination process, but leave the management of the process to individual States. Another commenter recommended that in addition to a notification process for impacted enrollees, States should also notify providers and family caregivers. One commenter opposed the proposed requirement for States to notify enrollees of a terminated ILOS.

Response: We appreciate commenters' requests for further details on the activities related to ILOS terminations, including notifications to enrollees, providers, and family caregivers. We believe States should follow their standard practices for termination of services. For example, some States provide enrollees (and their authorized representatives, if applicable) a notice, such as a postcard and web posting, announcing an update to the enrollee handbook as required in § 438.10(g) and

§ 457.1207 for Medicaid and CHIP, respectively. We believe using a consistent process for ILOSs is reasonable and makes it easier for enrollees. Managed care plans should also provide notice to providers in accordance with their usual protocols.

Comment: One commenter stated that managed care plans should not have the ability to reverse their decision to cover ILOSs and suggested that a different termination process should apply in this situation. Specifically, the commenter recommended that CMS prohibit managed care plans from terminating coverage of an ILOS within a contract year, and that if a plan chooses to terminate an ILOS at the end of a rating period, the plan should be required to provide a 6-month transition period after enrollee and provider notice. This same commenter raised concerns with the proposed transition of care policy only pertaining to enrollees currently receiving the ILOS that will be terminated, and the commenter recommended that new enrollees be able to receive the ILOS during the transition period.

Response: We do not agree with the commenter than CMS should place requirements on managed care plans regarding how long a managed care plan must provide an ILOS before it can choose to no longer offer it. 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 (88 FR 28161), and this is reflected in § 438.3(e)(2)(iii) which specifies that an ILOS is a substitute for a State-plan covered service or setting that will be offered to enrollees at the option of the managed care plan. As such, it is not appropriate for CMS to place limits on when a managed care plan can decide to no longer offer an ILOS to its enrollees. However, plans are obligated to ensure that enrollees have timely access to State-plan covered services and settings and should provide enrollees notice if they intend to change their coverage of an ILOS.

As we acknowledged in the proposed rule (85 FR 28174), we have concerns with enrollees being able to begin receiving an ILOS after the decision has been made that it is being terminated. We recognize that enrollees currently receiving an ILOS that will be terminated require time to transition to State plan services and settings and managed care plans must ensure that they are provided such services timely and with minimal disruption to care. However, we are concerned that allowing additional enrollees to receive an ILOS that is being terminated is

inappropriate particularly when an ILOS is being terminated because it is no longer medically appropriate or has triggered health and safety concerns. Therefore, we decline to adopt the commenter's suggestion and will only require transition plans to be implemented for enrollees who are currently receiving an ILOS that will be terminated, and not allow terminating ILOSs to be provided to new enrollees during the transition period.

Comment: A few commenters submitted comments related to the administrative steps associated with terminating an ILOS, namely the proposed requirements to amend the managed care plan contracts and any necessary revised rate certification to amend capitation rates. One commenter recommended that States be required to notify CMS through a different reporting mechanism, such as the MCPAR, instead of amending a managed care plan's contract. Another commenter opposed a requirement to amend managed care plan contracts and amend capitation rates, as necessary.

Response: While we recognize that there is additional State burden to revise managed care plan contracts and revise rate certifications, as applicable, we continue to believe that these actions are necessary in circumstances when a State or CMS requires, or a managed care plan chooses to terminate an ILOS. As currently required in § 438.3(e)(2)(iii), ILOSs must be identified in the managed care plan contracts, which necessitates amending them to reflect the termination of an ILOS. Additionally, ILOSs are considered in the development of actuarially sound capitation rates; therefore, if an ILOS is terminated from the managed care plan contract, the State and its actuary must evaluate if an adjustment(s) to the capitation rates is necessary to ensure Medicaid capitation rates continue to be actuarially sound. This is consistent with any programmatic change that may have a material impact to rate development.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.16(e) and 457.1201(e) as proposed with the following modifications:

- At § 438.16(e)(2)(i)(B), remove “this section” and replace it with “this part.”
- At § 438.16(e)(2)(iii), modify text as discussed in this section.
- At § 438.16(e)(2)(iv), renumber text proposed at § 438.16(e)(2)(iii) within this new section entitled “Requirements for an ILOS Transition Plan” as discussed in this section.

i. Applicability Dates (§§ 438.3(e), 438.7(g), 438.10(g)(2)(ix), 438.16(f) and 457.1200(d))

We proposed 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 proposed that States and managed care plans would comply with §§ 438.3(e)(2)(v), 438.16, and 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 proposed 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 proposed to adopt the applicability date at § 438.16(f) for separate CHIP by adding § 457.1200(d).

We summarize and respond to public comments received in this section related to ILOS applicability dates (§§ 438.3(e), 438.7(g), 438.16(f), 438.10(g), 457.1200(d)) below.

Comment: Some commenters requested that CMS delay the proposed applicability dates for ILOS provisions as they noted additional time was needed to make necessary contractual and operational changes. A few of these commenters requested delay of all ILOS provisions, one commenter requested delay of §§ 438.16(d) and 438.16(e), another recommended delay of § 438.66(c)(1), and one commenter recommended delay of § 438.66(e)(2)(vi). Other commenters were unclear which ILOS provisions they recommended be delayed. Additionally, we received commenters who requested CMS delay enforcement of the associated guidance published on January 4, 2023 until the effective date of the final rule.

There was also variability in the recommended revisions to applicability dates. One commenter recommended delaying all ILOS requirements to take effective with the next rate certification or contract submission. Another commenter recommended delaying ILOS provisions until the contract rating period beginning on or after 1 year following the effective date of the final rule. Other commenters did not provide specific recommendations on

applicability dates. The commenter who specifically requested to delay the documentation, monitoring, evaluation, and oversight in § 438.16(d) and (e) recommended allowing States until September 1, 2024. This commenter noted additional time was needed to finalize necessary contract amendments with managed care plans. This commenter indicated these contract amendments typically take at least 90 days, and managed care plans typically need 60 to 90 days after these contractual changes to update their member handbooks and related processes. The commenter who requested a delay for MCPAR changes in § 438.66(e)(2)(vi) recommended a 2-year delay to allow time for States to make necessary changes to contracting, reporting templates, and systems. The commenter who requested a delay for the ILOS cost percentage limit in § 438.66(c)(1) recommended a 5-year delay to allow States sufficient time for necessary ILOS implementation changes.

Response: We continue to believe that the proposed applicability dates give States ample time to comply with the proposed regulatory changes for ILOSs. On January 4, 2023, we published guidance²⁰² to clarify the existing option for States to pursue efforts to address enrollees’ unmet HRSNs, strengthen access to care, improve population health, reduce health inequities, and lower overall health care costs in Medicaid through the use of ILOSs. This guidance outlined our expectations for such ILOSs and provided a policy framework for States and managed care plans to ensure appropriate and efficient use of Medicaid resources. This guidance was effective with the date of publication; however, we acknowledged that States with existing ILOSs would need a glidepath to conform to the guidance given necessary procedural and contractual changes. Therefore, we allowed States with existing ILOSs to have until the contract rating period, beginning on or after January 1, 2024, to conform with the guidance for existing ILOSs. If States elected to add any new ILOSs, they were required to conform to this guidance for new ILOSs as of the publication of the SMDL. As the regulatory changes are generally consistent with the ILOS guidance, we believe States have had ample notice and should actively be making the necessary contractual and procedural

changes. As such, we are finalizing the applicability dates as proposed.

After reviewing the public comments, we are finalizing the provisions outlined in this section at §§ 438.3(e), 438.7(g), 438.10(g)(2)(ix), 438.16(f), 457.1200(d) as proposed.

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 and 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. MA plans are subject to similar (but not identical) requirements at § 422.152. In the proposed rule, we noted that § 422.152 outlines the quality improvement program requirements for MA organizations, including the development and implementation of a Chronic Care Improvement Program (CCIP) (88 FR 28175). We noted that CMS had previously 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. We removed the QIP requirement in the 2019 Final Rule (83 FR 16440). Accordingly, we proposed to update our regulations at § 438.330(d)(4) which still referenced a QIP as a substitute for a PIP in managed care plans exclusively serving dually eligible individuals.

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 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

²⁰² <https://www.medicaid.gov/sites/default/files/2023-12/smd23001.pdf>.

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 CCIP (83 FR 16669). As we noted in the proposed rule, we neglected to remove a reference to the QIP from § 438.330(d)(4) to conform with the changes at § 422.152. We proposed 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). Under our proposal, States could 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 noted our belief that 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 noted our belief 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 stated that we expected some States to already have CCIPs in place of QIPs, and therefore, we proposed 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 noted that 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.

We summarize and respond to public comments received on our proposal to allow States to permit plans 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), below.

Comment: Several commenters supported our proposal 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). A few commenters requested CMS provide clarification on the definition of the term “exclusively” and how CMS intends to define MCOs “exclusively” serving dually eligible individuals.

Response: For the comments regarding the definition of the term “exclusively,” our proposal would not change the intent of the previous policy that allowed States to permit Medicaid managed care plans that exclusively serve dually eligible individuals to substitute a quality plan required for their MA organization for a PIP required for the Medicaid managed care plan. It only replaces the reference to a QIP (which are no longer in use) with a CCIP. Under this final rule, like the previous policy, “exclusively serving dually eligible individuals” means the policy would only apply to Medicaid managed care plans whose enrollees are all dually eligible for Medicare and Medicaid.

After reviewing the public comments, and for the reasons described in the proposed rule, we are finalizing the change to § 438.330(d)(4) as proposed. We note that we are modifying the effective date of this provision to allow States with Medicaid managed care plans that exclusively serve dually eligible individuals to substitute an MA plan’s CCIP conducted under § 422.152(c) in the place of a Medicaid PIP effective with the effective date of this final rule. The proposed applicability date would have required States to 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) (88 FR 28175); however, this was an error. Since the change is optional for plans, we are not finalizing the applicability date proposed at § 438.310(d)(1), since separate applicability dates are only required if the effective date is different from that of the final rule.

b. Managed Care State Quality Strategies (§§ 438.340 and 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. 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 3 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 proposed several changes to increase transparency and opportunity for meaningful ongoing public engagement around States’ managed care quality strategies. We proposed that States must comply with these updates in § 438.340 no later than 1 year from the effective date of the final rule and proposed 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 proposed to increase the opportunity that interested parties have to provide input into States’ managed care quality strategy. 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 regulations did not require that the quality strategy be posted for public comment at the three-year renewal mark if significant changes had not been made. We proposed 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 believe should be made to the quality strategy, even if the State itself is not proposing significant changes. We noted that States would retain discretion under the proposed rule to define the public comment process. We proposed this change would apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

Second, we proposed 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 regulations clarify 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. We proposed revisions at § 438.340(c)(2)(ii) to make clear that the evaluation, as part of the review, must be posted. We noted that § 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). We proposed this 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.medicare.gov/medicaid/downloads/managed-care-quality-strategy-toolkit.pdf>.

Third, we proposed to clarify when States must submit a copy of their quality strategy to CMS. 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 regulations did 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 proposed 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 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 proposed to include this requirement into the provision at § 438.340(c)(3)(ii) for Medicaid by adding paragraphs (c)(3)(ii)(A) through (C), which applies to separate CHIP through an existing cross-reference at § 457.1240(e). We proposed 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 believed would give States time to update internal processes accordingly.

Finally, we proposed 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 proposed to replace "paragraph (b)(11)" with "paragraph (b)(10)" in § 438.340(c)(3)(ii). This proposed change will apply equally to separate CHIP through the existing cross-reference at § 457.1240(e).

We summarize and respond to public comments received on Managed Care State Quality Strategies (§§ 438.340, 457.1240) below.

Comment: Several commenters supported our proposals to increase the opportunity for public comment, clarify the requirements for posting the quality strategy evaluation on the State Medicaid website, and submit the quality strategy to CMS every 3 years regardless of whether significant changes were made. One commenter opposed the publication of the State's quality strategy for public comment every 3 years regardless of whether a significant change was made, and one commenter opposed the proposal to submit the quality strategy to CMS regardless of whether a significant change was made. The commenter opposing the provision requiring public comment noted that the requirement would be burdensome for States and that the current requirements are sufficient. Some commenters requested CMS impose more requirements on the State public comment process, such as requiring a certain amount of lead time

for the public to make comments, and requiring States to publicly document the actions they took in response to the public feedback, or the rationale for not taking actions requested by the public. One commenter requested clarification on what is considered a significant change.

Response: We disagree with commenters who thought the current requirements were sufficient. Under § 438.340(b)(10), it is up to the State to define what is considered a significant change, and to include that definition in their quality strategy. Without finalizing these changes, States may make revisions that do not rise to the level of "significant change," as defined by the State, and would not be required to post the quality strategy for public comment or submit the strategy to CMS for feedback. We believe these new requirements bring the regulations closer to the original intent—for the quality strategy to evolve over time with the shifting needs of the managed care population, and for the public and CMS to weigh in on the strategy every 3 years.

We also appreciate the comments recommending additional requirements on how States administer the public comment process. In the proposed rule, we stated that States would retain discretion to define the public comment process. We clarify that States are currently required under § 438.340(c)(1) to obtain input from the Medical Care Advisory Committee, beneficiaries and interested parties, as well as consult with Tribes, if applicable, during the public comment process. We did not propose additional requirements on the public comment process for the quality strategy, and are therefore, not finalizing any additional requirements at this time.

Comment: One commenter noted that the timeframe we proposed to implement these changes to the quality strategy requirements (1 year from the effective date of the final rule) was reasonable, and one commenter requested we consider a longer timeframe, such as 2 years, for compliance with these new requirements to help States manage the process.

Response: We continue to believe the timeframe we proposed is reasonable given that many States are already implementing the policies we proposed based on our review and feedback provided on quality strategies to date. Therefore, we are finalizing the implementation date as proposed.

We did not receive any comments on the proposed technical correction to replace "paragraph (b)(11)" with

“paragraph (b)(10)” in § 438.340(c)(3)(ii), and are therefore finalizing this provision as proposed.

After reviewing the public comments, we are finalizing the rules for the quality strategy as proposed. We note that the applicability date, though unchanged, will be finalized at § 438.310(d)(1), not § 438.310(d)(2) as proposed.

c. External Quality Review (§§ 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240 and 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 subpart E of part 438 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 proposed 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 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 final 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 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 called 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 FFS 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 proposed to remove PCCM entities described in § 438.310(c)(2) from the managed care entities subject to EQR under § 438.350. Other requirements in part 438, subpart E that currently apply to risk-bearing PCCM entities described at § 438.310(c)(2) are not impacted by this final rule.²⁰³ We noted that States may perform additional oversight and monitoring activities that are similar to mandatory 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 will not be subject to EQR regulations at part 438. Further, we believe that the removal of all PCCM entities from the mandatory scope of EQR would alleviate burden on States and PCCM entities while retaining appropriate tools for quality monitoring and oversight.

We proposed conforming amendments to remove reference to PCCM entities described in § 438.310(c)(2) at §§ 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 proposed 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 proposed a modification at § 438.354(c)(2)(iii) to clarify this. We note that these changes,

²⁰³ 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).

if finalized, would be effective as of the effective date of the final rule. For separate CHIP, we likewise proposed 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).

We summarize and respond to public comments received on Removal of PCCM entities from scope of mandatory External Quality Review below.

Comment: Several commenters supported our proposal to remove the EQR requirements for PCCM entities described at § 438.310(c)(2). Some commenters noted that States will continue to exercise optional participation for PCCM entities in the performance measure validation activity, especially where performance measures are not otherwise evaluated by an independent auditor.

Response: As we noted in the proposed rule, we intended to allow flexibility for States to continue to monitor PCCM entities at their discretion, including through EQR. Therefore, we are finalizing these changes largely as proposed, with one revision to more explicitly allow validation of performance measures and performance improvement projects conducted by PCCM entities described at § 438.310(c)(2) at the discretion of States, which was supported by public comments. Specifically, we proposed to remove § 438.358(b)(2) to implement our proposal to exclude PCCM-entities described at § 438.310(c)(2) from EQR. Instead, we are finalizing a modification to this provision to remove the word “must” and replace it with “may.” It now reads “For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section *may* be performed” (emphasis added). This change will allow States that choose to conduct these activities to continue to access FFP at the 50 percent rate in accordance with § 438.370(b). We are also finalizing a technical change to remove the references to PCCM entities described at § 438.310(c)(2) within the optional activities at § 438.358(c)(3) and (4) since they are no longer included in the required activities referenced at § 438.358(b)(1)(i) and (ii) but are included in the list of plans for which States can exercise optional activities at § 438.358(c).

After reviewing the public comments, we are finalizing the rules for the removing EQR requirements for PCCM

entity (described in § 438.310(c)(2)) with modifications at § 438.358(b)(2), and at § 438.358(c)(3) and (4).

(2) EQR Review Period

In the proposed rule, we noted that the regulations provided that most EQR activities are performed using information derived from the preceding 12 months, but did not clearly indicate to which 12-month period the activity should pertain. Specifically, the regulations at § 438.358(b)(1) (which apply to separate CHIP through an existing cross-reference at § 457.1250(a)) required 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) were also required to use information derived “during the preceding 12 months.” In addition, we did not previously specify in the regulations when the EQR activity must take place relative to the finalization and posting of the annual report. The result was a lack of uniformity in the review periods included in States’ annual EQR technical reports each year. In some cases, for example, States reported on the results of EQR activities conducted 3 or more years ago, while other States reported on the results of EQR activities conducted relatively close to the completion of the report. To support States’ and CMS’s ability to use the reports for quality improvement and oversight, we proposed 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 proposed to add paragraph (a)(3) in § 438.358 to define the 12-month review period for all but one of 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. We proposed at § 438.358(a)(3) that 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. We proposed that 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 will 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 will be March 2020–March 2021.

We also proposed 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 would create more consistency among States regarding the time period represented by the data. Consistency in what data are reported could help make the EQR technical reports a more meaningful tool for monitoring quality between plans within and among States.

We proposed 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 proposed 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 proposed 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. We 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 proposed that States must comply with these updates to § 438.358 no later than December 31, 2025, and proposed 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. We believed this timeline would allow States the time to make any contractual or operational updates following the final rule.

We summarize and respond to public comments received on EQR review period below.

Comment: Several commenters supported the proposed changes to the EQR review period, noting the importance of using the most recent

available data and creating more uniformity across State EQR reports. One commenter encouraged us to consider further standardizing the reporting periods along the calendar year. Another commenter supported the alignment of review periods but noted that some EQR activities may not be completed in the 12-month timeframe proposed.

Response: After reviewing the public comments, we are finalizing these provisions as proposed for EQR mandatory activities and, based on comments received about how some EQR activities are not completed in a 12-month timeframe, revising how the review period is applied to EQR optional activities. We considered the commenter's suggestion to align all review periods on the calendar year, but decided against this since many States use the contract year as a review period which may be more appropriate in some circumstances. In response to the commenter's concern about the EQR activities taking more than 12 months, we continue to believe applying these timeframes will result in the most recent available data for the three applicable mandatory activities at § 438.358(b)(1) (which apply to separate CHIP through an existing cross-reference at § 457.1250(a)). We encourage States to request technical assistance if they experience challenges with these new timeframes and anticipate that with our decision (discussed in section I.B.5.c.5. of this final rule) not to move up the EQR report deadline to December 31 will help States implement these changes. However, the commenter's concern about EQR activities taking more than 12 months did make us reconsider how the review periods apply to EQR optional activities, particularly with the finalization of the new optional activity at § 438.358(c)(7) for evaluations (discussed in section I.B.5.c.3. of the final rule). Based on comments received, we no longer believe the review period proposed applies equally between mandatory and optional EQR activities. If we finalized our proposed review period timeline for optional activities, the data and information used for optional activities would be limited to a 12-month period, which conflicts with the 3–5 year time periods required to be evaluated for quality strategies, SDPs and ILOSs. Therefore, we are finalizing the regulations at § 438.358(c) to remove the reference to a review period from the optional activities, and to remove the reference to the optional activities in the new review period regulation at § 438.358(a)(3). We believe this

modification will provide flexibility for States to determine the appropriate time periods for the optional activities they implement based on the intended use of the data obtained from these activities.

Based on our review of public comments, we are finalizing this provision with modifications at § 438.358(c) and finalizing the applicability at § 438.310(d)(2) for Medicaid (not § 438.310(d)(3) as proposed), and at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP.

(3) Using an Optional EQR Activity To Support Current and Proposed Managed Care Evaluation Requirements

We proposed 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 final 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 final rule, we finalize 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. of this final rule. We discussed at length the challenges States have demonstrated regarding the SDP evaluation plans and results in the proposed rule, which indicated to us that States will likely benefit from additional technical assistance and support in conducting evaluations under the new SDP and ILOS requirements. Additionally, we described how CMS's reviews of State quality strategy evaluations revealed many challenges for States and a similar need for greater technical assistance. For this reason, we proposed 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 focused 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 will 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, statistical analysis, and quality assessment and improvement methods. We believe this optional activity will provide States critical technical assistance via a CMS-developed protocol that will 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 final rule). For this reason, we proposed 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 final 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 ILOS evaluations and believe it would be beneficial to States to have this optional EQR activity. We proposed to adopt the new EQR optional activity for separate CHIP through an existing cross-reference to § 438.358 at § 457.1250(a). We intended this optional activity to be available to States as of the effective date of the final rule.

We summarize and respond to public comments received on using an optional EQR activity to support current and proposed managed care evaluation requirements below.

Comment: Several commenters supported our proposal to allow States to use an optional EQR activity to support the new evaluation requirements in the proposed rule. Some commenters noted that States would appreciate the flexibility to

conduct the evaluations themselves. One commenter noted concerns about whether the current EQRO vendors have the capabilities, staffing and expertise to support these activities. Commenters also noted that if a State Medicaid agency does use an EQRO, CMS should not require a new competitive procurement to amend the scope of an EQRO contract or other contract vehicle.

Response: In response to the comment about State flexibility, we clarify that States are allowed to conduct the evaluation themselves for their quality strategy, SDPs and ILOSs under these final rules. As we described in the proposed rule, we continue to believe the competencies of an EQRO required under § 438.354(b), including research design and methodology, statistical analysis, and quality assessment and improvement methods, could be leveraged for these activities. However, States have the discretion under § 438.358(a)(1) to conduct EQR activities themselves or use an agent that does not qualify as an EQRO, so long as it is not a managed care plan (the EQRO is, however, required to compile and write the final EQR reports). Regarding the comment about procuring a new EQRO contract, we note that § 438.356(e) currently requires States to follow an open, competitive procurement process for each contract with an EQRO that is in accordance with State law and regulation and requires State to comply with 45 CFR part 75 as it applies to State procurement of Medicaid services. We acknowledge, however, that state procurement laws may vary relative to what actions prompt a new competitive procurement process. We also note that under § 438.370(c) States, would need to obtain CMS approval of the EQRO contract or contract amendment including this optional activity prior to claiming a 75 percent FFP match for the activity. We intend to update the EQR protocols to provide guidance on this new activity in accordance with § 438.352, and once published, States can begin claiming FFP match for this activity.

After reviewing the public comments, we are finalizing the changes EQR optional activities at § 438.358(c) as proposed.

(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 will duplicate activities conducted as a part of either a Medicare review of a MA plan or a private accreditation review. Section 438.360(a)(1) required that, in

order for a State to exercise this option for 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 requirement at § 438.360(a)(1) meant that PAOs had to 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 meant the PAO had to 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 this regulation created an unnecessary administrative burden on both CMS and PAOs and restricted the availability of the EQR nonduplication option for States. We also do not believe that the 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) of the Act) or that has an external review conducted under section 1852(e)(3) of the Act, the external review activities conducted under subparagraph (A) for 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 interpret 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 will be eligible to participate in nonduplication, and providing organizations described in section 1852(e)(4) of the Act as an example.

Therefore, we proposed 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 proposed conforming changes to the title of § 438.362(b)(2) to remove language specific to Medicare Advantage deeming. Additionally, we proposed to remove the requirements for PAOs related to MA deeming authority at § 438.362(b)(2)(i). This proposal removed paragraph (b)(2)(i)(B) and modified paragraph (b)(2)(i) to include current § 438.362(b)(2)(i)(A). We believe this proposed change would reduce administrative burden among the private accreditation industry, as well as create more flexibility for States to leverage PAO reviews for nonduplication. We noted that under § 438.360(a)(2) States are 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), and need to explain the rationale for the State’s determination that the activity is comparable in their quality strategy at § 438.340. We proposed these changes would be effective as of the effective date of the final rule.

We summarize and respond to public comments received on non-duplication of mandatory EQR activities with Medicare or accreditation review below.

Comment: We received several comments on this proposal to remove the requirements on PAOs to obtain MA deeming authority. The two commenters that supported the proposal noted how the revisions would reduce burden, make data more accessible, and streamline EQRs by facilitating the use of accreditation data. Two commenters opposed the proposal. One commenter did not specify their objection; the second commenter stated concerns about States having to ensure that private accreditation standards are comparable to standards established through EQR protocols and consistent with a State’s quality strategy. This commenter stated that private accreditation should not substitute for Federal or State monitoring and noted that it is more efficient for CMS to make one determination regarding an accreditation organization rather than each State making its own determination.

Response: After reviewing the public comments, we are finalizing this rule as

proposed. We agree with commenters that this change will reduce burden and streamline the EQR process for States by removing barriers to using accreditation data. States may leverage the non-duplication option for EQR-related activities that would otherwise be performed by the State, the State's entity or an EQRO. In response to the concerns about the use of accreditation data for monitoring and State responsibilities for ensuring accreditation standards are comparable to those in EQR protocols, we note that the current regulations at § 438.360(a) already allow States to use information from a private accreditation review of an MCO, PIHP, or PAHP for the annual EQR, and at § 438.360(a)(2) already require each State to determine that the accreditation review standards are comparable to the standards established in the EQR protocols and include the rationale for this determination in its quality strategy. Furthermore, under § 438.360(c) the State must identify in its quality strategy under § 438.340 the EQR activities for which it has exercised the option described in this section, and explain the rationale for the State's determination that the Medicare review or private accreditation activity is comparable to such EQR activities. The removal of the requirement for PAOs to obtain Medicare deeming authority does not affect those existing requirements. Regarding the comment about efficiencies, the current regulations at § 438.360(b), already require the State to furnish all the data obtained from an accreditation review to the EQRO for analysis and inclusion in the annual EQR technical reports. Removing the requirement for PAOs to obtain Medicare deeming authority does not impact this requirement but would create efficiencies for the State by reducing barriers to obtaining data for the annual EQR. In addition, as noted in the proposed rule, we do not believe the requirement for PAOs to obtain Medicare deeming authority is compelled under the statute, and we do not believe the process has added value to a PAO's ability to conduct accreditation reviews that could be used for EQRs.

After reviewing the public comments, we are finalizing the changes to non-duplication at § 438.360(a)(1) as proposed.

(5) External Quality Review Results (§ 438.364)

(a) Data Included in EQR Technical Reports

The current regulations at § 438.364, included in separate CHIPs 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.

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 regulations, however, limited the data included in the reports to performance measurement data; the regulations did not require other types of data 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 was that reports often focused on whether the methods used to implement or evaluate the PIP were validated, but did not include the measurable data reflecting the outcomes of the PIP. Additionally, the regulations did not require the reports to include any data obtained from the mandatory network adequacy validation activity.

We believe validation alone was 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 was critical to understanding plan performance regarding timeliness and access to care. Therefore, we proposed 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 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 would result in more meaningful EQR technical reports because they would 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, would make the EQR technical reports a more effective tool to support quality improvement and oversight in managed care. We proposed that the revisions to § 438.364(a)(2)(iii) for Medicaid would apply to separate CHIP through an existing cross-reference at § 457.1250(a). We proposed 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 sought comment on 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 noted that stratification of performance measure data in EQR technical reports could support States' efforts to monitor disparities and address equity gaps. Stratifying performance measure data also aligns with requirements for the mandatory reporting of Medicaid and CHIP Core Sets and requirements in the MAC QRS proposed under new 42 CFR part 438 subpart G. We sought comment on how CMS could best support States in these efforts using future guidance we develop in the EQR protocols.

We summarize and respond to public comments received on Data included in EQR technical reports below.

Comment: Several commenters supported our proposal to expand the scope of data included in the EQR technical reports. Commenters in general supported these changes, noting that they would make the data more accessible and result in more meaningful reports that can be used to support quality improvement, oversight in managed care, and stronger managed care plan performance for beneficiaries. Commenters agreed that some States have limited their technical reports to include only information about the validation of quality data, while not including the results of performance measures or performance improvement projects. One commenter questioned whether we plan to require the secret shopper survey results be included in

the EQR Protocol 4 Technical Report. MACPAC noted that this proposal may help to address the concern that the reports do not focus on changes in performance and outcomes over time, and interested parties would like EQR process and findings to place more emphasis on outcomes and comparability.

Response: We agree with commenters about how this change will make reports more meaningful to support quality improvement. In response to the question about secret shopper survey results, we will include guidance in the updated EQR protocols on what the EQR technical reports must include, including guidance on results from quantitative assessments related to the network adequacy validation activity.

Comment: Several commenters supported the future addition of guidance in the EQR protocols for States to stratify performance measures collected and reported in the EQR technical reports under the performance measure validation activity. Commenters noted that additional guidance would facilitate monitoring health disparities and would promote alignment of the EQR technical report with the mandatory reporting of Medicaid and CHIP Core Sets and requirements we proposed for the MAC QRS. Some commenters noted concerns about data reliability and indicated that State Medicaid agencies would need significant time to develop their data infrastructure. Another commenter recommended that CMS use a phased approach with pre-validated subsets of the measures.

Response: We agree with commenters that adding guidance for the stratification of performance measure data in the EQR technical reports would support States in monitoring health disparities and addressing equity gaps. We appreciate the comments to align the guidance with the Core Sets and MAC QRS stratification requirements, as well as the concerns noted about State implementation time and data infrastructure and using a phased approach. We will consider these concerns and recommendations from commenters as we develop future EQR protocol guidance.

After reviewing the public comments, we are finalizing the changes to the data included in EQR reports at § 438.364(2)(iii) as proposed. As noted in the proposed rule, we intend to release an updated EQR protocol in accordance with § 438.352 to implement the changes finalized at § 438.364(a)(2)(iii). This applicability date, though unchanged, will be finalized at § 438.310(d)(3).

(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 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. Therefore, we proposed 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 needed more time to complete the EQR activities after receiving audited HEDIS data. We also believe December 31st is most appropriate because performance measurement data are most often calculated on a calendar year, so the December 31st date would result in data being at most one-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 final rule regarding changes to the EQR review period, would have improved the utility of the technical reports for States, CMS and interested parties by making the data reported in them more current. We proposed changes at § 438.364(c)(1) and (c)(2)(i) for Medicaid that would apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We solicited comments on changing the posting date to December 31st annually. We also solicited comments 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 proposed 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 will provide enough time for contractual and operational updates.

We summarize and respond to public comments received on revising the annual due date for EQR technical reports below.

Comment: Commenters both opposed and supported the proposal the change the annual due date from April 30 to December 31 each year. Some commenters requested to clarify whether the change represents more or less time to complete the reports. Commenters who supported the proposal noted that the change would better align with the availability of finalized HEDIS performance measures in the EQR technical reports, leading to more recent data and better comparability across States. Other commenters supported the change to make the reports more actionable but noted that the change would result in States incurring additional costs, and could result in data reporting lags as some measures would not make the "cut-off" date to be included in that year's report if it was due December 31. Commenters who opposed the change noted that it would be extremely challenging to complete the mandatory EQR activities under the new proposed due date, citing the burden and time constraints associated with this change. Some commenters detailed the timelines of their internal processes to conduct the EQR activities, for the EQRO to analyze and compile the report, and for State officials to review and approve the report before it is posted online. One commenter noted that the EQR activities typically occur in the second half of the calendar year, and the December 31 date would not allow enough time to complete all the individual activities to be incorporated into the annual report. Another commenter noted that the last step of the State officials reviewing and approving the report usually starts in February, and the December 31 date would be very difficult to meet.

Response: After reviewing the public comments, we are not finalizing this proposed change to the annual due date for EQR technical reports and are maintaining the current requirement for posting annually by April 30. We clarify for commenters that we did intend to reduce the time allowed to finalize the reports by 4 months in our proposal by moving the due date from April 30 to December 31. Based on comments received, we no longer believe the benefit of the EQR technical reports being posted 4 months earlier outweighs the current burden of changing State and EQRO processes for conducting annual EQR activities and compiling the EQR technical reports. Though the April 30 due date does create a considerable

lag time between the data and information included in the reports and when that data becomes available to the public, we believe our new provisions regarding the EQR review period is a sufficient step to making reports more current. We will consider where there may be efficiencies to be gained through standardization or electronic reporting that could help States post their EQR reports earlier to reduce this lag time and make the reports more timely and actionable. With this change we are also not finalizing the corresponding change at § 438.364(c)(2)(i), as well as the proposed applicability date of December 31, 2025, and the reference to § 438.364(c)(2)(iii) was removed from § 438.310(2).

After reviewing the public comments, we are not finalizing the changes proposed to the EQR report due date at § 438.364(c)(1).

(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 proposed 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, 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. We described that this change would facilitate our review and aggregation of the required data and ensure that all States' data are included in the annual report. We proposed that the notice to CMS be provided "in a form and manner determined by CMS." However, we sought 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) will 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 did not believe will impose a great burden on States since most States already notify CMS when their EQR technical reports are posted by email.

We summarize and respond to public comments received on Notifying CMS when annual EQR technical reports are posted below.

Comment: One commenter supported our proposal to require that States notify

CMS within 14 calendar days of posting their EQR technical reports on their website, noting that the State already notifies CMS once the State's EQR technical report is posted.

Response: After reviewing the public comments, we are finalizing the change to require States to notify CMS when their EQR reports are posted as proposed, but we are not finalizing the proposed change to the due date, which we are keeping as April 30 (per our discussion in section 5.c.5.b. of this final rule).

(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 proposed 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 will 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 will provide other interested parties insight into historical plan performance. We noted that 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 sought comment on whether archiving 5 years of reports will pose a significant burden on States. We proposed to add this provision to the requirements at § 438.364(c)(2) for Medicaid, which will apply to separate CHIP through an existing cross-reference at § 457.1250(a).

We proposed that States must comply with this update to § 438.364(c)(2)(iii) no later than December 31, 2025, and proposed 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. We believe this applicability date would provide the time needed to update websites accordingly.

We summarize and respond to public comments received on revising website

requirements for historical EQR technical reports below.

Comment: Several commenters supported our proposal to require States to maintain at least the previous 5 years of EQR technical reports on their website. Commenters in general supported this revision, noting there is little additional burden to keep technical reports available to the public over an extended period, and that having an archive of EQR technical reports would make it easier to track responses to recommendations, evaluate progress on performance improvement projects, and monitor changes in quality performance. Three commenters requested that we consider extending this requirement for States to maintain at least 10 years of EQR technical reports on their website and two comments requesting CMS provide clarification on how State agencies are expected to display this data.

Response: In response to commenters requesting the requirement be extended to at least 10 years, we encourage States to maintain a publicly available archive of EQR technical reports dating back as long as feasible, however we are not requiring more than 5 years of reports to be posted at this time. We understand that EQR technical reports can be lengthy and vary greatly from State to State, so at this time we are not specifying how the data must be displayed. We will consider developing technical assistance resources to help States make the EQR data more accessible and usable for interested parties.

After reviewing the public comments, we are finalizing this change to the website posting requirements for EQR at § 438.364(c)(2)(iii) as proposed.

(6) Technical Changes

We proposed a technical change at § 438.352 to eliminate the apostrophe from National Governors Association to align with the correct name of the organization.

We did not receive any comments in response to our proposed technical change. Therefore, we are finalizing this provision as proposed.

6. Medicaid Managed Care Quality Rating System (§§ 438.334 and 457.1240)

We proposed significant revisions to the requirements for the Medicaid and CHIP managed care quality rating system, including revisions to existing regulations and the adoption of a new subpart in part 438 for regulations governing the rating system. In response to supportive comments we received and for the reasons outlined in this

rulemaking, we are finalizing most provisions related to the mandatory measure list, the flexibility for States to request to implement an alternative MAC QRS, the proposed subregulatory process to make updates to the mandatory measure list in the future, and the ability for States to include additional measures in their MAC QRS. We are finalizing several modifications from our proposal to clarify the scope of the alternative QRS and to reduce the implementation resources States need for their MAC QRS, including when, or if, a State chooses to adopt an alternative QRS.

Specifically, many comments we received on our alternative quality rating system proposal suggested that commenters did not understand what changes to the MAC QRS developed by CMS would require CMS approval as a State alternative MAC QRS. The current regulations at § 438.334(b)(1) identify two components of the MAC QRS framework: (1) The quality measures used to assess plan performance and (2) the methodology for calculating quality ratings based on the measure data reported for each plan rated by the QRS. Current § 438.334(c) establishes a process by which States may request CMS approval to display different performance measures or apply a different methodology to generate quality ratings in their MAC QRS after requesting and receiving CMS approval. As described in more detail in section I.B.6.h. of the proposed rule, we proposed to narrow the scope of actions that require CMS approval under the alternative quality rating system flexibility to only modifications to the MAC QRS methodology. We also proposed that States could display additional measures in their MAC QRS without requiring CMS approval if they requested input from a broad range of interested parties and documented the input received and the state's response. Therefore, we proposed to change the existing QRS rule (reflected in the regulation at § 438.334(c)), to allow States to include *additional* measures, meaning that States would include these measures in addition to the CMS-identified mandatory measures for the QRS. Upon review of the comments, we realized that this was misinterpreted, and that commenters thought that our proposal was intended to allow States to implement alternative mandatory measures to replace CMS-identified selected measures as opposed to being in addition to those measures.

A number of commenters also misunderstood our proposal and thought that we proposed to allow States to request alternatives to the

website display features proposed in § 438.520 as a third MAC QRS framework component. Although the proposed rule anticipated that States could add *additional* website display features, we did not propose to allow States to eliminate or use alternatives to the QRS website design features included in the proposed MAC QRS rules. To summarize, the proposed rule included that States would no longer need CMS approval to add measures that are in addition to those identified as mandatory measures by CMS; would be able to implement website display features in addition to those newly proposed in § 438.520 (also without CMS approval); and would continue to have the option to use an alternative methodology (meaning an alternative to the rating methodology described in § 438.515(b)), for calculating quality ratings for mandatory measures identified by CMS, subject to CMS review and approval).

To address these issues, we are finalizing the provision enabling States to request an alternative QRS as part of the section of the regulation governing the QRS methodology with changes to more clearly and accurately reflect the State flexibility option to apply an alternative QRS rating methodology. We believe this makes clear that States must request CMS approval to apply an alternative methodology but need not seek CMS approval to include additional measures or website display features in their MAC QRS. We stress that these changes in the final rule compared to the proposed rule are merely organizational. Under this final rule, States will have the flexibility to display additional measures not included in the mandatory measure set, as well as to develop additional QRS website display features, as proposed. States also retain flexibility currently available under § 438.334, and finalized in this final rule at § 438.515(c) to use an alternative QRS methodology, if they request and receive CMS approval to do so, subject to fewer procedural requirements.

We also are finalizing changes compared to the proposed rule to reduce State burden in implementing a QRS. As discussed throughout the proposed rule, our proposals were meant to minimize burden on States, managed care plans, and other interested parties, such as providers, and to maximize access to the information that beneficiaries identified as useful and desirable in selecting a plan. However, while commenters were overwhelmingly supportive of the MAC QRS, many commenters stated concern that the overall administrative complexity of implementing the MAC

QRS, including the time and resources needed to do so, would be substantial. Based on feedback received from commenters, we are finalizing five modifications to our proposal that we believe will further reduce QRS implementation burden with minimal impact on beneficiaries' access to the information it is important for them to have.

First, as discussed in additional detail in section I.B.6.d of this final rule, we are finalizing an option for States to request a one-time, one-year extension to fully comply with one or more of the requirements of the MAC QRS rating methodology under § 438.515(b) and certain website display requirements under § 438.520(a), if the State, despite a good faith effort, would be unable to fully implement the requirements in § 438.515(b) or § 438.520(a)(2)(v) and (a)(6) by the implementation deadline specified for CMS in subpart G. As discussed in section I.B.6.g. of the proposed rule, we proposed that States will implement a MAC QRS in two phases and we are finalizing that approach. In the first phase of implementation, States must fully comply with all MAC QRS requirements, except for requirements under § 438.520(a)(6), by the implementation date specified in § 438.505(a)(2) (by the end of the fourth calendar year following July 9, 2024. This rule is being finalized July 9, 2024, which means States must implement a MAC QRS by December 31, 2028. States granted an extension for eligible first phase requirements—those under § 438.515(b) or § 438.520(a)(2)(v)—will have until December 31, 2029 to fully comply with these requirement(s). Requirements under § 438.520(a)(6) will be implemented in a second phase. CMS will specify the implementation date of the second phase in the future, but this date must be no earlier than 2 years after implementation of the first phase as per § 438.520(a)(6). Therefore, States will be required to implement the requirements under § 438.520(a)(6) no earlier than calendar year 2030, and States granted an extension for requirements under § 438.520(a)(6) will have until at least until calendar year 2031 to fully comply with the requirement.

Second, under the proposed rule, States would have been required to display a quality rating for all MAC QRS mandatory measures. As discussed in section I.B.6.e. of this rule, this final rule narrows the scope of mandatory measures for which a quality rating must be displayed in a State's MAC QRS to only those that are applicable to the managed care program(s) established by the State (meaning those MAC QRS

mandatory measures that assess a service or action covered by one or more of the State's managed care contracts). As a result of this change, the scope of data that States must collect and validate to calculate quality ratings for mandatory measures will be narrowed—to only data for measures that are applicable to a State's managed care program(s). Third, as described in section I.B.6.h. of this final rule, we are removing the requirement (proposed to be redesignated from current § 438.334(c)(2) to proposed § 438.525(b)(1) and (2)) that requires States to obtain input from the State's Medical Care Advisory Committee and provide an opportunity for public comment of at least 30 days on a request for, or modification of a previously approved, alternative Medicaid managed care quality rating system. Fourth, we proposed at § 438.520(a)(6)(i) and (ii) that States would be required to display a search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user and a search tool that enables users to identify available managed care plans that include a specific provider in the plan's network. In this final rule we are narrowing the scope of these proposed MAC QRS requirements to apply only to managed care plans that participate in managed care programs with two or more participating plans; this change is discussed in section I.B.6.g.2 of this final rule.

Finally, under the proposed rule States would be required to collect the data necessary to calculate quality ratings for each MAC QRS mandatory measure from Medicaid FFS, Medicare, or both if all data necessary to calculate a measure could not be provided by Medicaid managed care plans. Furthermore, States would be required to ensure that the collected data are validated and then used to calculate performance rates for MAC QRS measures. In the proposed rule, we acknowledged that challenges currently exist to the collection and use of Medicare data and, to some extent, Medicaid FFS data that may be necessary to calculate quality ratings for Medicaid plans. We therefore proposed an undue burden standard under which States would be required to collect necessary Medicare and Medicaid FFS data when such data are available for collection by the State *without undue burden*. We are largely finalizing these requirements as proposed, but with modifications throughout § 438.515(a) and (b) to clarify that the scope of the undue burden standard extends beyond

the collection of Medicaid FFS and Medicare data and may be applied also to the validation of collected data and the use of validated data to calculate quality ratings for MAC QRS mandatory measures for Medicaid managed care plans. As finalized, States will be required to collect Medicaid FFS and Medicare data, validate the collected data, and use the validated data to calculate quality ratings for managed care plans for MAC QRS mandatory measures *the extent feasible without undue burden*. This change is discussed in section I.B.6.f of this final rule.

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 final 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, with most beneficiaries offered a choice of plans.²⁰⁴

Numerous States have implemented rating systems for Medicaid and CHIP managed care plans, but the MAC QRS represents the first time that States will 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 MAC QRS is intended to be a one-stop-shop where beneficiaries can 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 select a plan that meets their needs.

Current requirements at § 438.334(b)(1) for Medicaid, which are 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. 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 the previous 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

²⁰⁴ <https://www.medicaid.gov/medicaid/managed-care/downloads/2020-medicaid-managed-care-enrollment-report.pdf>.

place between 2018 and 2022 and are summarized in section I.B.6.a of the proposed rule, 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 set forth in the proposed rule.

Based on this consultation, we proposed 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 will be an additional third component of the MAC QRS framework. We proposed 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 methodology. This would represent a change from the current regulations that include both mandatory and non-mandatory measures in the CMS-developed framework. We proposed the initial mandatory measure set that States must use regardless of whether they use the MAC QRS CMS methodology or a CMS-approved alternative QRS methodology, as well as a subregulatory process under which CMS will engage regularly with interested parties to update the mandatory measure set over time.

Additionally, after consulting with prospective MAC QRS users, we came to understand that 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. Therefore, we proposed website display requirements as a new component of the overall framework, and 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, considering the diverse starting points from which States will begin to implement their MAC QRS, we proposed 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 website 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, though enhanced FFP would only be available in the case of MCOs. 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.

The MAC QRS proposals in the proposed rule were made under our authority to implement and interpret 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 relied 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 the proposed rule, we noted 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 were 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 would 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 the proposed rule and of this final rule, on the design of the MAC QRS, including the mandatory measure set, methodology, and display requirements. Under this final rule, we will 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 final rule (regarding § 438.510(b)(1)), we are finalizing 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 final rule (regarding § 438.515(e)), we are finalizing our proposal to propose new rules to implement domain-level quality ratings after consulting with States and interested parties to update the MAC QRS methodology; and in section I.B.6.g. of this final rule (regarding § 438.520(d)), we are finalizing our proposal to periodically consult with States and interested parties (including Medicaid managed care quality rating system users) to evaluate the website display requirements for continued alignment with beneficiary preferences and values.

b. Provisions of the Proposed Rule (§§ 438.334, 438 Subpart G and 457.1240(d))

We proposed 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. We proposed to redesignate and revise existing regulations at § 438.334 to newly created proposed sections in Subpart G with proposed revisions, discussed in detail in section I.B.6 in this final rule. For separate CHIP, we proposed to adopt the new provisions of subpart G in part 438 by cross-reference through an amendment at § 457.1240(d). We did not receive any comments on this general approach and are moving the QRS provisions to subpart G, as proposed.

c. Definitions (§§ 438.334, 438.500 and 457.1240(d))

We proposed definitions for several technical and other terms at § 438.500 for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). Additional definitions are discussed in more detail later in this final rule in connection with specific proposals for which the definitions are relevant.

- *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 and 423 of this chapter.

- *Qualified health plan quality rating system (QHP quality rating system)* means the health plan quality rating system developed in accordance with 45 CFR 156.1120. We inadvertently used the term “Qualified health plan rating system (QHP quality rating system)” in the proposed rule and are updating the terminology here by adding the word quality after “Qualified health plan” and before “rating system.”

- *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.

We did not receive any public comments on these proposed definitions (§§ 438.334, 438.500, and 457.1240(d)). We are finalizing these definitions as proposed, with the minor correction outlined above regarding the term “Qualified health plan rating system (QHP quality rating system),” and use the terms consistent with the definitions throughout part 438, subpart G. We are also finalizing our approach that CHIP managed care programs be subject to the same quality rating system rules, except where otherwise explicitly noted, by using a cross-reference in § 457.1240(d) to the Medicaid rules.

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 proposed 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 currently in § 438.334(a)(3) would provide States more time to make the operational and contractual changes needed to meet the requirements in this final rule and give States flexibility to determine what time of year to publish their quality ratings.

To illustrate the proposed timeline change, we provided the following example: if the final rule were 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 final 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 final rule, after the proposed implementation date. We also discuss, in section I.B.6.g. of this final 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 sought comment on whether these proposed policies, all together, would give States sufficient time to implement their MAC QRS on a timeline that meets their operational needs.

We also proposed 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 section I.B.6.g. of the 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 noted in the proposed rule that 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. Therefore, we proposed at § 438.505(a)(3), 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 discussed the importance of providing this assistance in section I.B.6.g. of the 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 did 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 to reduce State burden across Federal quality reporting systems. We believe this requirement should continue to apply broadly to the MAC QRS framework, and therefore, proposed to require this alignment, to the extent appropriate, as part of CMS’s updates to the MAC QRS mandatory measures and

methodology. We proposed 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 during our pre-rulemaking consultations, which informed the policy reflected in our current regulations that, to the extent possible, the MAC QRS should 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.²⁰⁵ We also proposed, at § 438.505(c), that in maintaining the MAC QRS mandatory measure set and rating methodology, CMS would 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 proposed 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) were also proposed to apply to separate CHIP through a cross-reference at § 457.1240(d) but excluded all references to beneficiary support systems. We noted 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 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 excluded 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).

We summarize and respond below to public comments received on the general rule and applicability provisions (§§ 438.334(a), 438.505(a) and 457.1240(d)).

Comment: Most commenters supported our proposal to extend the implementation date for the MAC QRS another year, from 3 years to the end of the fourth calendar year following the publication of the final rule. Commenters who supported the timeline stated that the proposal balances the burden on States, health plans, and providers with the needs of beneficiaries. Some commenters urged CMS to accelerate the initial implementation so users could access the information sooner. Several commenters requested that CMS consider further extending the implementation timeline beyond the proposed additional year, with many suggesting that CMS provide another additional year to implement, giving States 5 calendar years to implement a MAC QRS following the publication of the final rule. A couple of commenters encouraged CMS to consider implementing a voluntary performance year prior to mandating full implementation of the proposed MAC QRS, effectively requesting an additional year to implement a MAC QRS. Several commenters suggested that CMS consider an extension process for MAC QRS requirements (especially for States with a small number of managed care plans) to allow States additional time to implement MAC QRS requirements. States noted several challenges to meeting the implementation dates, including collecting the data necessary to calculate measures for certain beneficiaries, such as those who are dually eligible, and collecting data needed to stratify quality ratings. A couple of commenters requested that CMS phase in the proposed mandatory measures, starting with a subset of mandatory measures, such as ten, required for the first year, and moving toward display of the full measure set over time.

Response: We agree that States may be challenged to implement all MAC QRS requirements by the proposed implementation date despite a good faith effort. We considered but are declining the suggestion to further extend the implementation dates as a whole by an additional year or to phase in use of the full mandatory measure set over time. We believe that the additional year that was proposed

(extending the current 3-year timeframe under the current regulation to 4 years), as well as our proposal to implement the MAC QRS website requirements in two phases, giving additional time to implement the search tools and display of measures stratified by beneficiary characteristics required under § 438.520(a)(6) that may require more advanced technological capabilities or more challenging data collection, is sufficient to implement the MAC QRS, particularly since many of our requirements build upon existing information and data States either already have or are currently required to report publicly or to CMS. We note that the deadline specified in § 438.505(a)(2) as finalized is the end of the fourth calendar year after the effective date of this final rule (meaning the fourth calendar year after July 9, 2024), unless otherwise specified in the part 438, subpart G regulations.

Nonetheless, we recognize that some States may need additional time to fully comply with all MAC QRS requirements and we are adding new provisions at §§ 438.515(d) and 438.520(b) to this final rule to allow States to request a one-time, one-year extension for certain MAC QRS requirements for which commenters identified specific concerns and barriers to implementation. These include the methodology requirements established at § 438.515(b)(1) and (2), as well as the website display requirements established at § 438.520(a)(2)(v) and (6). We discuss additional details related to extensions for methodology requirements in section I.B.6.f. and related to extensions for website display requirements in section I.B.6.g but address here the overall elements common to both types of extensions.

States may submit a request for an extension under either §§ 438.515(d) or 438.520(b) of the final rule by submitting an extension request to CMS that includes the information and by the deadline(s) identified in these respective sections. We are finalizing identical content requirements for requests for both types of extensions. First, the State must identify the specific requirement for which the extension is requested. Second, the State must describe the steps the State has taken to meet the requirement as well as the anticipated steps that remain to implement the requirement. Third, the State must explain why it will be unable to comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement by its implementation date. Finally, the

²⁰⁵ <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

State must include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, the operational steps the State will take to address identified implementation barriers by the end of the extension year as the extension is for only one-year, and it is a one-time extension. If a State wishes to request an extension for multiple requirements, the State need not submit multiple extension requests, but must provide the required information for each individual requirement identified in its single extension request. We discuss the types of information a State could provide to meet these requirements for each type of extension in more detail in sections I.B.6.f. and I.B.6.g of this final rule.

We are also finalizing the same standard for approving extension requests for implementation of the methodology (§ 438.515(d)(3)) and the website display requirements (§ 438.520(b)(3)). CMS will approve a State's request for an extension if CMS determines that the request: (1) includes the information required for the extension request; (2) demonstrates that the State has made a good-faith effort to identify and begin executing an implementation strategy for the requirement but is unable to comply with the specified requirement by the implementation date specified in the regulations in part 438 subpart G; and (3) demonstrates the State has an actionable plan to implement the requirements by the end of the one-year extension. If a State requests an extension for multiple requirements, CMS will review each request separately against these standards and will provide the State with an individual determination for each requirement for which the State has requested an extension.

We believe that providing States with an opportunity to request an extension for these individual MAC QRS requirements, if needed, best balances the important policy goals and burdens associated with implementation of the MAC QRS requirements adopted in this final rule and addresses the various policy discussions in the comments to accelerate or postpone MAC QRS implementation. We discuss the implementation extension for rating methodology requirements in additional detail in section I.B.6.f of this final rule and the implementation extension for website display requirements in additional detail in section I.B.6.g of this final rule.

Comment: Many commenters supported our proposal to require States to provide support to beneficiaries, enrollees, or both, seeking assistance as

to how to use the MAC QRS through the State's existing beneficiary support system. Most of these commenters agreed that this would require additional training and financial resources and requested that CMS ensure that States have access to an enhanced Federal match (FFP funding) to provide these services. A couple of commenters noted the importance of ensuring that any choice counseling provided include information and resources related to Medicare coverage for people who are dually eligible. One commenter recommended that CMS issue guidance or best practices for communicating with dually eligible beneficiaries about the differences between the MAC QRS ratings and Medicare and Part D quality rating system ratings.

Response: We appreciate commenters' support for our proposal to require States to use their beneficiary support system to assist beneficiaries, enrollees, or both, using the MAC QRS implemented by the State. We agree that this requirement will necessitate additional training and resources for call center staff, and we acknowledge that the MAC QRS requirements may be more complex than information currently provided through the beneficiary support system. To address this concern, we will consider developing technical assistance resources to support States in training call center staff, including how to best address the unique needs of dually eligible individuals, and differences between the MAC QRS ratings and the MA and Part D quality rating system ratings.

In response to the commenters that requested increased FFP funding to support States in the design and development of their MAC QRS, we clarify that there are existing pathways States can use to receive enhanced FFP related to the implementation of the MAC QRS. As was discussed in the proposed rule and reiterated in section I.B.6.f. of this final rule, under the EQR optional activity at § 438.358(c)(6), States may use their EQRO to assist with quality ratings, which could include the collection of data, validation of data, and calculation of performance rates. States may be eligible for a 75 percent FFP for such EQRO services in the case of an MCO, as provided in § 438.370. We appreciate commenters requesting clarity on FFP regarding the other aspects of the MAC QRS implementation. If the requirements for the enhanced match are met, a State may be eligible for enhanced FFP as part of the State's Medicaid Enterprise System (MES) for the design,

development, and implementation of a new public facing website—and the data infrastructure that supports it—when necessary to comply with the new MAC QRS website requirements we are finalizing in § 438.520. We refer States to SMDL #22–001²⁰⁶ for more information and encourage States to meet with their MES State Officer for technical assistance on which operational elements of their MAC QRS implementation may be eligible for enhanced FFP. We will also consider developing more specific guidance on FFP availability for MAC QRS to help States plan their implementation.

We also agree with commenters that information developed by the State that is related to the MAC QRS, including choice counseling, should also address the unique needs of dually eligible individuals. We will consider using the information and perspectives gathered during our pre-rulemaking engagement with beneficiaries, described in section I.B.6.a. of the proposed rule, to inform future guidance on best practices for how to assist MAC QRS users, including dually eligible beneficiaries, and how to explain the differences between the MAC QRS ratings and the MA and Part D rating system ratings.

Comment: Commenters overwhelmingly supported alignment of the MAC QRS with existing CMS quality measurement and rating initiatives, when appropriate, and encouraged continued focus on alignment to reduce burden on both States and plans. Many cited the QHP quality rating system and MA and Part D quality ratings system, specifically, as well as the Adult and Child Core Sets and the Universal Foundation as particularly important initiatives with which to align.

Response: We agree with commenters that alignment of the MAC QRS with existing CMS quality measurement and rating initiatives is an important way to reduce burden on States and plans and we appreciate the support for our proposal at § 438.505(c) to continue alignment between the MAC QRS and existing CMS quality measurement and rating initiatives for other markets and programs to the extent appropriate.

After consideration of the public comments and for the reasons outlined in the proposed rule and this final rule, we are finalizing § 438.505 largely as proposed, with some modifications. As finalized, § 438.505(a)(1) reflects changes to clarify the scope of flexibility for States regarding the methodology

²⁰⁶ See State Medicaid Director Letter #22–001, <https://www.medicaid.gov/sites/default/files/2023-06/smd22001.pdf>.

used in the QRS and to clarify that States may display additional quality measures and website features in addition to the mandatory minimum measures specified by CMS and the mandatory minimum content of the MAC QRS website identified in § 438.520(a). In addition, we are finalizing minor changes throughout paragraph (a) to improve the readability of the provision. We are also finalizing the cross-reference in § 457.1240(d) to part 438, subpart G to require CHIP managed care programs to comply with implementing their MAC QRS (or alternative QRS) by the end of the fourth calendar year following the effective date of this final rule as proposed. We note that although the MAC QRS changes in this rule are intended to work harmoniously to achieve a set of goals and further specific policies, they are not so interdependent that they will not work as intended even if a provision is held invalid. Many of the MAC QRS provisions may operate independently of each other. For example, quality ratings for mandatory measures can be displayed in accordance with the requirements of phase one of the website display implementation even if website display requirements in phase two are successfully challenged. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements). We intend that if any amendment or new provision regarding the MAC QRS adopted in this rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from the remaining provisions.

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 section I.B.6.e.1. of the proposed rule, we discussed the standards that guided CMS in identifying the initial mandatory measures and proposed an initial mandatory measure set. We sought comment on our proposed initial mandatory measure set, which we are finalizing in this final rule. We noted that we would not duplicate the list of

the mandatory measures and specifications in regulation text considering the regular updates and revisions that would occur under the subregulatory process at least every other year to include the addition, removal, or update of the mandatory measure set proposed in § 438.510(b). We also proposed to codify both the standards that guided development of the initial mandatory measure set and the standards for a subregulatory process to modify the mandatory measure set over time.

(1) Standards for Including Measures in Mandatory Measure Set (§§ 438.510(c) and 457.1240(d))

Three distinct considerations guided the process of selecting individual measures to establish a concise proposed initial mandatory measure set. We proposed at § 438.510(c)(1) through (3) to codify these three considerations as standards that we would apply in subsequent years in adding measures to the mandatory measure set, making substantive updates to an existing mandatory measure, and in some circumstances when removing measures from the mandatory measure set. Specifically, a measure was only included in our proposed initial mandatory measure set if: (1) it met five of six measure inclusion criteria proposed in § 438.510(c)(1); (2) it will contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas in the mandatory measure set; and (3) the burdens associated with including the measure will not outweigh the benefits to the overall quality rating system framework of including the new measure based on the measure inclusion criteria we proposed. Performance areas are domains of care, such as preventive health and long-term services and supports. We discussed in section I.B.6.e.4. of the proposed rule that these same standards will be applied in determining whether a measure may be added to or removed from the mandatory set.

As discussed in section I.B.6.e.1. of the proposed rule (and reflected in proposed § 438.510(c)(1)), during our pre-rulemaking discussions with States and other interested parties, we identified six measure criteria for determining whether a given measure is a good candidate for including in the mandatory MAC QRS measure set: (1) *Usefulness*: is the measure meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan; (2) *Alignment*: is the measure currently used by States and other

Federal programs and does it align with other CMS rating programs described in § 438.505(c) of this chapter; (3) *Relevance*: 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) *Actionability*: does the measure provide an opportunity for managed care plans to influence their performance on the measure; (5) *Feasibility*: 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) *Scientific Acceptability*: does the measure demonstrate scientific acceptability, meaning that the measure, as specified, produces consistent and credible results.

We provided the following explanation in the proposed rule of each of these criteria and how we assessed (and, if finalized, how we will assess) whether a given measure met it for inclusion in the initial mandatory measure set.

- *Usefulness*: For the initial 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 and determined that measures that assess the quality of care or services most identified by beneficiaries as relevant to selection of a health plan. We noted that when adding, updating, or removing measures through the proposed process, we would rely on the continued engagement with beneficiaries proposed in § 438.520(c) and discussed in section I.B.6.g.4. of the proposed rule to determine whether a measure meets this criterion of being meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan. We noted that input from beneficiaries or beneficiary advocates with experience assisting beneficiaries was particularly important in evaluating this criterion, but input from other interested parties was also considered.

- *Alignment*: For measures in the initial mandatory measure set, we assessed whether a measure met 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. If the measure is not currently in use, we assessed whether it overlaps with an existing, widely used measure. This approach reflects the continuing evolution of quality measurement and allowed for consideration of new, better measures.

- **Relevance:** For each measure under consideration, we determined, using measure information and technical specifications, whether the measure evaluated or measured at least one of these areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity. If it was determined that the measure evaluated or measured at least one of these areas, it was considered to meet the criteria.

- **Actionability:** For the proposed measure set, we assessed whether a measure met this criterion by considering input from States, plans, and other interested parties 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 measure at the plan (as opposed to provider or State) level because individual plans cannot effectively impact performance of all plans aggregated across the state.

- **Feasibility:** 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.

- **Scientific Acceptability:** For the proposed measure set, we assessed whether the intervention included in the measure directly correlates to the quality of care provided and provides consistent and credible results by reviewing evidence that the measure can be used to draw reasonable conclusions about care in a given domain.²⁰⁷

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 consultations, we received feedback confirming our assessment 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 extremely 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. Therefore, we proposed 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 sought comment on the six criteria we proposed to evaluate prospective measures for the mandatory measure 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 sought comment on our proposal to require measures to meet five out of the six proposed criteria, and whether that threshold produces enough measures to consider for the MAC QRS. Finally, we sought comment on the extent to which the measures in our proposed measure set met the proposed measure inclusion criteria, including the reasons and/or supporting data for why the measure meets or does not meet the criteria.

Through our work to develop the proposed mandatory measure set, we found that many measures met at least five of the six measure inclusion criteria and came to understand that additional standards would be needed to narrow the initial mandatory measure set to a manageable size and to prevent future measure sets from becoming too large. States and managed care plans recommended limiting the mandatory set to between 10 and 30 measures to ensure that plans can improve on selected measures, that States will be able to report all measures, and that implementing a QRS would not overwhelm State and plan resources. Furthermore, our 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 and concise information on the big picture using fewer measures.

The first standard which a measure must meet for inclusion in the mandatory measure set, under the proposed rule, reflected at § 438.510(c)(1), is to satisfy at least five of the six criteria discussed above. The two additional standards that we proposed to codify in § 438.510(c)(2) and (3) reflect the feedback we received for a concise mandatory measure list

and allow us to consider how a measure would contribute to the measure set as a whole. First, in § 438.510(c)(2), we proposed 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 since we included as part of our standard proposed in § 438.510(c)(2) that the overall measure set should be “concise.” We stated our intent to maintain a goal of no more than 20 measures for the initial mandatory measure set, but proposed to allow flexibility for the number of measures to increase as the mandatory set is updated over time. We stated that we would consider each suggested measure in relation to other suggested measures, as well as the measures already in the 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.

The second standard, proposed in § 438.510(c)(3), is that a measure would be added to the mandatory measure set when the burdens of adding the measure do not outweigh the benefits. To make this assessment, the extent to which the measure meets the six criteria proposed at § 438.510(c)(1)(i) through (vi) would be considered. If several similar measures are suggested for inclusion (that is, those that measure performance within similar subpopulations of beneficiaries, health conditions, services, and performance areas), we would assess the extent to which each suggested 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 and identify a measure that best balances burdens and benefits. We proposed to include a measure when all three of the standards proposed in § 438.510(c) are met. We also proposed that CMS would use the subregulatory process proposed in § 438.510(b) and discussed in section 1.B.6.e.3. of the proposed rule, to determine which measures meet the proposed standards.

We sought comment on the standards proposed at § 438.510(c)(2) and (3) and how measures should be assessed using these standards. We sought 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 sought comment on whether there are additional considerations that CMS

²⁰⁷ CMS Measures Blueprint: <https://mmshub.cms.gov/measure-lifecycle/measure-testing/evaluation-criteria/overview>.

should consider in the weighing of burdens and benefits of a measure under proposed § 438.510(c)(3).

We summarize and respond to public comments received on standards for including and adding mandatory measures for the MAC QRS (§§ 438.334(b), 438.510(c) and 457.1240(d)) below.

Comment: We received many comments supporting our standards for measure selection, including our proposed measure selection criteria. One commenter supported our proposed measure selection criteria but recommended that we revise the feasibility criterion to consider burden on providers. Another commenter recommended that we consider the burden of chart review abstraction in data collection and reporting when weighing the benefits and burdens of a measure.

Response: We agree with the commenter that recommended that we revise the feasibility criterion to consider provider burden and we are modifying the proposed feasibility measure selection criterion at § 438.510(c)(1)(v) to add “providers” to ensure that provider burden, as well as State and plan burden, is considered when assessing whether data collection associated with the measure is feasible. This means that feasibility of a measure will be determined by whether data are available without undue burden on States, plans, or providers such that it is feasible to report by many States, managed care plans, and providers. We believe that this change also addresses the commenter that requested that we specifically consider the burden of chart review abstraction on providers in data collection and reporting when assessing the burdens and benefits of a measure. In § 438.510(c)(3), we proposed that the benefit and burden assessment would be made based on the six criteria listed at § 438.510(c)(1). By finalizing our feasibility criteria at § 438.510(c)(1)(v) with modifications to include the feasibility and potential burden of data reporting for providers, CMS may consider the extent to which chart review abstraction may burden providers when assessing a measure for inclusion in the mandatory measure set.

Comment: One commenter requested additional clarification on how CMS intends to assess the administrative burden associated with a potential measure and evaluate the reasonableness of that burden, as well as the relative benefit to the larger quality rating system, noting that CMS’s determination of burdens associated with data collection and reporting and whether they are reasonable is not

always consistent with States’ views or experiences.

Response: In section I.B.6.e.1 of the proposed rule, we provided an overview of the process by which we identified the three standards for adding mandatory measures, finalized in this final rule at § 438.510(c)(1)–(3). We emphasize here that we did not develop the standards for including a measure without input and do not intend to apply them without an opportunity for input from interested parties. Rather, the standards proposed and finalized in this rule reflect the thought process and concerns discussed by and among interested parties, including States, over several years of engagement.

Furthermore, as discussed in section I.B.6.e.3 of the proposed rule and finalized in § 438.510(b), before adding a measure to the mandatory set, we must engage in a subregulatory process through which States and other interested parties evaluate the current mandatory measure set, make recommendations to add mandatory measures, and provide comment on modifications to the mandatory measure set. When a measure meets all three of the standards finalized at § 438.510(c)(1)–(3), per § 438.510(c), we will add the measure to the mandatory set—an assessment that must be based on available relevant information, including the input received during the subregulatory process. Following the engagement required under § 438.515(b)(1), as proposed and finalized at § 438.510(b)(2), we must provide 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. During this second phase of engagement, we will gather additional input from the public on any mandatory measures identified by us as meeting the three standards for adding a measure, which will be reviewed and considered prior to finalizing the measure in the technical resource manual.

In combination, the subregulatory process, finalized at § 438.510(b), and the requirement, finalized at § 438.515(c), that we base the decision to add a measure on available relevant information (which would include the input received during the subregulatory process) ensures that assessment of whether a measure meets the standards, including that the benefits of a given measure outweigh the burdens, will take into account the input that we receive through the subregulatory process. This process will allow us to assess each proposed measure based on—among other things—the identified benefits and

burdens of a given measure and how those benefits and burdens are perceived and weighed across the health care system, the existence of alternative measures that may better balance burdens with benefits, and the extent to which CMS can provide support that addresses the challenges that create burdens for a given quality measure, such as through technical assistance or reasonable implementation timelines.

After considering the commenter’s concerns, we do, however, believe that additional clarity on how CMS will assess a measure under the balancing standards in §§ 438.510(c)(2) and (3) is warranted to ensure that, when providing their own perspective on how they would assess the measure under these two balancing standards, those who provide measure input through the subregulatory process finalized in § 438.510(b) have a clear understanding of the types of CMS’s considerations. As noted, in section I.B.6.e, the proposed rule detailed many of the factors and considerations considered by participants in our pre-rulemaking engagement. We are finalizing a new (c)(4) at § 438.510 to reflect these considerations by establishing that, when making the determination required under § 438.510(c)(1) through (3), to add, remove, or update a measure, CMS may consider the measure set as a whole, each specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas when assessing the measure under the balancing standards in § 438.510(c)(2) and (3). This modification reflects what we observed during pre-rulemaking discussions among interested parties about potential MAC QRS measures. Participants in these discussions did not just assess each measure in a vacuum, but assessed measures on their own merits and also engaged in robust discussion on both how a measure would work together with other measures considered for inclusion in the MAC QRS mandatory set and whether other, similar measures exist that may be more appropriate for inclusion. As finalized, our intent in adding new § 438.510(c)(4) is to encourage participants in the subregulatory process to include these considerations when providing their perspective on how they would assess a measure under § 438.510(c)(2) and (c)(3) through the subregulatory process so that CMS can may use input from across the healthcare system to assess the measure against the measure standards, including the balancing standards in § 438.510(c)(2) and (3). We note that we

are not including a reference to § 438.510(c)(1) in new (c)(4) as whether a measure meets a given measure selection criterion is not impacted by whether any other measure does so as well.

Comment: Several commenters suggested additional criteria including those that would require the measure to advance health equity; be an outcomes-based measure (as opposed to a process measure); be endorsed by the National Quality Foundation (NQF); and be validated, audited, and publicly reported.

Response: We considered commenters' requests to finalize additional measure selection criteria, but we are declining to add to our existing list of criteria. We agree with commenters that a measure's potential impact on improving health equity is an important consideration in assessing a measure for inclusion in the mandatory measure set. We considered adding a selection criterion related exclusively to health equity but concluded that advancing health equity is already considered during measure selection as it is a consideration under the relevance criteria in § 438.510(c)(1)(iii), which assesses whether a proposed measure evaluates health plan performance in at least one area specified by CMS including customer experience, access to services, health outcomes, quality of care, and health equity. We recognize that the relevance criteria does not require that a measure evaluate performance in health equity to be considered for addition to the mandatory set. However, when providing perspective on whether a measure meets the standards in § 438.510(c)(2) and (c)(3), participants in the subregulatory process could provide input on whether a measure that evaluates health equity alone, or in addition to other priority topics, would result in a better balance of representation, provide more benefits to the overall quality rating system framework, or both, as compared to those measures that do not evaluate health equity, which CMS may then consider when assessing the measure under the standards in § 438.510(c).

After consideration, we have decided not to add a criterion that would require measures to be outcomes-based measures (instead of process measures). While outcomes-based measures are considered by many to be the "gold standard" of quality measures, the outcomes addressed by these measures are often influenced by multiple factors, including those outside the control of a health plan. In many cases, a process measure may be a better way to

determine the degree of access a health plan's enrollees have to important services, such as preventive care. Furthermore, beneficiaries often find certain process measures informative and desirable. Therefore, we do not want to exclude process measures from inclusion in the MAC QRS measure set.

We considered the suggestion to require NQF endorsement, however we are declining to add endorsement as a measure selection criterion because the criteria used for NQF endorsement overlap with the MAC QRS measure selection criteria in § 438.510(c) as finalized in this rule and would therefore be redundant.²⁰⁸ Likewise, while we agree that whether a measure rating is validated and audited, and whether the measure is publicly reported, are also important considerations, we decline to add these suggestions as additional selection criteria. Validation and auditing are sufficiently addressed through our requirement in § 438.515(a)(3) that States validate data used to calculate quality ratings for mandatory measures.

Finally, our alignment measure criterion considers the extent to which a measure is publicly reported as it assesses the extent to which a measure aligns with other CMS rating programs, that is, the measure is already reported to CMS. To the extent that managed care plans or States already report a measure, that would also have bearing on the criterion at § 438.510(c)(1)(v), which addresses the level of burden of reporting a measure such that it is feasible to report.

Comment: A few commenters suggested that we make certain measure selection criteria, or combinations of measure criteria, mandatory including usefulness to beneficiaries, feasibility, actionability, and scientific acceptability. One commenter recommended that CMS make the actionability and feasibility criteria mandatory, noting that these criteria are essential to ensuring that all measures included in the MAC QRS meet the goals described by CMS in section I.B.6.a. of the proposed rule. The commenter noted that if CMS only requires measures to meet five of six inclusion criteria, the mandatory measure set could include measures that managed care plans cannot reasonably be expected to impact, or that are not feasible to report. Another commenter recommended that a measure should only be included in the MAC QRS

²⁰⁸ https://www.qualityforum.org/Masuring_Performance/ABCs/What_NQF_Endorsement_Means.aspx (includes criteria: important to measure, scientifically acceptable, useable, relevant, and feasible to collect.)

mandatory measure set if it meets the usefulness to beneficiary's standard given the stated role of the MAC QRS. Another commenter suggested that CMS make the usefulness, feasibility, and scientific acceptability criteria mandatory to better align with the measure evaluation criteria that is widely accepted by the quality measurement ecosystem and used by the CMS consensus-based entity.

Response: We considered but are declining commenters' suggestions to make certain measure selection criteria, or certain combinations of selection criteria, mandatory. In section I.B.6.e.1 of the proposed rule, we discussed how we considered each of the six measure selection criteria to be important, but that our own process of identifying the initial mandatory measure set showed that requiring a measure to meet all six criteria severely limited the measures that could be included in the MAC QRS. Similarly, we believe that requiring certain measure selection criteria to be mandatory could prevent flexibility to include important measures in the future. Additionally, there was no consensus among those who commented on this aspect of the proposed rule about which criteria should be made mandatory, highlighting the difficulty of establishing this additional designation. Instead of identifying a subset of mandatory criteria, we believe that the subregulatory process for adding measures finalized at § 438.510(b) and described in the proposed rule in section I.B.6.e.4 will allow CMS to gather for consideration varying viewpoints on whether a measure does or does not meet certain measure selection criteria and on the relative importance of a criterion and other considerations specified in § 438.510(c), which CMS may use when assessing the overall benefits and burdens of adding the measure in applying § 438.510(c)(2) through (4). Furthermore, we are finalizing in new § 438.510(c)(4) that when assessing whether a measure meets the measure standards in § 438.520(c)(2) and (3), CMS may consider the measure set as a whole, each specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas. This provision will allow CMS to consider input gathered through the subregulatory process on how interested parties balance and weigh the importance of the measure standards, including the measure selection criteria when assessing measures for inclusion in the mandatory set.

Comment: One commenter suggested that new measures undergo a 2-year

pilot period to allow States and CMS to collect benchmark data before implementing in the QRS. The commenter did not identify the perceived benefits of adopting this approach. Furthermore, the commenter did not specify what they would consider to be “new” measures—whether these would include any measure newly added to the mandatory measure set or only measures added to the mandatory set that are “new” in that they were recently developed or adopted by a measure steward.

Response: After consideration, we are declining the commenter’s suggestion to implement a pilot period prior to implementing new measures in the MAC QRS, both when a measure is newly added to the mandatory measure set or when a measure is added that is recently developed. Benchmarks for a given quality measure help health plans to assess how well they are currently performing on a given quality measures, identify any need for improvement, and make educated decisions on how to assign finite resources towards quality improvement. We believe that our established selection criteria, which include scientific acceptability and alignment with other CMS programs such as the QHP quality rating system and MA and Part D quality rating system, the Adult and Child Core Sets, and other programs identified at § 438.505(c), will make it likely that measures added to the measure set are well-established and already in use. As such, we believe that States and health plans will have a sense of both State and plan performance on the measures added to the mandatory measure set as well as the feasibility of reporting the measure. However, we noted in the proposed rule at I.B.6.e.1 that when considering whether a measure that is not currently in use (such as a newly developed measure) meets the alignment criterion we would assess whether it overlaps with an existing, widely used measure. As such, we recognize that our current policy accepts the possibility that a newly developed measure (including one that may not have data from which benchmarks could be developed) could be added to the mandatory measure set. We continue to believe that this approach is appropriate as it reflects the continuing evolution of quality measurement, allows for consideration of new, better measures, and the measure would still need to meet at least 5 of the 6 measure selection criteria.

If a newly developed measure is added to the mandatory measure set (following the subregulatory process

requiring extensive public engagement and application of the measure selection standard finalized in § 438.510), this final rule provides CMS with flexibility to determine the implementation date for such a measure, which could allow something like the pilot period recommended by the commenter prior to mandatory implementation. As finalized in § 438.510(f), States will have at least 2 calendar years after a measure is added to the mandatory measure set to display the measure in its MAC QRS. The flexibility to give States more than 2 years to implement a mandatory measure newly added to the measure set would allow CMS to implement a voluntary implementation period or pilot program. Furthermore, the extensive subregulatory engagement process would provide CMS with many opportunities to gather input on an appropriate implementation timeline and any additional steps that may be desirable prior to mandatory implementation. We recognize that other programs may use pilot periods similar to what the commenter generally described but believe that the specific policy goals and implementation structure for the MAC QRS means that setting mandatory pilot periods as part of adopting or changing the mandatory minimum measure set is not necessary.

Comment: One commenter expressed concern that the alignment measure selection criteria in § 438.510(c)(1)(ii) could make it harder for new HCBS measures to be included as HCBS measures will never align with the QHP quality rating system or the MA and Part D quality rating system since neither Medicare nor QHPs provide coverage for HCBS.

Response: We agree with the commenter that HCBS measures will likely not align perfectly with MA and Part D quality rating system or QHP quality rating system measures because those quality rating systems do not include measures specifically developed to assess HCBS plans. While we do not believe that our current alignment requirement would hinder the inclusion of HCBS measures in the MAC QRS mandatory measure set, we are finalizing modifications to paragraph (c)(1)(ii) to require alignment, *to the extent appropriate*, with other CMS programs described in § 438.505(c), which include the MA and Part D quality rating system and QHP quality rating system and other similar CMS quality measurement and rating initiatives. Under finalized § 438.510(c)(1)(ii), it would not be appropriate to require measures developed specifically for HCBS to align with either the MA and Part D or QHP

quality rating system, but it would be appropriate to look to whether the measure is aligned with other similar CMS quality measurement and rating initiatives, such as the HCBS Quality Measure Set. If a measure is proposed for which there is no existing CMS program with which it would be considered appropriate for the measure to align, CMS would consider the proposed measure to meet the alignment criterion.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.510(c) as proposed except for revisions to § 438.510(c)(1)(ii) and (v). We are finalizing paragraph (c)(1)(ii) with the additional phrase “to the extent appropriate” to clarify that if alignment is appropriate, it should be considered when determining whether a measure meets this criterion. We are finalizing § 438.510(c)(1)(v), with a modification to include provider burden when considering whether a measure meets the feasibility criterion established in § 438.510(c)(1) of the final rule.

(2) Mandatory Measure Set (§§ 438.510(a) and 457.1240(d))

We proposed 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 would be identified by CMS in the technical resource manual as proposed in § 438.530(a)(1). We note that proposed § 438.520(b), discussed in section I.B.6.g.5. of the proposed rule and this final rule, would allow States to include other, additional measures outside the mandatory measure set. We received input through our pre-rulemaking consultations with interested parties, detailed in section I.B.6.a. of the proposed rule, on the 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 pre-rulemaking consultations described in section I.B.6.a. of the proposed rule, and applying the standards discussed in section I.B.6.e.1. of the proposed rule, we proposed for public comment an initial set of 18 mandatory measures. The proposed mandatory measures reflected a wide range of preventive and

chronic care measures representative of Medicaid and CHIP beneficiaries. The proposed list of measures included:

1. Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics;
2. Initiation and Engagement of Substance Use Disorder (SUD) Treatment;
3. Preventive Care and Screening: Screening for Depression and Follow-Up Plan;
4. Follow-Up After Hospitalization for Mental Illness;
5. Well-Child Visits in the First 30 Months of Life;
6. Child and Adolescent Well-Care Visits;
7. Breast Cancer Screening;
8. Cervical Cancer Screening;
9. Colorectal Cancer Screening;
10. Oral Evaluation, Dental Services;
11. Contraceptive Care—Postpartum Women;
12. Prenatal and Postpartum Care;
13. Hemoglobin A1c Control for Patients with Diabetes;
14. Asthma Medication Ratio;
15. Controlling High Blood Pressure;
16. CAHPS survey measures: how people rated their health plan, getting care quickly, getting needed care, how well doctors communicate, and health plan customer service;
17. MLTSS–1: LTSS Comprehensive Assessment and Update; and
18. MLTSS–7: LTSS Minimizing Institutional Length of Stay.

See also 88 FR 28187 through 21891 for additional details on the proposed measures.

At the time the proposed rule was published, 15 of the 18 measures were commonly reported by States,²⁰⁹ 16 of the 18 measures overlapped with the 2023 and 2024 Core Set measures, 11 with the QHP quality ratings system, 13 with the 2021 Medicaid and CHIP Scorecard, 5 with the MA and Part D quality rating system, and 2 with the HCBS Quality Measure Set.

In the proposed rule, we also provided an overview of several measures that we considered but decided not to include in the proposed initial mandatory set. We noted that these other measures were not included because they did not meet one or more of the standards proposed at § 438.510(c). We also identified these other measures and the reasons we did not include them in the measure set in the proposed rule as follows:

- *Contraceptive Care—All Women Ages 15 to 44 (CCW) and Person-Centered Contraceptive Counseling*

(PCCC): During our pre-rulemaking engagement, States and other interested parties stated a desire for the MAC QRS to include a quality measure involving contraceptive services that will 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 we proposed. The additional measures that we considered on this topic included 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 is an emerging measure that fails to meet two of the six measure inclusion criteria and is not currently used in any other CMS quality measurement and rating initiatives. First, PCCC does not currently meet our measure inclusion 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. We note, however, that emerging measures would still be assessed based on the criteria and standards proposed at § 438.510(c), and it could take time for emerging measures to meet the proposed regulatory standards.

Both CCW and CCP meet at least five of the six inclusion criteria and both measure access to contraception that reduces unintended pregnancy in a defined population. 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, we believe the benefits of including CCP are greater than those of including CCW because CCP is more actionable than CCW due to the larger proportion of individuals

who are enrolled in a health plan during the postpartum period (the focus of CCP) as opposed to the preconception period (the focus of CCW). 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)*: States and other interested parties supported including FUM, as well as Follow-up After Hospitalization for Mental Illness (FUH) in the initial mandatory measure list. Both measures met the measure inclusion criteria and had similar benefits and burdens, 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. The two measures assessed important, but very similar services. We concluded that including both would not add sufficiently to the goal of achieving balanced representation given the need also to select a concise overall mandatory set. Upon balancing benefits and burdens associated with each measure, we proposed to include FUH because it was more commonly collected and reported by States and other Federal programs 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 the proposed rule in the Table 2-Example Inclusion Criteria Assessment.

- *Childhood Immunization Status (CIS)*: We considered including the CIS measure; however, we included the well-child visit measures (Well-Child Visits in the First 30 Months of Life (W30) and Child and Adolescent Well-Care Visits (WCV)) instead. All three 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 well-child visit measures will have greater benefit to beneficiaries based on our beneficiary testing, which 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

²⁰⁹ As reported by States for the 2020–2021 EQR reporting cycle.

Measure Workgroup. However, we did not include this measure because it did not meet two of our six inclusion criteria, including the feasibility and alignment criteria, at the time of our evaluation.

We also note that we are retaining flexibility in the final rule for States to display quality ratings for additional measures not included in the mandatory measure set after following the process described in § 438.520(c). We encourage States to work with plans and providers regarding the selection of additional measures.

We summarize and respond to public comments received on the MAC QRS mandatory measure set (§§ 438.510(a), (b), and 457.1240(d)) below.

Comment: Many commenters supported the use of a mandatory measure set for the MAC QRS, stating that a unified reporting structure of mandatory measures would bring a level of discipline and consistency that would foster more reliable data across the Medicaid program. Commenters also agreed that the uniformity in tracking plan quality will enable CMS to determine if certain States or managed care plans across States are underperforming.

Response: We appreciate the support and agree that using a minimum mandatory measure set will facilitate comparisons of managed care plan and program performance nationwide. To ensure that our use of a mandatory measure set for the MAC QRS maximizes the uniformity and consistency supported by commenters, we are finalizing § 438.510(a) with modifications to clarify that the mandatory minimum measure set includes only measures calculated using the technical specifications identified and specified by CMS in the technical resource manual. As discussed in section I.B.6.h of the proposed rule, when quality ratings calculated for a mandatory measure do not use the technical specifications approved by the measure steward, we consider those to be ratings for a different measure (that is, an additional measure that may be displayed only once the requirements in finalized § 438.520(c)(2) are met); therefore, display of a measure calculated or used with different specifications than those identified in the technical resource manual would not meet the requirement in § 438.510(a)(1)(i). To the extent that the technical resource manual identifies flexibilities for calculating ratings for MA (either explicitly or through reference to flexibilities approved by the measure steward), calculating the mandatory measure using those

flexibilities complies with § 422.510(a)(1). We intend to provide additional guidance on what modifications or flexibilities we would consider to be approved by the measure steward in the technical resource manual. For example, as discussed in the proposed rule, steward-approved modifications could include allowable adjustments to a measure's specifications published by the measure steward or measure specification adjustments requested from and approved by the measure's steward. This approach supports consistency in the use of the measures and ensures comparability by clearly establishing that quality ratings for such measures must be produced using specifications approved by the measure steward, which have been reviewed and subjected to the measure steward's own process to ensure that modified specifications allow for comparisons across health plans.

Comment: Many commenters supported the proposed MAC QRS mandatory measure set, with several suggesting prioritization of certain types of measures such as those that assess health outcomes, promote health equity, or present opportunities for quality improvement in the Medicaid and CHIP populations and incorporation of stronger assessments of the services provided under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.

Response: We agree with the measure topics identified by commenters as priorities and believe our measure selection criteria addresses them sufficiently. Specifically, whether a measure addresses health plan performance for health equity and health outcomes is considered under the relevance measure selection criteria in § 438.510(c)(1)(iii), and whether a measure presents an opportunity for plans to influence performance on the measure is considered under the actionability criteria in § 438.510(c)(1)(iv). We agree with commenters on the importance of measuring quality of care and services delivered to children, including those eligible children under the EPSDT benefit, and believe that the MAC QRS will supplement ongoing efforts we are making to strengthen quality reporting in this area. For example, current ongoing efforts to monitor services provided under the EPSDT benefit include the CMS collection of information on the delivery of EPSDT services at the State level annually through the Annual EPSDT Participation Report (Form CMS-416) and the Child Core Set, which will be

mandatory for States to report in 2024. We believe the measures included in our initial mandatory measure set for the MAC QRS will supplement the State level data received from the CMS-416 and Child Core Set by enabling interested parties to view the MAC QRS measures for children at the health plan level within a State. The MAC QRS mandatory measures that are focused on children include measures that help to assess whether eligible children are receiving EPSDT services, such as the Well-Child Visits in the First 30 Months of Life. The rating for this measure will indicate the percentage of children who received this preventive health service for each plan that is responsible for delivering those services. The MAC QRS measures for children will also help parents select a health plan that meets their child's needs, which is one of the objectives of the MAC QRS.

Comment: Many commenters suggested either specific measures or types of measures to add to the initial mandatory measure set. Specific measure recommendations included HIV Viral Load Suppression, Adherence to Antipsychotic Medications for Individuals with Schizophrenia, Kidney Health Evaluation for Patients with Diabetes, and Proportion of Days Covered: Adherence to Direct-Acting Oral Anticoagulants measure. Measure topics recommended for inclusion included Cesarean deliveries, child lead screening, adult immunization status, and measures that support patient-primary care team relationships such as child and adolescent well-care visits, prenatal and postpartum care visits, and adults' access to preventive/ambulatory health services. We also received several comments that advocated for the inclusion of a measure of social determinants of health (SDOH) and measures that reflect quality of care for people with rare disorders. One commenter recommended that we include measures that cover a wide array of potentially avoidable events, and another commenter suggested that we include a metric related to newborn screening that benchmarks health plan performance to the Recommended Uniform Screening Panel (RUSP), but the commenters did not suggest a specific measure.

We received comments in response to our request for feedback on our decision to exclude the following measures: Childhood Immunization Status, Contraceptive Care—All Women Ages 15–14 (CCW), Person-Centered Contraceptive Counseling (PCCC), and Postpartum Depression Screening. Some commenters provided feedback in support of including the CCW measure

because measuring contraceptive access for all individuals, regardless of pregnancy status, is important to improve health outcomes and effectively compare access to contraception from State to State. One commenter encouraged CMS to consider mandating the use of various measures that exist for contraceptive need screening such as Pregnancy Intention Screening Question (PISQ) and Self Identified Need for Contraception (SINC). Some commenters recommended inclusion of the Childhood Immunization Status measure to ensure that the MAC QRS assesses not only access to care, but also quality of care, and commitment to the health of members and the community. Other commenters provided feedback indicating that while they understood the rationale for not including the Postpartum Depression Screening measure at this time, they requested this metric to be included in the future due to the short-term and long-term consequences if left untreated.

Response: We thank those who suggested additional measures for inclusion in the initial mandatory measure set. We reviewed the comments for each additional measure suggestion and, based on our assessment of the measures according to our measure selection criteria in § 438.510(c), we are declining to add additional measures at this time. Regarding the suggestions to add HIV Viral Load Suppression, Adherence to Antipsychotic Medications for Individuals with Schizophrenia, Kidney Health Evaluation for Patients with Diabetes and Proportion of Days Covered: Adherence to Direct-Acting Oral Anticoagulants measure, we appreciate these suggestions and believe they meet many (but not all) of the measure criteria. However, to keep the initial mandatory measure list concise, we are not adding them at this time. Furthermore, while we agree with the importance of these measures and that they show promise in meeting our measure standards, we believe that it is important to gather additional input through the public and notice comment process finalized in § 438.510(b), and we do not believe it is appropriate to bypass that process by adopting an additional measure without providing a clear opportunity for comment on the specific measure. Additional rationale for not including these measures in the initial mandatory measure set is indicated below.

We are declining to include the HIV Viral Load Suppression measure because the measure does not meet two of the measure selection criteria

described in § 438.510(c)(1). It does not meet the feasibility criterion in paragraph (c)(1)(v) because the data required to calculate the measure is not consistently available to health plans and it does not meet the actionability criterion in paragraph (c)(1)(iv) for plan-level reporting because it has only been used at the provider and State level and the data are not consistently available at the plan level. We are declining to add the Adherence to Antipsychotic Medications measure for Individuals with Schizophrenia as we have concluded after analysis that the benefits of the measure would be outweighed by the burdens given that many health plans are likely to be unable to display this measure due to small denominator sizes.

While the Kidney Health Evaluation for Patients with Diabetes measure and the Proportion of Days Covered: Adherence to Direct-Acting Oral Anticoagulants measure meets at least five of six measure selection criteria in § 438.510(c)(1), we are excluding them, and measures of Cesarean birth, child lead screening, and adult immunization status, from the initial mandatory measure set for two reasons. First, the proposed mandatory measure set already includes preventive health measures for both adults and children and reproductive health measures and, to maintain a balanced and concise set of measures as required under § 438.510(c)(2), we believe that we would need to remove an existing measure in these performance areas to add the suggested measures. Second, using the standard at § 438.510(c)(3), we carefully considered the burdens and benefits of the suggested measures against those from our current list and believe that the benefits of our current measures outweigh those of the suggested measures. Specifically, our current measure for Prenatal and Postpartum Care represents a larger proportion of pregnant individuals than the Cesarean birth measures.

Regarding the comment to include measures that support patient-primary care team relationships such as child and adolescent well-care visits, prenatal and postpartum care visits, and adults' access to preventive/ambulatory health services, we agree with the importance of these measures and several of these types of measures are included in the initial mandatory measure set, including, for example, the Child and Adolescent Well-Care Visits measure which is described as the percentage of members who had at least one comprehensive well-care visit with a primary care practitioner or an

obstetrician/gynecologist during the measurement year.

We agree with the importance of measures that address social determinants of health (SDOH) and support measure development in this area. In our consultations, beneficiaries stated preferences for measures that reflect critical upstream services that impact health, which could include the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) Social Needs Screening and Intervention (SNS-E) measure. However, no existing SDOH measure has yet been widely publicly reported at a plan-level so we are not convinced that they are appropriate for inclusion in the initial mandatory measure set. We will consider adopting SDOH measures in the future through the subregulatory process set forth in § 438.510(b). Regarding the suggestion to add measures for rare diseases, due to the limited number of beneficiaries with rare diseases, we have concerns that these measures would ultimately not be included in a State's QRS website due to low denominator sizes despite State efforts to collect, validate, and use these data to calculate such measures. We understand the importance of capturing information about quality and experience of care among individuals with rare diseases and will look for ways to address this within our other quality focused Medicaid and CHIP efforts. Regarding the recommendation to add measures that cover a wide array of potentially avoidable events and metrics related to newborn screenings under RUSP, we will obtain input from interested parties through the subregulatory process to determine whether these types of measures would be a good fit for inclusion in the mandatory measure set.

Regarding the measures not included in the initial list and for which we requested feedback, we reviewed the public comments and have concluded that our original rationale for not including these measures on the initial mandatory measure set, set forth in section I.B.6.e.2. of the proposed rule, still holds. We agree with commenters that Childhood Immunization Status is an important measure. However, as discussed in I.B.6.e.2 of the proposed rule, when reviewing the burdens and benefits to the overall MAC QRS, we concluded the well-child visit measures will have greater benefit to beneficiaries based on our beneficiary testing, which 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. We also agree with commenters about the importance of CCW but our original rationale for not including CCW as set forth in section I.B.6.e.2 of the proposed rule still holds, and we note that both the Adult and Child Core Sets include the CCW measure to enable comparisons among States.

Regarding the request to include a contraceptive need screening measure, we appreciate the commenter's suggestion to include a measure that assesses contraceptive need. While the commenter suggested a couple screening tools (Pregnancy Intention Screening Question (PISQ) and Self-Identified Need for Contraception (SINC)), they did not recommend, and we are unaware of, quality measures related to contraceptive needs assessment that meet the measure inclusion criteria. We will monitor measure development in this area and consider additional contraceptive measures through our subregulatory process. We agree with commenters that PCCC, as well as other contraceptive needs screening measures are promising given their focus on measuring person-centered care, which was frequently identified as highly desirable in our conversations with beneficiaries. Furthermore, we also agree with commenters on the importance of including a postpartum depression screening measure in a future mandatory measure set. However, as we previously noted, we believe that measure additions should occur through the subregulatory process to update the mandatory measure set finalized in this rule to allow for public notice and comment prior to any decision to add or not add a measure to the mandatory set. We will continue to monitor the evolution of these suggested measures, their ability to meet our measure selection criteria, and input on these measures from those who participate in our subregulatory process.

Comment: Several commenters requested that specific measures be removed from the initial mandatory measure set and replaced with alternative measures. A few commenters suggested the removal of the Asthma Medication Ratio (AMR) because they do not believe it includes an accurate depiction of asthma control for the pediatric population. These commenters recommended replacement with an alternative measure that would better capture asthma outcomes for children, but they did not suggest a specific alternative measure. Two commenters suggested removal of the Initiation and Engagement of Substance Use Disorder

Treatment (IET) because it captures a minimum number of encounters but does not assess the effectiveness of the treatment or clinical outcome. One of these commenters suggested replacing IET with other NCQA measures related to alcohol use screening, such as Unhealthy Alcohol Use Screening and Follow-up. We received two comments regarding the Prenatal and Postpartum Care (PPC) measure. One commenter supported the inclusion of PPC in the initial mandatory measure set, while the other commenter suggested removal of PPC and replacement with another maternity measure such as Cesarean birth. Another commenter suggested that we remove the Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF) measure and replace it with the NCQA HEDIS Depression Screening and Follow-Up for Adolescents and Adults (DSF) measure because CDF is no longer endorsed by NQF and has measure specifications that differ from a similar measure included in HEDIS. We received a couple of comments regarding our proposal to include the Dental Quality Alliance's (DQA) Oral Evaluation, Dental Services (OEV) measure into the initial mandatory measure set. One comment was in support of including OEV, and the other suggested the removal of OEV and replacement with the NCQA HEDIS measure Oral Evaluation, Dental Services (OED). The commenter who suggested replacement of DQA's OEV with NCQA's HEDIS OED indicated that HEDIS measures are audited and certified by an NCQA auditor, and that using OED would reduce the administrative burden for State agencies and their external quality review office by eliminating the need to perform separate measure audits and would ensure that the rates published in the QRS were calculated the same way across all managed care plans.

We did not receive support for inclusion of the two MLTSS measures that were proposed. Several commenters requested the removal of MLTSS-1: LTSS Comprehensive Assessment and Update because it is not endorsed and requires case management and record review, which would be burdensome to collect. Several commenters requested the removal of MLTSS-7: LTSS Minimizing Institutional Length of Stay because it is not endorsed. Two commenters suggested removal of MLTSS-7 because MLTSS plans are limited in their ability to influence the length of the institutional stay within the first 100 days for dually eligible beneficiaries. These commenters

recommended that we engage with States, plans, and other interested parties to determine the best two MLTSS measures to incorporate, and suggested MLTSS-8: LTSS Transition after Long-Term Facility Stay²¹⁰ or other measures as options to replace MLTSS-7. Commenters also recommended that the MAC QRS MLTSS measures align with the initial HCBS core measure set as part of CMS's proposals in the Medicaid Program; Ensuring Access to Medicaid Services proposed rule (88 FR 27960 (May 3, 2023)).

Response: Regarding the suggestion to remove AMR and replace it with an alternative measure, since there was not an alternative asthma measure suggestion, and since we are unaware of a better replacement measure, we continue to believe that AMR is the appropriate measure to include in the initial mandatory measure set because of its alignment with CMS programs and initiatives such as the Core Sets, Scorecard, and QHP quality rating system. Regarding the suggestion to remove Initiation and Engagement of SUD Treatment (IET) and replace it with an NCQA measure related to alcohol use screening, we continue to believe that IET is the appropriate measure to include in the initial mandatory measure set because it includes both alcohol and drug abuse or dependence, which will contribute to balanced representation of beneficiary subpopulations and health conditions. Additionally, we are including IET because of its alignment with CMS programs such as the Adult Core Set, Scorecard, and QHP quality rating system. Regarding the suggestion to remove PPC and replace it with another maternity measure such as Cesarean Birth, we continue to believe that PPC is the appropriate measure to include because it applies to a broader set of beneficiaries than the Cesarean Birth measure, and because of its alignment with CMS programs such as the Core Sets, Scorecard, and QHP quality rating system. We will continue to monitor the evolution of asthma and substance use measures to identify a better replacement measure, should one be developed in the future, through the subregulatory process set forth in § 438.510(b) to update the mandatory measure set address inclusion in the MAC QRS mandatory measure set. Regarding the suggestion to remove CDF because it is not endorsed and replace it with NCQA's DSF, endorsement by a consensus-based entity is not a

²¹⁰ Centers for Medicare and Medicaid Services Measures Inventory Tool ([cms.gov](https://www.cms.gov)).

requirement for the MAC QRS mandatory measures. We included CDF in the initial mandatory measure set over DSF because, while both measure similar care, when balancing the benefits and burdens of these two, similar measure under § 438.510(c)(3), we believe CDF would result in a smaller burden to report (and therefore more feasible) because CDF is aligned with the Core Set and States are already collecting, calculating, and reporting this measure at the State level for the Core Sets. Regarding replacement of the OEV measure with OED, we agree with the commenter on the importance of reducing burden and ensuring consistency in measure calculation across health plans. Like our rationale with CDF, we included OEV in the initial mandatory measure set because OEV aligned with the Child Core Set and alignment with mandatory Child Core Set measures increases feasibility and reduces burden on States. Further, to ensure quality ratings remain comparable within and among States, we note that validation of all data collected is required under § 438.515(a)(2).

Regarding the request to remove MLTSS measures because they are not endorsed, endorsement by a consensus-based entity is not a requirement for MAC QRS mandatory measures. We reassessed our proposal to include MLTSS-1 based on comments that the case management and record review required for reporting on MLTSS-1 would be burdensome for providers and plans. Additionally, we reassessed MLTSS-7 based on the comments received about implications for dually eligible individuals. Based on the comment suggesting that we replace MLTSS-7 with MLTSS-8, we also considered MLTSS-8, but we did not include MLTSS-8 because we have concerns that this measure could not be displayed in the QRS due to low denominator sizes and potential privacy concerns.

Based on our reassessment of MLTSS-1 and MLTSS-7, we are not finalizing the proposal to include these two MLTSS measures in the initial mandatory measure set adopted in this final rule, but we intend to continue evaluating them and other available MLTSS measures for inclusion as future additions to the mandatory measure set. Because of the concerns about potential burden for reporting MLTSS-1, we believe it would not be appropriate to finalize the inclusion of MTLSS-1 without additional feedback from States and other interested parties that will allow CMS to evaluate it more fully against both the feasibility criterion in

§ 438.510(c)(1)(v) and under § 438.510(c)(3) (weighing the burdens and benefits of including the measure). As we are finalizing paragraph § 438.510(c)(1)(v) with a modification to consider provider burden (in addition to State and plan burden) when considering whether a measure is based on data available without undue burden, we believe that it is appropriate to gather additional thought and consideration through the subregulatory process to identify whether there is a more appropriate MLTSS measure than MLTSS-1 to include. (See § 438.510(c)(4) as finalized.) As for MTLSS-7, we intend to use the subregulatory process to gain additional feedback to determine whether it is a better measure for influencing plan performance (the criterion in § 438.510(c)(1)(iv)) than other available measures and whether it will contribute meaningfully to a balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a concise mandatory measure set (the standard in § 438.510(c)(2)). We believe that it is important to finalize measures that are a good fit with the standards we are adopting at § 438.510(c) to ensure that the MAC QRS provides useful information about managed care plan performance in this important area.

Inclusion of these or other MLTSS measures in a future mandatory set will be assessed during the subregulatory process set forth in § 438.510(b), both through the process finalized in § 438.510(b)(1), through which we will obtain input from interested parties to determine whether there are MLTSS measures that meet our standards for inclusion in the mandatory measure set, and the process finalized in § 438.510(b)(2), through which we will provide notice and an opportunity for comment on any MLTSS measures identified by CMS for addition to the mandatory set following the process in paragraph (b)(1). Specifically, through the subregulatory process States and other interested parties will have the opportunity to provide additional information and input on MLTSS measures not finalized here for CMS to consider for future updates to the mandatory set. States and interested parties also could propose and consider other MLTSS measures that may better align with our measure selection criteria. We believe that these MLTSS measures could include MLTSS-6: LTSS Admission to an Institution from the Community (which, like MLTSS-7, is a rebalancing measure) or the NCQA

HEDIS Long-Term Services and Supports Comprehensive Care Plan and Update (CPU-AD) measure, which meets all six of the measure selection criteria in § 438.510(c)(1), and, like MLTSS-1, assesses person-centered planning. Further, though CPU-AD requires case management and record review, it is on the Adult Core Set and the alignment between programs could address the concerns about potential burden. We considered these measures as alternatives to MLTSS-1 and 7 but chose not to finalize here to allow consideration through the subregulatory process. Feedback on MLTSS measures that we receive through the initial subregulatory process in 438.510(b)(1) will be used, in addition to other relevant information, to conduct a preliminary analysis under § 438.510(c)(1), (2) and (3) to prepare the call letter (or other mechanism for public notice and comment) required by § 438.510(b)(2). CMS would evaluate the respective potential burden of including MLTSS 1 versus CPU-AD or MLTSS-7 versus MLTSS-6 (and other measures proposed for consideration through the subregulatory process). For example, we believe that CPU-AD combined with MLTSS-6 could contribute to a balanced representation of beneficiary subpopulations who receive MLTSS services.

Although we are not including either of the proposed MLTSS measures (that is, MTLSS-1 and MTLSS-7) in the initial mandatory measure set, States may display quality ratings for additional measures after following the process described in § 438.520(c)(2). Additional measures are discussed further in this section and in section I.B.6.g.5 of the final rule. Regarding the recommendations that the MAC QRS MLTSS measures align with the initial HCBS quality measure set, alignment is one of the measure selection criteria that will be used to evaluate these and other MLTSS measures for addition to the MAC QRS measure set through the subregulatory process.

Comment: Several comments pertained to electronic clinical data systems (ECDS) measures. One commenter supported our proposal to include ECDS measures like Colorectal Cancer Screening that can be collected using administrative or electronic means while another commenter requested confirmation that the administrative specification is an acceptable data collection method for the Breast Cancer Screening (BCS) measure. Another commenter cautioned against using electronic clinical data measures because they require significant resources for implementation

of more robust interoperability between provider EMR and MCOs. One commenter requested the addition of NCQA's Healthcare Effectiveness Data and Information Set (HEDIS) Depression Remission or Response for Adolescents and Adults ECDS measure (DRR-E) to the mandatory measure set and for CMS to provide support to States seeking to improve capabilities for reporting ECDS measures. Another commenter cautioned against using the ECDS version of DSF (DSF-E) because DSF-E has first-year status for measurement year 2023, and therefore, NCQA has not yet completed its validation process.

Response: Regarding the comments cautioning against using electronic clinical data measures, we understand that States and plans are in different stages of utilization of digital measures, including ECDS, and that some experience significant challenges in reporting HEDIS ECDS measures. As discussed in section I.B.6.f., we are requiring States to calculate MAC QRS quality ratings using approved measure steward technical specifications, which would require States to calculate ratings as ECDS-only specified as such by a measure steward's technical specifications. CMS will provide technical assistance to States and plans to ensure adherence to measure steward technical specifications for these measures.

Comment: We received several comments supporting our proposal to include Agency for Healthcare Research and Quality (AHRQ) Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures in the initial mandatory measure set. Several commenters relayed concerns with the industry-wide challenge of declining response rates to the CAHPS survey. These commenters encouraged CMS to allow for greater flexibility in how the CAHPS survey is fielded to increase response rates, for example, by allowing web-based and mixed-mode surveying, testing the use of interactive voice response (IVR) technologies, and use of proxy respondents. One commenter encouraged CMS to consider using the current AHRQ database directly to report out the CAHPS measures and suggested that CMS could populate the templates using the CAHPS data and States could link to the templated page to reduce burden and promote consistency in the display of these data across States. One commenter stated CMS should align patient experience survey questions across Medicaid and Medicare such as the CAHPS for Merit-based Incentive Payment System (MIPS) Survey but did not specify how they should be aligned. One commenter

requested clarification on how States should handle situations where there are fewer than 100 responses for specific plans for the CAHPS measures included in the mandatory measure set. One commenter stated that the proposed rule does not clarify the relationship between the enrollee experience survey required under § 438.66, the required MAC QRS enrollee experience measures, and other enrollee experience survey efforts.

Response: We appreciate the comments in support of our proposal. We acknowledge the concerns about CAHPS and will consider commenters' suggestions as we continue to work in partnership with AHRQ to identify longer-term solutions to improve CAHPS response rates and streamline CAHPS reporting. Regarding the comment to align patient experience survey questions across Medicaid and Medicare, such as MIPS CAHPS survey questions, we highlight that both the CAHPS health plan survey used by the Medicaid and CHIP programs as required in the MAC QRS and the MIPS CAHPS survey contain questions regarding getting care quickly and how well doctors communicate. Regarding the comment requesting clarification on situations where there are fewer than 100 responses for CAHPS survey questions, we will include guidance on how to handle these situations in accordance with measure steward specifications and, as applicable, existing CMS guidance such as the CMS Cell Suppression Policy²¹¹ in the technical resource manual and will also provide links to additional resources from AHRQ on administering the CAHPS Health Plan Survey. We note that the minimum enrollment threshold established in § 438.515(a)(1)(i) requiring States to collect data necessary to calculate quality ratings for MAC QRS measures from the State's contracted managed care plans that have 500 or more enrollees does not provide a standard for the public display of CAHPS survey responses but is about data collection, meaning that managed care plans with less enrollment would not be required under these Federal rules to provide this data to the State (State contract requirements or regulations may impose additional survey or data collection obligations). Regarding the request to clarify the relationship between the different enrollee experience survey requirements in this final rule, we note that the five CAHPS measures included in the

mandatory measure set make up the CAHPS health plan survey. By including all of these CAHPS measures in their MAC QRS, States could also meet the enrollee experience survey requirements in § 438.66, but may be sufficient for monitoring, oversight, and quality improvement activities of some, but not all, programs, such as those with a narrow set of populations or benefits. For instance, the requirements are different in that § 438.66 applies to all managed care plans (regardless of enrollment), whereas the MAC QRS requirement for CAHPS is only applicable to a portion of a State's managed plans (that is, those with more than 500 enrollees, per § 438.515(a)(i) of this final rule).

Comment: Many commenters supported our proposal that States may include additional measures in their MAC QRS. Commenters recommended that States should have flexibility to use additional measures specific to their population needs and that the use of additional measures by States is critical to local health initiatives. Several commenters suggested that CMS should limit the number of additional measures that State Medicaid and CHIP agencies can include in their MAC QRS. These suggestions included limiting the number of additional measures States can add by requiring them to select from a small menu of additional measures and prohibiting States from adding more than five additional measures. One commenter requested CMS to provide detailed guidance on the appropriate use of additional measures.

Response: We continue to believe it is preferable for States to have the flexibility to display additional measures that align with State priorities and are representative of beneficiary subpopulations. Therefore, we are not limiting the number or type of additional measures that a State may use in its MAC QRS. However, based on the feedback we received from beneficiaries and other interested parties during our pre-rulemaking consultation process, we encourage States to limit their QRS measure list to under 30 measures. We will take the request for detailed guidance on the appropriate use of additional measures into consideration when developing the design guide. Further discussion on the use of additional measures in a State's MAC QRS and the steps a State must take prior to their display can be found in section I.B.6.g.5. of this final rule.

Comment: Several commenters suggested that CMS should not permit States to create their own custom measures, and stated concern that allowing States to create their own

²¹¹ See CMS Cell Suppression Policy, January 1, 2020, <https://www.hhs.gov/guidance/document/cms-cell-suppression-policy>.

measures when there are multiple measures to choose from will only confuse providers, create misalignment, and increase costs. Another commenter recommended that CMS further incentivize States to continue to develop new, innovative measures, and that CMS should continue to act as a conduit to share measures across States to promote collaboration so that multiple States can report new measures for possible future inclusion in a national data set. Other commenters were concerned about State variation in the use of additional measures, and recommended CMS limit this variation by providing States a list of vetted measures that are nationally recognized or requiring that States use the CMS measure selection criteria described in § 438.510(c), and that CMS should develop a process for States to submit potential measures for inclusion in the list of vetted measures. One commenter suggested that we prohibit States from displaying any measure removed from the MAC QRS mandatory minimum measure set because of a lack of validity.

Response: As to State use of custom measures, we understand that custom measures can be challenging for health plans and providers. However, we want to preserve State flexibility and encourage States to work with health plans and providers regarding the selection and use of additional measures, including custom measures. As described in § 438.520(c)(2) of the final rule (proposed at § 438.520(b)), we note that if the State chooses to display quality ratings for additional measures not included in the mandatory measure set described in § 438.510(a)(2) for Medicaid, which applies to separate CHIP through a proposed revision to § 457.1240(d), the State must first obtain input on the additional measures 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. We encourage States to also work with plans and providers regarding the selection of additional measures. Additionally, we appreciate the suggestion to share measures across States to promote collaboration and will take this into consideration when providing technical assistance to States and establishing the workgroup process to update the mandatory measure set. We will use State reporting to monitor the use of additional measures, including measures that a measure steward no longer considers valid, and to inform whether any limitations are necessary in future rulemaking.

After considering all comments on the measure list, we are finalizing 16 measures for inclusion in the mandatory measure set of the 18 measures that were proposed. We are not finalizing inclusion of MLTSS–1: LTSS Comprehensive Assessment and Update, and MLTSS–7: LTSS Minimizing Institutional Length of Stay in the initial mandatory measure set based on considerations raised by public comment received as discussed previously in this section. Under this final rule and subject to the process adopted in § 438.510, we retain flexibility for the number of measures to increase as we update the mandatory measure set over time. We are finalizing flexibility for States to display quality ratings for additional measures not included in the mandatory measure set after following the process described in § 438.520(c)(2), (proposed at § 438.520(b)). We encourage States to work with plans and providers regarding the selection of additional measures.

Table 2 includes a list of the measures in the initial mandatory measure set for the MAC QRS finalized in this rule,

which maintains a high level of alignment with CMS programs and initiatives.²¹² The table of finalized measures incorporates necessary, non-substantive changes to align with updates implemented by the measure steward to the proposed measures that occurred after the proposed rule was published and to address a handful of non-substantive errors in the measure descriptions that were included in the proposed initial measure table. Specifically, the non-substantive measure steward updates include changes to a proposed measure's description, acronym or data sources, incorporation of gender-affirming terminology within the measure description,²¹³ and, in the case of Hemoglobin A1c Control for Patients with Diabetes (HBD), a measure name change (to Glycemic Status Assessment for Patients with Diabetes (GSD)) and conforming edits to the measure's description.²¹⁴ The finalized measure table also corrects the non-substantive errors in the proposed measure table measure descriptions. We are updating the measure description for FUH (which inadvertently included the description of the FUM measure) as well as the measure descriptions for FUH, COL, and CAHPS—Health plan customer service (which each identified the incorrect age range).

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²¹² Table 2 includes updates to use the CMIT identifiers instead of NQF identifiers for the measures.

²¹³ Table 2 includes updates to measure steward descriptions for APP, IET, CDF, FUH, WCV, BCS, CCS, CCP, PPC, AMR.

²¹⁴ See HEDIS MY 2024: What's New, What's Changed, What's Retired, August 1, 2023, <https://www.ncqa.org/blog/hedis-my-2024-whats-new-whats-changed-whats-retired/>. The measure title for HBD. was updated in NCQA HEDIS's measure year 2024 along with conforming changes to the measure description to include a glucose management indicator with hemoglobin A1c.

TABLE 2: Initial MAC QRS Mandatory Measure Set

| CMIT #* | Measure Steward | Measure Name | Measure Description | Data Collection Method |
|---------|-----------------|--|---|------------------------|
| 743 | NCQA | Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP) | 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** |
| 394 | NCQA | Initiation and Engagement of Substance Use Disorder Treatment (IET) | The percentage of new substance use disorder (SUD) episodes that result in treatment initiation and engagement. Two rates are reported: • Initiation of SUD Treatment. The percentage of new SUD episodes that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter, partial hospitalization, telehealth, or medication treatment within 14 days. • Engagement of SUD Treatment. The percentage of new SUD episodes that have evidence of treatment engagement within 34 days of initiation. Ages: 13 and older | Administrative or EHR |
| 672 | 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 qualifying encounter. Ages: 12 and older | Administrative or EHR |
| 268 | NCQA | Follow-Up After Hospitalization for Mental Illness (FUH) | The percentage of discharges for members who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are reported: • The percentage of discharges for which the member received follow-up within 30 days after discharge. • The percentage of discharges for which the member received follow-up within 7 days after discharge. Ages: 6 and older | Administrative |
| 761 | 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. Ages: 0 to 15 months 15 to 30 months | Administrative |
| 123 | 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. | Administrative |

| CMIT #* | Measure Steward | Measure Name | Measure Description | Data Collection Method |
|---------|-----------------|---|--|---|
| | | | Ages: 3 to 21 | |
| 93 | NCQA | Breast Cancer Screening (BCS-E) | The percentage of members who were recommended for routine breast cancer screening and had a mammogram to screen for breast cancer. Ages: 50 to 74 | Electronic Clinical Data System (ECDS)♦ |
| 118 | NCQA | Cervical Cancer Screening (CCS, CCS-E) | The percentage of members who were recommended for routine cervical cancer screening who were screened for cervical cancer using any of the following criteria: <ul style="list-style-type: none"> • Members 21 to 64 years of age who were recommended for routine cervical cancer screening and had cervical cytology performed within the last 3 years. • Members 30 to 64 years of age who were recommended for routine cervical cancer screening and had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years. • Members 30 to 64 years of age who were recommended for routine cervical cancer screening and had cervical cytology/high-risk human papillomavirus (hrHPV) co-testing within the last 5 years. Ages: 21 to 64 | Administrative, hybrid, EHR, or ECDS |
| 139 | NCQA | Colorectal Cancer Screening (COL-E) | The percentage of members who had appropriate screening for colorectal cancer. Ages: 45 to 75 | ECDS |
| 897 | 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 |
| 166 | OPA | Contraceptive Care - Postpartum Women (CCP) | Among women who had a live birth, the percentage that: <ol style="list-style-type: none"> 1. Were provided a most effective or moderately effective method of contraception within 3 days of delivery and 90 days of delivery. 2. Were provided a long-acting reversible method of contraception (LARC) within 3 days of delivery and 90 days of delivery. Ages: 15 to 44 | Administrative |
| 581 | 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. For these members, the measure assesses the following facets of prenatal and postpartum care: <ol style="list-style-type: none"> 1. Timeliness of Prenatal Care. The percentage of deliveries that received a prenatal care visit in the first trimester, on or before the enrollment start date, or within 42 days of enrollment in the organization. 2. Postpartum Care Rate. The percentage of deliveries that had a postpartum visit on or between 7 and 84 days after delivery. Ages: All Ages | Administrative or hybrid |

| CMIT # ^a | Measure Steward | Measure Name | Measure Description | Data Collection Method |
|---------------------|-------------------|---|--|--------------------------------|
| 148 | NCQA | Glycemic Status Assessment for Patients with Diabetes (GSD) | The percentage of members with diabetes (types 1 and 2) whose most recent glycemic status (hemoglobin A1c [HbA1c]) was at the following levels during the measurement year: <ul style="list-style-type: none"> • Glycemic Status <8.0%. • Glycemic Status >9.0%. Ages: 18 to 75 | Administrative or hybrid |
| 80 | 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 64 | Administrative |
| 167 | NCQA | Controlling High Blood Pressure (CBP) | The percentage of members who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mm Hg) during the measurement year. Ages: 18 to 85 | Administrative, hybrid, or EHR |
| 151/152 | AHRQ ^v | 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 |
| 151/152 | AHRQ ^v | CAHPS – Getting care quickly | Composite of the following items: <ul style="list-style-type: none"> • 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 |
| 151/152 | AHRQ ^v | CAHPS – Getting needed care | Composite of the following items: <ul style="list-style-type: none"> • 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 |
| 151/152 | AHRQ ^v | CAHPS – How well doctors communicate | Composite of the following items: <ul style="list-style-type: none"> • The percentage of members who indicated that their doctor always noted 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 |
| 151/152 | AHRQ ^v | CAHPS – Health plan customer service | Composite of the following items: | Consumer survey |

| CMIT #* | Measure Steward | Measure Name | Measure Description | Data Collection Method |
|---------|-----------------|--------------|---|------------------------|
| | | | <ul style="list-style-type: none"> 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: 0 to 17 18 and older | |

*The CMS Measures Inventory Tool (CMIT) is the repository of record for information about the measures that CMS uses in various quality, reporting, and payment programs. More information is available at <https://www.cms.gov/medicare/quality/measures/cms-measures-inventory>. A public access quick start guide for CMIT is available at <https://cmit.cms.gov/cmit/assets/CMIT-QuickStartPublicAccess.pdf>.

**Examples of administrative data collection methods are claims, encounters, vital records, and registries.

^ AHRQ is the measure steward for the survey instrument (CMIT 151/152) and NCQA is the developer of the survey administration protocol.

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After reviewing the public comments and for the reasons outlined in the proposed rule and in response to comments, we are finalizing § 438.510(a), including the cross-reference at § 457.1240(d) to apply the mandatory minimum measure set to CHIP, as proposed.

(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 CMS 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 noted in the proposed rule that 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. 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. Our proposal reflected that commitment and our understanding of our obligations under these statutory provisions.

We noted that 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. A robust

subregulatory process involving extensive input from interested parties would ensure that any changes the mandatory measure set are consistent with the regulatory standards established in the final rule. Therefore, we proposed 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 would use 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. Under our proposal, we would adopt the initial mandatory measure set in the final rule (see section I.B.6.e.) and subsequent, periodic updates to add, remove, or update measures would occur through a subregulatory process. To ensure that the mandatory measure set stays current to changes in the quality field, we proposed to engage in this subregulatory process to make any needed modifications 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 § 438.510(e)(1), we proposed 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 like 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 proposed at § 438.510(b)(1) that CMS will 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 will be to ensure the mandatory measures continue to meet the standards proposed in § 438.510(c). We noted our vision that this engagement could take several forms. For example, a workgroup could be convened to hold public meetings where the workgroup attendees will 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 proposed that recommendations would be based on the standards proposed in § 438.510(c) and discussed in section I.B.6.e.1. of the proposed rule.

At § 438.510(b)(2), we proposed 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 sets forth the mandatory measures identified for addition, removal or updating and that this second step would provide an opportunity for interested parties to provide comments. Following this public notice and opportunity for comment, we proposed at § 438.510(f) that we would publish the modifications to the mandatory measure set and the timeline for State implementation of such modifications in the technical resource manual proposed at § 438.530. Section § 438.510(f) is discussed in section I.B.6.e.7. of this final rule. The technical resource manual is discussed in more detail in section I.B.6.i. of the final rule.

This subregulatory process is like the process used by the QHP quality rating system, which uses a call letter to communicate changes and gather feedback on proposed measure updates and refinements to the QHP quality rating system. 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 the input in the final, updated Core Sets (see 88 FR 60280). Details on this process are available at <https://www.medicaid.gov/medicaid/quality-of-care/downloads/annual-core-set-review.pdf>. We noted that while we are aligning the MAC QRS workgroup processes, as noted above, with the QHP quality rating system and Core Set processes as appropriate, the MAC QRS is independent and the process for changes to the MAC QRS measure set would be conducted separately.

We provided an example of when the measure set might be updated using this subregulatory process as follows. Assuming that the proposal was finalized with an effective date in 2024, the implementation deadline for each State's MAC QRS per proposed § 438.505(b) (which provides for 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 proposed 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 States' MAC QRS. We noted our belief that 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)).

We solicited comments 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 was finalized in 2024). We also solicited comments on the types of engagement that would be important under the 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.

We summarize and respond to public comments received on subregulatory process to update mandatory measure set (§§ 438.510(b) and 457.1240(d)) below.

Comment: Many commenters supported our proposal to use a subregulatory process to update the mandatory measure set, and several of these commenters indicated that using a rulemaking process would be too cumbersome and slow. One commenter was opposed to creating a separate MAC QRS subregulatory process and suggested that we use the Medicaid and CHIP Child and Adult Core Sets Annual Review Workgroup process instead. Several commenters suggested that we use CMS's consensus-based entity (CBE) and existing pre-rulemaking process to obtain input on the proposed MAC QRS mandatory measure set and future updates to the mandatory measure set.

Response: We believe that the proposed subregulatory process—the use of an engagement process to evaluate the current measure set and gather potential changes for consideration and the public notice and comment process before changes are finalized—is sufficiently flexible to address the underlying policy goals described by the commenters.

Regarding the comment to use the Medicaid and CHIP Child and Adult Core Sets Annual Workgroup process to

determine inclusion of measures in the MAC QRS mandatory measure set, we believe that the MAC QRS should have its own process to determine mandatory measures because the Core Sets and MAC QRS have different purposes. The measures on the Core Sets are collected and reported on the State level and are intended to serve as a set of measures which, taken together, can be used to estimate the overall national quality of health care for Medicaid and CHIP beneficiaries. The MAC QRS measures are collected and reported at the plan level and are intended to provide beneficiaries and their caregivers with information to compare Medicaid and CHIP managed care plans, to hold States and plans accountable for care provided through its managed care program, and to provide a tool for States to measure and drive improvement of plan performance and quality of care. Each program has similar, but different, measure selection criteria based on the program's scope and purpose. Having separate processes will allow us and interested parties to focus on the specific standards and goals in each program.

Regarding the suggestion to use CMS's CBE review process to obtain interested party input on the mandatory measure set, that process is not used in Medicaid programs or for the Core Sets and we do not believe using that process for public input on updates to the mandatory measure set for the MAC QRS would be most appropriate or fitting. However, we may use available relevant information from the CBE process when we consider measures for inclusion in the MAC QRS. For example, to the extent that an MA quality measure is evaluated under the CBE review process, and we consider that measure for inclusion in the MAC QRS against the criteria we proposed and are finalizing at § 438.510(c), information from the public CBE process may be considered by CMS in making the necessary determinations whether to add that measure to the MAC QRS mandatory measure set. We proposed (and are finalizing at § 438.505(c)) that the MAC QRS be aligned with the MA and Part D and QHP quality ratings systems and the Core Sets to the extent possible, and we maintain this guiding principle in the final rule. Therefore, information and perspectives gathered as part of the processes for adopting quality measures for those other programs may be used, as relevant and appropriate, by CMS in applying § 438.510(b) and (c) to make changes to the minimum mandatory measure set adopted in this final rule.

Comment: Most commenters supported the proposed schedule to

conduct the subregulatory process to modify the mandatory measure set at least biennially. One commenter recommended that we update the mandatory measure set more frequently than biennially to ensure that consumers will receive data in a transparent and timely manner. Regarding future modifications of the mandatory measure set, several commenters recommended that we provide consistent schedules for when we plan to provide public notice and the opportunity to comment and that we give adequate time for health plans to review and respond to proposed changes to the MAC QRS measures.

Response: Regarding the comment that we shorten the two-year timeline, our proposal was to review the measures in the QRS mandatory measure set *at least* biennially, meaning we may conduct the subregulatory process to update the mandatory measure set more frequently if there is a need to keep pace with changes in the quality field and user preferences. We intend to regularly assess whether there are changes in the quality field and user preferences (such as a public health emergency, the availability of a new or improved quality measure, or a technology improvement) that would necessitate conducting the subregulatory process more frequently than biennially. Establishing the biennial minimum timeframe avoids imposing an unnecessary burden on us and interested parties to identify, evaluate, and make changes when it might not be necessary. Upon further consideration, we are modifying § 438.510(b) to make clear that, while we are required to engage in the subregulatory process described in § 438.510(b)(1) at least every other year, we are not *required* to update the mandatory measure set at least every other year after completing the subregulatory process, per § 438.510(b). As proposed, our requirement would have required us to make at least one update to the mandatory measure set, whether by adding, removing, or making a substantive update to an existing measure, at least every other year. Finalizing this change recognizes the real possibility that no updates are identified or necessary after we go through the process described in § 438.510(b)(1).

We agree with commenters on the importance of consistent schedules for providing public notice and the opportunity to comment with adequate time for health plans to respond to proposed changes to the MAC QRS measures and are finalizing these provisions as proposed. A robust

subregulatory process will ensure that any changes to the mandatory measure set will reflect input from interested parties to take it into consideration when we establish the workgroup process. We expect and hope for extensive input from interested parties based on the level of public comments on this proposal and on scope of the MAC QRS goals and use. Having varied and diverse viewpoints on whether any measure meets five of the six criteria specified in § 438.510(c)(1) and on how to apply the standards in § 438.510(c)(2) and (3) would help ensure that the minimum measure set for the MAC QRS reflects important quality metrics and provides an accurate and reliable picture of quality in the Medicaid and CHIP managed care programs.

Comment: Most commenters supported our proposal that we engage 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) as the first step of the subregulatory process for changing the minimum measure set and commenters supported the examples of engagement that we provided. Several commenters suggested additional types of engagement as part of the subregulatory process. One commenter suggested that we convene listening sessions with health plans in addition to a formalized workgroup of experts and interested parties. One commenter recommended that we engage the existing Core Sets Annual Workgroup in the subregulatory process. Another commenter suggested that CMS establish a quality measure workgroup to develop and test quality measure sets before requiring mandatory reporting.

Response: We appreciate commenters suggestions on the types of interested parties we should engage and the forms of engagement we should use. Throughout the development of the MAC QRS, we engaged with a broad spectrum of interested parties through numerous workgroups, listening sessions, and other means of obtaining input on the MAC QRS mandatory measures set and other parts of the MAC QRS framework. As discussed in section I.B.6.e.3 of the proposed rule, our continued dedication to engagement with interested parties to ensure continuous improvement of the MAC QRS is the basis for the requirement at § 438.510(b)(1), which sets a minimum level of engagement with at least States and other interested parties including, but not limited to, State officials, measure experts, health plans, beneficiary advocates, tribal

organizations, health plan associations, and external quality review organizations. We believe that the subregulatory process will allow for robust input from interested parties to ensure varied and diverse viewpoints and that the types of engagement recommended by commenters are permissible under the regulation we proposed and are finalizing at § 438.510(b). Therefore, we do not believe that establishing a specific set of procedures (for example, workgroups, public hearings, listening sessions with specific interested groups) in the regulation is necessary or appropriate.

We appreciate the recommendation from a commenter that we establish a quality measure workgroup to develop and test the mandatory measure set before requiring mandatory reporting, but are declining to implement this suggestion. We agree with the commenter that such engagement is important and a useful way to gather information and viewpoints, however, as described in section I.B.6.a of the proposed rule, we have already participated in several years of engagement to identify the MAC QRS mandatory measure set identified in this final rule, including a measure set workgroup through which an initial mandatory measure set was identified and refined over the years through our engagement with States, health plans, potential MAC QRS users, and other interested parties. As described in section I.B.6.g of the proposed rule, this engagement included several years of testing with potential MAC QRS users to gain additional feedback and insight of the MAC QRS measure set.

Furthermore, as part of our mandatory measure set development, we engaged in extensive research to identify quality measures already collected or reported by States. Requiring the same level of engagement for all potential modifications to the MAC QRS measure set would be unnecessarily burdensome, especially when some years will only require minimal or routine updates to the measure set.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.510(b) and 457.1240(d) related to the subregulatory process to update the mandatory measure set as proposed.

(4) Adding Mandatory Measures (§§ 438.510 and 457.1240(d))

Under proposed § 438.510(c), CMS would add a measure to the mandatory measure set if all three standards proposed at § 438.510(c)(1) through (3) are met, based on available information,

including input from the subregulatory process. We proposed that, 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. CMS could request an assessment from the engaged interested parties of the whether each of the measures suggested for addition (from the interested parties, CMS, or both) meets each of the three proposed standards at § 438.510(c)—that is, (1) whether it satisfies at least five of the criteria set forth at proposed § 438.510(c)(1); (2) whether it contributes to balanced representation of measures across the mandatory measure set as a whole per proposed § 438.510(c)(2); and (3) whether the benefits outweigh the burden of adopting the measure per proposed § 438.510(c)(3). Under our proposal CMS would use this input and could identify a subset of measures from the

list of potential suggested additional measures that meets all three 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 own research and evaluation. Through the call letter process, CMS would gather public comment to obtain additional evidence, explanations, and perspectives to make a final determination of which measures meet the standards in proposed § 438.510(c). Measures that meet these standards would be added to future iterations of the mandatory measure set.

To further illustrate how we intended for the standards proposed in § 438.510(c) to be applied using the subregulatory process, we provided more specific detail of our assessment of two measures (Follow-Up After ED Visit for Mental Illness (FUM) and the

Follow-Up After Hospitalization for Mental Illness (FUH)) which were considered for inclusion in the proposed mandatory measure set. We intended for the proposed subregulatory process for adding measures to follow that same approach.

In discussions prior to developing the proposed rule, States and other interested parties had 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 in considering these measures, we used our own research and input from various consultations to assess the measures against the measure inclusion criteria that we proposed as our first standard under § 438.510(c)(1) and concluded that both measures meet each of the six proposed criteria (see Table 3).

TABLE 3: Example Inclusion Criteria Assessment

| Criteria | FUM | FUH |
|-----------------------------|--|---|
| Alignment | <ul style="list-style-type: none"> 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. | <ul style="list-style-type: none"> 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 quality rating system measure. |
| Usefulness to Beneficiaries | <ul style="list-style-type: none"> The importance of timely access to mental health services were consistently identified in our conversations with Medicaid beneficiaries. | |
| Relevance | <ul style="list-style-type: none"> Both measures address access to services. | |
| Actionability | <ul style="list-style-type: none"> States and plans identified various ways in which plans can address follow-up. The 30-day measure was 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. | <ul style="list-style-type: none"> States and plans identified various ways in which plans can address follow-up. The 30-day measure was 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 | <ul style="list-style-type: none"> Relies on administrative data from claims that plans already have or are available to plans but will require coordination between plans in States that offer behavioral services through a separate managed care program. | |
| Scientific Acceptability | <ul style="list-style-type: none"> Generally regarded as reliable and valid measure in our listening sessions. Endorsed by the National Quality Forum (former CBE). | |

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 both 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's benefits compared to the burden associated with reporting it. As represented in Table 3, we found that both measures had similar benefits and burdens, but the FUH measure imposed less burden and 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. Therefore, we chose to include the FUH measure in the proposed mandatory set.

We did not receive any comments in response to our proposal related to adding mandatory measures using the proposed subregulatory process and proposed criteria and standards in § 438.510. For the reasons outlined in the proposed rule and our responses to comments in other sections of this final rule on § 438.510(b) and (c), we are finalizing these provisions as proposed.

(5) Removing Existing Mandatory Measures (§§ 438.510(d) and 457.1240(d))

We proposed 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 proposed to use the same approach we described in section I.B.6.e.2. of the proposed rule (relating to selection of the selection of the initial mandatory measure set) and stated that the discussion of how we selected the FUH measure (in section I.B.6.e.4. of the proposed rule) illustrated how we would assess whether a measure continues to meet our measure inclusion criteria to remain in the mandatory measure set. We also proposed 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 that would indicate that a measure would no longer be an appropriate indicator of health plan performance: (1) if the measure steward (other than CMS) retires or stops maintaining a measure (proposed § 438.510(d)(2)); (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 § 438.510(d)(3)); or (3) if CMS determines that a measure shows low statistical reliability under the standard identified in 42 CFR 422.164(e) (proposed § 438.510(d)(4)).

When a measure steward such as NCQA or PQA retires a measure, the steward goes through a process that includes extensive review by experts and solicitation of 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. When there is a change in clinical guidelines such that measure specifications no longer align with or promote positive health outcomes or when a measure is shown to have low statistical reliability (that is, how much variation between measure values that is due to real differences in quality versus random variation), we believe and thus proposed that it would be appropriate to remove the measure. The proposed criteria for removing measures outside the subregulatory process align with similar criteria in the current regulations at §§ 422.164(e) and 423.184(e) governing the MA and Part D quality rating system.²¹⁵ Under the proposed rule, we would use 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 any of the three circumstances proposed at § 438.510(d)(2) through (4) would be announced in the annual technical resource manual proposed at § 438.530. We sought comments on the proposal, including specifically 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).

We summarize and respond to public comments received on the proposed regulations for removing existing mandatory measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d)) below.

Comment: Overall, commenters supported our proposal for removing existing mandatory measures for the

specified reasons. Two commenters recommended that a measure no longer endorsed by the consensus-based entity (CBE) should no longer be included in the MAC QRS.

Response: Regarding the comment to develop criteria to remove a measure, we believe that the standards we proposed in § 438.510(d) are sufficient to determine whether a measure should be removed from the mandatory measure set. Sections § 438.510(b)(1) and (2) describe the subregulatory process we will use at least biennially to determine whether measures should be added, removed, or updated and § 438.510(d)(1) specifies that CMS will use that subregulatory process and the criteria and standards in § 438.510(c) to identify measures that CMS may remove if and when a measure that is in the mandatory measure set no longer meets the regulatory requirements to be required for the MAC QRS. This approach sufficiently preserves the integrity of the mandatory minimum measure set by using the same standards to add and remove measures. In addition, § 438.510(d)(2) through (4) provide that a measure will be removed without use of the subregulatory process (and without public input) if the measure steward retires or stops maintaining a measure, if the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes, or if CMS determines that the measure shows low statistical reliability. When one of these things happen, we believe that a measure is no longer suitable to be mandated for State use in the MAC QRS. When a measure steward retires a measure, when a measure is no longer aligned with clinical guidelines, or when the measure shows low statistical reliability, the measure would not provide the type of information we believe is most useful for evaluating managed care plan or program performance. This is like the process that the MA and Part D quality rating system (§§ 422.164(e) and 423.184(e)) uses to determine removal of measures; those regulations also provide for removal of measures by CMS when a measure steward other than CMS retires a measure.

Related to the commenters' recommendation that we remove measures that are no longer endorsed by the CBE, as discussed in section I.B.6.e.3 of this final rule, we do not require CBE endorsement for MAC QRS mandatory measures and therefore do not believe that it would be appropriate to modify § 438.510(d)(2) to allow CMS to unilaterally remove a mandatory

²¹⁵ See also "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), which appears in the April 12, 2023, *Federal Register* (88 FR 22120). Available online at <https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf>.

measure due to loss of CBE endorsement. However, we noted in section I.B.6.e.3 of this final rule that available relevant information from the CBE process could be considered when assessing a measure for inclusion in the MAC QRS measure set. Similarly, we believe that information from the CBE process could be considered to determine whether a measure meets the criteria for removal by CMS under § 438.510(d) and may also be considered during the process described in § 438.510(b) to determine whether a measure should be recommended for removal from the MAC QRS mandatory measure set. For example, to the extent that an MA quality measure is evaluated under the CBE review process and lost endorsement for any of the reasons identified at § 438.510(d)(2) through (4), we could rely on information identified through the CBE process showing that the measure meets any of the removal criteria in paragraph (d)(2) through (4) to choose to remove the measure from the MAC QRS mandatory measure set.

Comment: One commenter recommended that CMS set a transparent, robust reliability standard of no less than .75, which is generally the minimum standard for high statistical validity, to assess whether the measure meets the scientific acceptability criterion in § 438.510(b)(vi). The commenter also noted that they have consistently voiced their concern that CMS' statistical validity minimums for other quality programs are much too low and undermine the integrity of the data.

Response: We appreciate commenter's recommendation on how to assess whether a measure is statistically reliable and will consider this recommendation as we continue to reflect on our data reliability standards. We did not propose and are not adopting a new CMS standard that would apply across CMS program here. For the MAC QRS, we intend to align with existing CMS policy in this area. For instance, the MA and Part D Quality Rating System uses the HEDIS reliability standard for HEDIS measures for contracts with low enrollment (those with at least 500 but less than 1,000 enrollees), which are included only if the measure score reliability is equal to or greater than 0.7.

After reviewing public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.510(d) and 457.1240(d) as proposed.

(6) Updating Mandatory Measure Technical Specifications (§§ 438.510(e) and 457.1240(d))

In addition to adding and removing measures, we also proposed 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 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 proposed different subregulatory processes by which non-substantive and substantive updates to existing technical specifications for mandatory measures would be made. First, in paragraph § 438.510(e)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed 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, we did not propose to use the subregulatory notice and comment process proposed in § 438.510(b) for non-substantive changes because we believe this type of update reflects routine measure maintenance by measure stewards that do not significantly affect the measure and would not need additional review by the interested parties and CMS. We proposed 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 identified and described the proposed non-substantive updates in detail as listed below and sought comment on 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 will 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 used in the measure specifications 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 that could be updated this way, 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 but are not limited to:

- + Adding additional tests that will 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 proposed at § 438.510(e)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that we could 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) only after following 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 sought 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.

We did not receive any comments in response to our proposals for updating mandatory measure technical specifications. For the reasons outlined in the proposed rule, we are finalizing proposed §§ 438.510(e) and 457.1240(d) substantively as proposed. We are making one minor revision to the proposed regulation in the last sentence of the introductory language of paragraph (e) to remove the phrase “but not limited to” because it is repetitive and unnecessary. The text is clear that the list in paragraphs (e)(1)(i) through (iv) is a non-exhaustive list of examples of non-substantive changes to measure specifications.

Additionally, in section I.B.6.e.2 of the proposed rule we incorrectly stated that we proposed 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 the 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. While we proposed, and are finalizing, that whether CMS is the measure steward should be considered to determine whether CMS may remove a measure from the mandatory measure set under § 438.510(d)(2), the regulation text at § 438.510(e)(1) did not include, and we are not finalizing, that CMS being the measure steward is a consideration for updates to existing measures made under § 438.510(e) for either non-substantive or substantive 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 proposed 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 that appear in the annual technical resource manual.

We proposed to use the technical resource manual (described in proposed § 438.530) to communicate the final changes to the mandatory measure set for the MAC QRS. We proposed 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 2026 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 could elect to display the ratings for a new mandatory measure sooner. As 2 years from the start of the measurement year will always be in January, we sought 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 proposed 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 proposed 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 did not propose a specific deadline for States to stop display of a measure that has been removed from the mandatory measure set because States would have the option to continue to display measures removed from the mandatory set as additional measures (see section I.B.6.g.5 of this final rule). We sought comment on this flexibility, considering the criteria under which measures can be removed at proposed § 438.510(d). We sought comment on whether our timeframes are appropriate for updates to the mandatory measure set or

whether we should allow for more or less time, and why.

We also noted that under our proposal, we would release the technical resource manual annually regardless of whether we made any modifications to the mandatory measure set, to address any non-substantive changes to measure specifications or any removals that occurred outside of the subregulatory process.

We did not receive any comments in response to our proposals regarding finalization and display of mandatory measures. For the reasons outlined in the proposed rule we are finalizing §§ 438.510(f) and 457.1240(d) regarding the finalization and display of mandatory measure updates as proposed.

f. MAC QRS Methodology (§§ 438.334(d), 438.515 and 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 a State 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 the 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 proposed, 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 Providers²¹⁶ final rule (referred to as

²¹⁶ “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

“CMS Interoperability and Patient Access final rule”) published on May 1, 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, enrollees, and providers. Based on these considerations, at § 438.515(a) we proposed requirements for collecting and using data to calculate managed care quality ratings for mandatory measures and, in § 438.515(a) a MAC QRS methodology that must be applied to calculate quality ratings for MAC QRS mandatory measures, unless we have approved an alternative QRS. The same requirements were 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 are 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 proposed to replace that policy with more specific requirements in proposed new § 438.515(a), pursuant to which States would collect and validate data to be used to calculate and issue quality ratings for each mandatory measure for each plan on an annual basis. We proposed, at § 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 larger contracted managed care plans and, as applicable and available to the extent feasible without undue burden, from the State’s Medicaid FFS program providers and Medicare. Specifically, we proposed 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 enrollee satisfaction survey system that evaluates the level of enrollee satisfaction with QHPs offered through a Marketplace.²¹⁷

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). Available online at <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicare-programs-patient-protection-and-affordable-care-act-interoperability-and>.

²¹⁷ See section 1311(c)(4) of the Patient Protection and Affordable Care Act. Also see 45 CFR 156.1125

We believe that requiring States to calculate quality ratings for plans with fewer than 500 enrollees would be overly burdensome, as such 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 raise privacy or validity concerns in issuing and displaying quality ratings for some measures. Further, through an analysis of 2019 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. Under the proposed rule, 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 proposed that States would also be required to collect available data from the State’s Medicaid FFS program, Medicare (including Medicare Advantage (MA) 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 Medicaid 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 the proposed behavioral health mandatory measures. This is because many of the behavioral health measures require, in addition to data on the behavioral health service provided by the managed care plan, data on hospital services or pharmaceutical claims provided through the State’s FFS program to calculate the measure. Similarly, if a managed care plan provides services to enrollees who are dually eligible for Medicare and Medicaid services, it will be necessary for the State to collect data about services provided by Medicare to such

and Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2024, section 6.1.

enrollees to calculate quality ratings for some measures included on the proposed mandatory set. While we proposed 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 did not propose that States will 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 can 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 were 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 the 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 if States were only required to collect data from their contracted managed care plans. Similar issues are raised for obtaining all data needed to generate quality ratings 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 would mitigate the risk of

underreporting of mandatory measures, particularly those measures assessing behavioral health and substance use services.

We stated that our proposal aligned with ongoing efforts to expand access to health plan data at both the State and Federal levels. For example, State data collection required for measures in the Child Core Set²¹⁸ and behavioral health measures in the Adult Core Set²¹⁹, which will become mandatory effective for CY 2024, requires States to report measures that will require the use of data from both Medicaid managed care and FFS programs, as well as Medicare data for dually eligible beneficiaries.²²⁰ Many of these measures overlap with the mandatory measures proposed for the MAC QRS, which means States already will 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. We noted that at the time of the 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 stated our belief that the collection of such data would rarely result in an undue State burden. We also noted that States can request Medicare Parts A, B and D data for dually eligible beneficiaries free of charge through the CMS State Data Resource Center (SDRC), though not all States do so. Although Medicare 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. We believe obtaining Medicare Part C data from D-SNPs will not cause additional undue burden for those States that have

already opted to obtain some Medicare Part C data from these plans 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 proposed the "without undue burden" standard in the regulation to facilitate a gradual implementation of contract or system changes to collect the necessary data. We also noted that CMS would be available to provide technical assistance to help States acquire and use available Medicare data to calculate MAC QRS quality ratings. We sought comment on the proposed requirement that States collect available data from multiple sources on the mandatory measures. In addition, we requested 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, proposed § 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 submit validated data for the QHP quality rating system, and § 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 proposed the same definition for purposes of new subpart G at § 438.500. We noted that States could 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 proposed 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 plans 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 in this section, 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 might need to be collected from two managed care plans. However, a State could determine that only one of the services or actions for which data must be collected is being assessed by the measure. In such a case, the State would need to identify, among those plans from which the State collected data, the plan(s) whose contract includes the service or action identified by the State as being assessed by the measure, and calculate and assign quality ratings to that plan accordingly.

We discussed an example in the proposed rule to illustrate this: the Follow-Up After Hospitalization (FUH) measure listed in Table 3 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, the proposed rule 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 be required to identify all plans that are contracted to provide the follow-up mental health services that are 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. However, based on feedback we received from beneficiaries, we proposed to revise the current policy

²¹⁸ See 2024 Child Core Set, <https://www.medicaid.gov/media/145571>.

²¹⁹ See 2024 Adult Core Set, <https://www.medicaid.gov/media/161841>.

²²⁰ See 437.15(a)(4)(requiring States to report on all Medicaid and CHIP beneficiaries, including those enrolled in fee-for-service and managed care, in their reporting of all Child and Adult Core Set measures, unless otherwise specified by the Secretary).

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 proposed § 438.515(a)(3) for each measure). 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. We solicited comments on our proposal to issue individual performance rates and sought additional input on our decision not to require additional percentage ratings to reflect a national baseline for each mandatory measure.

We noted that 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 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. We concluded that this beneficiary feedback demonstrated the value of requiring individual measure quality ratings.

Our user testing suggested that displaying managed care plan quality ratings both at the individual measure and the domain level would be most desirable to beneficiaries. Examples of potential care domains include behavioral health, chronic conditions, infants and children, and preventive care. 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 the 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 proposed at § 438.515(c) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS would engage with States, beneficiaries, and other interested parties before proposing to implement domain-level quality ratings for managed care plans through future rulemaking.

As 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 stated by beneficiaries who participated in testing of a MAC QRS prototype, we intend to propose care domains, methodology, and website display requirements for domain-level quality ratings in future rulemaking. We sought 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 proposed 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. We noted that 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 Medicare data needed to generate the quality rating for a given measure. While we recognized 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 Core Set measures also require both Medicaid and Medicare data (see Core Set Final Rule, 88 FR 60278, 60299). We stated that 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 services exclusively through Medicare. We indicated in the proposed rule our intent 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 proposed at § 438.530. 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 proposed that States would be required to calculate quality ratings at the plan level by managed care 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 will 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 managed care program using only the service data described in § 438.515(b)(1) of beneficiaries enrolled in that plan under that managed care program. A managed care plan that participates in multiple managed care programs would therefore 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 would 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 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 single plan-level ratings would not provide useful information to potential enrollees because 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 choices. 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 could not be reported for a plan at the program level this way due to low denominator sizes, the plan would be issued an appropriate indicator that data for the measure is not available for that measure as the quality rating. We sought comment on how this proposed policy would interact with our proposed minimum enrollment threshold, such as the extent to which a State's smaller plans may report data unavailable messages.

We considered the level at which ratings are assigned in the MA and Part D quality rating system and the 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. If assigned at the contract-level, quality ratings would be calculated based on data from all enrollees served under a given contract between a State and a managed care plan, subject to the technical specifications of the measure.²²¹ However, we did not believe that contract-level ratings will 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. Different products may provide access to different provider networks and/or require enrollees follow different processes to obtain services. Examples include Exclusive Provider Organization Plans (EPO), Health Maintenance Organizations (HMO), Point of Service Plans (POS), and Preferred Provider Organizations (PPO). These products typically provide coverage of a similar set of comprehensive health care services but vary in terms of how enrollees can access these services and at what cost. If a QHP issuer of health care offers multiple products, each separate product will receive its own ratings. In Medicaid, product level ratings could correlate with ratings assigned at the Prepaid Inpatient Health Plan (PIHP), Prepaid Ambulatory Health Plan (PAHP), or MCO level. Like our concern about contract-level ratings, one organization could offer multiple PIHPs, PAHPs, or MCOs across different managed care programs.

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, Part D, or QHP quality rating systems, we believe that this additional work would 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 noted 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.

We solicited comments 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.

We summarize and respond to public comments received on the proposed rules for the collection and validation of data necessary to calculate MAC QRS quality ratings, the MAC QRS methodology and calculation and issuance of measure-level ratings (§§ 438.515 and 457.1240(d)) below.

Comment: Several commenters supported the use of Medicaid FFS and Medicare data, in addition to Medicaid managed care data, as necessary to calculate mandatory measures, if it can be used without undue burden. These commenters agreed that the proposal would provide a more comprehensive view of a State's populations, and that it would be unfair to exclude mandatory measures if some portions of an enrollee's care were provided outside of Medicaid managed care. Several other commenters opposed the use of other data (for example, Medicaid FFS and Medicare data), and a few opposed the use of data from more than one Medicaid managed care plan to calculate ratings for a single managed care plan. The commenters raised concerns about the availability of data from sources outside of Medicaid, especially Medicare. Some commenters noted that it could take several years to obtain Medicare encounter and claims data, which would not be feasible with the proposed timelines.

Response: We appreciate commenters' support for our proposal to require States to collect and use data necessary to calculate quality ratings from sources outside of Medicaid and CHIP managed care plans when such data are available for collection by the State without

²²¹ Some MA quality measures are limited to MA special needs plans.

undue burden. We considered the concerns raised by commenters that were not in favor of this policy as well. We continue to believe that our proposed approach best balances State flexibility to provide Medicaid services through multiple delivery systems and/or multiple managed care programs, the person-centered goal of measuring quality of care for a managed care beneficiary even when their care is provided through multiple delivery systems, and feasibility for providers, plans, health systems, and States.

We recognize the concerns about States' ability to include certain populations of Medicaid managed care enrollees in the MAC QRS ratings, particularly dually eligible enrollees as the Medicaid managed care program is not the primary payer for most health care services for this population. We also recognize that there are challenges with collecting, validating, and integrating the data from both Medicare and Medicaid FFS that are necessary to achieve the inclusion of these individuals. However, we disagree with those recommending that States should not include these individuals in quality ratings for MAC QRS measures. In the 2023 Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting Final Rule, we stated that our intent in implementing mandatory reporting requirements for the Adult and Child Core Sets is for the data collected to be as inclusive of all beneficiaries as possible and noted that dually eligible individuals experience the health care system and incur health outcomes as individuals, regardless of whether Medicare or Medicaid pays for the service.²²² We believe that this statement is true for both dually eligible individuals and Medicaid beneficiaries who receive their care through a Medicaid program that provides services through both FFS and managed care. As such, we intend the MAC QRS data collection and quality ratings to be as inclusive of all managed care beneficiaries as possible. Our intention is reflected in the requirements proposed and finalized at § 438.515(a)(1)(ii) and § 438.515(b)(1).

In the proposed rule, we noted that the proposed "without undue burden" standard is meant to facilitate a gradual implementation of contract or system changes to collect the data necessary to calculate managed care quality ratings

that include the enrollees described in § 438.515(b)(1), which may extend past the implementation date proposed and finalized in § 438.505(a)(2). Because our proposal to require data collection from non-Medicaid managed care sources applied to the extent that the collection of data from such additional sources did not result in an undue burden, we disagree with commenters that it would not be feasible for States to collect data from sources outside of Medicaid managed care within the MAC QRS' proposed timeline. As proposed, States experiencing an undue burden preventing them from collecting one or more of these additional sources of data necessary to calculate fully inclusive MAC QRS ratings, which could not be resolved within the MAC QRS implementation timeline, would have the flexibility to identify and build a pathway to collect that data over a timeline that would not constitute an undue burden, which may extend past the implementation timeline.

However, based on commenter input that the challenges related to utilizing non-Medicaid managed care data to produce quality ratings for the MAC QRS extend beyond data collection—to the State's ability to validate collected data and then use the validated data to calculate and issue a quality rating as well—we are finalizing § 438.515(a)(1)(ii), (a)(2), and (a)(3) with modifications to clarify that, for Medicare and Medicaid FFS data, the requirements of these provisions apply "to the extent feasible without undue burden."

As finalized, this standard—"to the extent feasible without undue burden"—would apply at each of the three stages of quality rating production described in § 438.515(a). By including the phrase "to the extent feasible without undue burden" in paragraphs (a)(1)(ii), (a)(2) and (a)(3), we are acknowledging that there may be unique challenges related to Medicaid FFS, Medicare Advantage, or other Medicare data at each of these step and we are focusing the flexibility the standard provides on the specific activities to which we intend this flexibility to apply. As finalized, the specific requirements in these paragraphs (collection of data from certain sources outside Medicaid managed care organizations, validation of that data, and calculation of ratings using the data) apply to the State in its administration of its MAC QRS only to the extent that it is feasible for the State to comply without undue burden. By including "to the extent feasible" in this regulation text, we are clear that we anticipate that, even where there is an

undue burden, it will likely be feasible without undue burden for a State to comply—to some extent—with each of the requirements in paragraph (a). That is, the State will be able to collect some data from these additional sources beyond Medicaid managed care, validate some data from these additional sources, and/or calculate ratings using some of the data from these additional sources, and § 438.515(a) requires the State to collect, validate and use that data to calculate MAC QRS quality ratings. We note that we are not including the "to the extent feasible without undue burden" standard in paragraph (a)(4) because we view the issuance of the MAC QRS ratings as fairly nonburdensome once those ratings are calculated based on data that has been collected from relevant sources and validated.

For example, a State that can collect and validate necessary Medicaid FFS, Medicare Advantage or other Medicare data for the initial MAC QRS display year could experience barriers to using that validated data to calculate performance rates if the State does not yet could integrate data from those other sources with Medicaid managed care data to produce plan quality ratings. In such a case, the undue burden standard could permit the State additional flexibility to continue to work towards the ability to integrate such data without undue burden over a timeline that extends past the implementation date finalized in § 438.505(a)(2). However, we expect instances where States are unable to include *any* data from non-Medicaid managed care sources, including Medicare data for *any* dually eligible individuals, in *any* MAC QRS ratings will be the exception, and not the rule.

We emphasize that we do not believe that there will be an undue burden on a State performing the required steps indefinitely. We intend the MAC QRS data collection and quality ratings to be as inclusive of all managed care beneficiaries as possible and for the undue burden standard to facilitate the gradual implementation of contract or system changes to collect, validate, and use the Medicaid FFS and Medicare data necessary to accomplish this goal. While there may be cases where the ability to collect, validate, and use Medicaid FFS and Medicare data to calculate a quality rating is all or nothing, we believe that it is more likely that some of this data can be collected, some can be validated, and some can be used to calculate quality ratings for some mandatory measures. Our regulations, as finalized, reflect our belief that some States will be unable to

²²² See Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting Final Rule Core Set Final Rule, 88 FR 60297, available online at <https://www.govinfo.gov/content/pkg/FR-2023-08-31/pdf/2023-18669.pdf>.

fully comply with § 438.515(b)(1) initially; the goal and intent of including “to the extent feasible” in the undue burden standards are to give States the ability to continue to work towards full inclusivity over time. Similarly, we stress that whether the work and effort necessary to collect, validate and use the data constitute an undue burden will evolve over time as resource availability, data systems, and data availability continue to progress. We emphasize here that as the duties specified in § 438.515 are to occur each year for the annual issuance of MAC QRS ratings, the evaluation of the feasibility and scope of the State’s burden must also occur each year, applying the regulatory standard of “as feasible without undue burden.”

Finally, we note that the obligation in paragraph (b)(1) to include data for all enrollees who receive coverage through the managed care plan for a service or action assessed by a measure necessarily means the data that has been collected, validated, and used as specified in paragraphs (a)(1) through (a)(3) and the ratings issued as required by paragraph (a)(4). Repeating the standard “to the extent feasible without undue burden” in paragraph (b)(1) would be repetitive and suggest that data that can be collected, validated, and used without undue burden could nonetheless be excluded from the final measure ratings. Similar to our thinking related to (a)(4), we are not including this standard (“to the extent feasible without undue burden”) in paragraph (b)(2) because we believe that issuance of a quality rating at the program level will be fairly nonburdensome given that States should have knowledge (or should have the ability to easily acquire knowledge) of which beneficiaries should be attributed to which plans under its established programs at the time quality ratings are calculated using data collected from relevant sources and validated.

In combination, we believe that the MAC QRS’s extended timeline and the undue burden standard best balance our intent for the MAC QRS data collection and quality ratings to be as inclusive of all managed care beneficiaries with the implementation of this goal within a landscape in which the availability of the data necessary to do so is constantly evolving and expanding. We intend to provide technical assistance to States to help support our goal of inclusivity, and are also finalizing § 438.535 with modifications to include additional information in the MAC QRS annual report that will allow us to identify technical assistance that will best support the ability of States to collect,

validate and use Medicaid FFS and Medicare data in their MAC QRS quality ratings and monitor the extent to which the MAC QRS ratings are inclusive of all plan enrollees as required by § 438.515(b)(1).

We are therefore including a new paragraph (a)(8) at § 438.535 that will require States to report the following data if the data necessary to calculate a measure described in § 438.510(a)(1) of this subpart cannot be provided by the managed care plans described in § 438.515(a)(1) of this subpart: (i) a description of any Medicare data, Medicaid FFS data, or both that cannot, without undue burden, be collected, validated, or used to calculate a quality rating for the measure per § 438.515(a) and (b), including an estimate of the proportion of Medicare data or Medicaid FFS data that such missing data represent; (ii) a description of the undue burden(s) that prevents the State from ensuring that such data are collected, validated, or used to calculate the measure, the resources necessary to overcome the burden, and the State’s plan to address the burden; and (iii) an assessment of the missing data’s impact on the State’s ability to fully comply with § 438.515(b)(1).

Finally, in the Core Set final rule, we recognized that States were unlikely to successfully report dually eligible individuals by the implementation date for that final rule, in 2024, which is four years prior to the implementation date for the MAC QRS (December 31, 2028).²²³ In addition to the MAC QRS’ longer implementation timeline and the flexibility afforded to States by the undue burden standard, we are also finalizing at § 438.515(d) (discussed in more detail in this section) the opportunity to request a one-time, one-year extension to requirement in § 438.515(b). Such an extension could apply to the requirement in (b)(1) that all data for applicable enrollees, including dually eligible individuals, must be included in each plan’s quality rating(s), if the State has requested, and CMS has approved, an extension for this requirement. States with an approved extension for § 438.515(b)(1) will have 5 years (until December 31, 2029) to comply with § 438.515(b)(1). Given the relationship described in this response between the ability to comply with paragraph (b)(1) and the State’s ability to collect, validate and use enrollee data to produce MAC QRS quality ratings, the barriers to comply with (b)(1) that must be identified by a State per

finalized § 438.515(d)(iii) when requesting approval for an extension under § 438.515(d) could include the State’s inability to collect, validate, or use data for dually eligible enrollees, even when the State’s ability to complete these steps does not rise to the level of an undue burden.

Comment: Some commenters were concerned that using data from more than one plan to calculate and assign quality ratings would not result in valid quality ratings or in fair and accurate comparisons.

Response: We do not agree with commenters that the proposed policy would result in unfair comparisons because our intent is not to hold plans accountable for services provided by other plans. Rather, our intent is for States to use all data obtainable without undue burden to calculate and assign quality ratings to managed care plans for services they are accountable for under a given State managed care program, thereby ensuring that such ratings are as inclusive of all Medicaid managed care beneficiaries as possible. Furthermore, as finalized in § 438.515(b)(2) and discussed in the proposed rule and this final rule in sections I.B.6.f, ratings for MAC QRS measures must be assigned to managed care plans per program. Therefore, measure ratings must be calculated using the data of beneficiaries enrolled in a given managed care plan through the rated program who receive the service or action being assessed by the measure for which the plan is being rated, even if some of the data used to calculate the measure comes from other sources. We also do not believe the validity of the rating would be affected since all measures are required to be validated as required by finalized § 438.515(a)(2) for Medicaid, and § 457.1240(d) for CHIP.

Comment: A few commenters supported our proposal to rate managed care plans only on measures for which they are accountable and agreed that managed care plans should be held accountable for the full range of outcomes their enrollees experience. However, we received many comments expressing concern that our proposed rule would require States to include measures in their MAC QRS that are not applicable to the State’s managed care program(s). These commenters sought clarification on whether all mandatory measures would be reported in all States, noting that not all services assessed by each of the proposed MAC QRS mandatory measures are furnished through managed care in a State. A couple of commenters stated concern that managed care plans would be required to report data for services that

²²³ The initial round (2024) of Core Sets reporting must be submitted and certified by States by December 31, 2024.

they are not contracted to provide. Others commented that States would be required to collect and validate data for measures that assess services not covered through the State's managed care program(s), and therefore, would ultimately not be used to calculate quality ratings for any managed care plan.

Response: We agree with commenters that, as proposed, the requirement in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), should be finalized with narrower language to avoid implying that States are required to include measures in their MAC QRS that are not applicable to the State managed care programs because they assess services or actions that are not covered through a managed care program established by the State. Because we proposed in § 438.515(a)(1) and (2) that States must collect and validate data for the measures identified in § 438.510(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), the proposal could have been interpreted as requiring States to collect and validate data for measures that were not applicable to the State's managed care program(s). Therefore, we are finalizing our proposal with modifications to address these concerns.

First, we are modifying § 438.510(a) (finalized as § 438.510(a)(1)) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), to narrow the scope of measures that must be included in a State's MAC QRS to those measures in the mandatory measure set that are applicable to the State because the measures assess a service or action covered by a managed care program established by the State. As finalized, States will be required to include in their MAC QRS only those mandatory measures that assess the performance of their managed care plans and report that plan level performance by managed care program(s). For example, if a State does not offer dental services through managed care, the Oral Evaluation, Dental Services (OEV) measure would not be applicable to the State because the service or action assessed by the measure is not covered by a managed care program established by the State. Similarly, all States that provide Medicaid services through managed care would include the five measures from the CAHPS survey as they assess customer experience, and therefore are applicable to every State's managed care program. This modification in the scope of the measures and rating system

(finalized at § 438.510(a)(1)) narrows the scope of measures that States must include in their MAC QRS and therefore could narrow the scope of data that must be collected and validated under § 438.515(a)(1) and (2) if a State provides some Medicaid services through FFS. For example, if a State provides LTSS services through its FFS program, the State would have no obligation to collect or validate any data on any LTSS measures because such services are not covered by a managed care program established by the State.

Second, we are finalizing the reporting requirement in § 438.535(a)(1) with modifications to require that States provide a list of any mandatory measures identified as not applicable by the State under § 438.510(a)(1) along with a brief explanation for why the measure is not applicable to the State's managed care program(s). (See section I.B.6.j. of this final rule for more detail on § 438.535). The change to the proposed Medicaid provisions at §§ 438.510(a) (finalized at § 438.510(a)(1)) and 438.535(a)(1)(i) are equally applied to separate CHIP by cross-reference through revised 457.1240(d).

Comment: One commenter questioned the appropriateness of including requirements for Medicaid FFS in a Medicaid managed care final rule and whether there is statutory authority for the reporting of Medicaid FFS measures under the managed care regulations. However, the commenter did not specify what specifically they believed that FFS programs would be required to do under our proposal.

Response: Our rule does not require States to calculate and report quality ratings for measures that assess services provided to a State's beneficiaries through FFS and we disagree that our rule establishes requirements for FFS. First, States are responsible for holding managed care plans responsible for the quality and timeliness of services they are contracted to provide, and this may require care coordination between the managed care plan's providers and providers participating in other delivery systems, such as Medicaid FFS. In a State that offers Medicaid services through FFS and managed care, it would be impossible to assess the quality or timeliness of some managed care services provided to Medicaid beneficiaries that require care coordination between the managed care plan and FFS without using the FFS service data owned by the State.

Second, in the mandatory measure set we are finalizing in this rule, the FFS data that may be needed to hold managed care plans responsible for

services for which they are accountable is limited to 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). As we discussed in section I.B.6.f. of the proposed rule, these MAC QRS measures require data from more than one care setting and calculating quality ratings for one of these measures for a Medicaid managed care plan could require FFS data, but only if a State splits coverage of the services associated with the measure between FFS and managed care. For example, to calculate the three behavioral health measures, it is necessary to collect mental health or substance use service data, as well as either pharmacy or physical health data. In a State that provides physical and behavioral health services through managed care, but offers pharmacy benefits through FFS, FFS data would be required to calculate quality ratings for AAP. If available FFS data is not leveraged, beneficiaries that receive services necessary to calculate quality ratings for these measures through both FFS and managed care would not be represented in the MAC QRS ratings. As stated previously in this final rule, it is our intent for the data collected and quality ratings issued in the MAC QRS to be as inclusive of all managed care beneficiaries as possible. Therefore, our policy to leverage FFS data is an important mechanism for achieving our goal and is consistent with our intention identified in the Adult and Child Core Sets Final Rule in which we stated our intent for the data collected for mandatory Adult and Child Core Set Reporting to be as inclusive of all managed care beneficiaries as possible.

While it is our intent for the data to be as inclusive of all managed care beneficiaries as possible, we reiterate that the requirement to collect, validate, and use data from other delivery systems is subject to the undue burden standard described in § 438.515(a)(1)(ii), (a)(2), and (a)(3) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), and discussed in section I.B.6.f. of the proposed rule and this final rule. Given that FFS data is owned by the States and such data's role in monitoring services provided through a State's FFS program and the quality of those services, we believe that FFS data should almost always be available for collection without undue burden. However, at least one commenter

communicated that they do not currently collect FFS data and, depending on the unique circumstances within a State, we recognize that there could be situations in which it would be an undue burden for States to validate or use FFS data to calculate certain MAC QRS mandatory measures. However, we emphasize again that this does not mean that an undue burden would exist indefinitely in such a State. We noted in the proposed rule and throughout our responses in this final rule that we intend for the undue burden standard to facilitate the gradual implementation of contract or system changes to collect necessary data and we would expect States to identify a pathway that would allow for FFS data to be collected, validated, and used by the State for MAC QRS quality ratings. Furthermore, we have noted throughout our responses in this final rule that finalized § 438.515(a) requires States to collect, validate and use FFS data necessary to calculate MAC QRS ratings that is feasible to collect, validate and use without undue burden. We expect that instances where States cannot collect, validate, or use any Medicaid FFS data to calculate MAC QRS quality ratings will be the exception and not the rule given that the State is responsible for administering and ensuring the quality of services provided by its FFS program.

Comment: One commenter requested flexibility for States to provide explanatory information regarding the inclusion of multiple data sources as part of the MAC QRS reporting or website display.

Response: Although not required for the MAC QRS website display under § 438.520 for Medicaid (which also applies to separate CHIP through a cross-reference at § 457.1240(d)), States have flexibility to include additional explanatory language in their MAC QRS that will assist MAC QRS users, and we encourage States to do so. Such explanations could include the source of data used for the different measures or a description of the specific activities or services furnished by the managed care plan that are reflected in the measure rating.

Comment: Several commenters appreciated the undue burden standard proposed to limit when a State would be required to collect and use data from Medicaid FFS and Medicare sources and recommended CMS consider factors such as Medicaid agency administrative capacity, systems burden, and the general availability of data sources outside of Medicaid managed care when determining if an undue burden exists.

Response: We agree with commenters that Medicaid agency administrative capacity, systems burden, and the general availability of data sources outside of Medicaid managed care should be considered, among other factors, when determining undue burden. We believe that whether an undue burden exists for the collection, validation, or use of Medicare data or Medicaid FFS data to calculate quality ratings for MAC QRS measures may be highly dependent on the circumstances within a specific State. The answer to how to obtain and use Medicaid FFS and Medicare data without undue burden may share similarities and best practices but will often be unique in each State and for each data source. We intend to work with States that have identified challenges—such as through the reporting in § 438.535(a)(8)—and provide technical guidance on how to address these challenges and determine how CMS may best support States in collecting and using such data. We also intend to provide additional guidance on circumstances that may constitute an undue burden and will continue to engage with States, plans, providers and other interested parties in the development of this guidance. We previously noted in this final rule that we proposed the “without undue burden” standard to facilitate a gradual implementation of contract or system changes to collect the necessary data that allows States to implement these changes over time, which may extend past the implementation date proposed in § 438.505(a)(2). As such, what constitutes an undue burden will evolve over time as resource availability, data systems, and data availability continue to progress and, likewise, the technical assistance and guidance on what constitutes an undue burden will also evolve over time. We reiterate that the undue burden standard permits States to exclude the specific data for which the undue burden applies. Where it is feasible to collect, validate, and use necessary data without undue burden, the State must ensure that these steps are completed, and the data are used in the calculation of MAC QRS measures.

Comment: A few commenters supported the proposed minimum enrollment threshold. One commenter suggested a modification to our proposal 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. The commenter requested that CMS add a requirement that plans also have 500 or more members as of January 1st of the rating year, which would align

with the Medicare and Marketplace enrollment threshold.

Response: We appreciate the commenter’s suggestion to modify our proposed minimum enrollment threshold to require 500 or more enrollees on July 1 of the measurement year *and* as of January 1 of the rating year to align with other CMS quality rating programs. We agree with commenters that the MAC QRS should align the dates used to determine whether a plan meets a minimum enrollment threshold with other CMS quality ratings programs. However, neither the QHP nor the Medicare Advantage and Part D quality rating system regulations codify a specific date used for an overall minimum enrollment threshold for collection of all quality data and reporting of all quality ratings. Instead, both the QHP and the Medicare Advantage and Part D quality rating systems establish minimum enrollment requirements in annual technical guidance. For instance, the participation criteria for QHP issuers that must collect and submit validated clinical measure data for the QHP quality rating system include, among other criteria, that the QHP issuer “had more than 500 enrollees as of July 1, 2024, and more than 500 enrollees as of January 1, 2024.”²²⁴ Similarly, the MA and Part D quality rating system uses its Medicare 2023 Part C & D Star Ratings Technical Notes to identify minimum enrollment thresholds for Medicare Advantage and Part D plans that are awarded Star Ratings. Instead of establishing a threshold that applies across the program like the QHP quality rating system, the MA and Part D quality rating system identifies minimum enrollment thresholds for some of its quality measures if such thresholds are specified in the measure steward’s technical specifications.

To better align with the QHP quality rating system and the MA and Part D quality rating system, we are not finalizing use of the July 1 marker in the regulation text. Like the QHP quality rating system, this information will instead be communicated through the annual MAC QRS technical resource manual. To reflect this, we are finalizing § 438.515(a)(1)(i) with modification to

²²⁴ See 2024 Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Operational Instructions” <https://www.cms.gov/files/document/qrs-qhp-enrollee-survey-operational-instructions-2024.pdf>. The enrollment threshold used for the QHP quality rating system aligns with the one for the QHP enrollee satisfaction survey. See section 1311(c)(4) of the Patient Protection and Affordable Care Act and 45 CFR 156.1125. Also see the *Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2024, section 6.1*.

specify that the enrollment threshold of 500 will be calculated as described by CMS in the technical resource manual. CMS intends to require States to use plan enrollment at both the January and July dates to determine whether a Medicaid managed care plan meets the minimum enrollment threshold of 500 finalized in § 438.515(a)(1)(i). We recognize that changes to the MAC QRS's minimum enrollment threshold could impact the scope of data collection required for the MAC QRS and could be burdensome on States and plans if modified frequently. While the technical resource manual will be issued annually, CMS does not intend to modify the minimum enrollment thresholds discussed here unless CMS determines that changes are necessitated to better align with other Federal rating programs or to ensure that Medicaid beneficiaries are appropriately represented in MAC QRS ratings. We note that the minimum enrollment threshold finalized by CMS at § 438.515(a)(1)(i) and used to identify which *plans* must be included in the MAC QRS is distinct from measure steward specifications that may use dates of plan enrollment to identify the eligible *beneficiary population* for a specific measure and documented in the measure's technical specifications. This information from measure stewards would also be provided in the Technical Resource Manual as part of the MAC QRS technical specifications and any updates to these specifications would be made per finalized § 438.510(e).

Lastly, in section I.B.6.f. of the proposed rule we noted that States would have the option to include plans that do not meet the minimum enrollment threshold in their reported measures, and that we would encourage States to do so when appropriate. For example, a State may decide to include in its MAC QRS managed care plans for pregnant individuals that enroll fewer than 500 individuals because, despite not meeting the minimum enrollment threshold, the State is able to calculate and issue quality ratings that are valid and reliable to the plan for mandatory measures related to the care of pregnant persons because all enrollees are likely to be part of the beneficiary population included in such measures. Should a State decide to include plans with fewer than 500 enrollees in its MAC QRS, this approach would not be considered an alternative methodology for which the State would need approval under § 438.515(c) so long as the State ensures that quality ratings issued to the plan(s) meet the requirements in § 438.515(b). The requirement at § 438.515(a)(1)(i)

establishes a floor for the plans that must be included in the MAC QRS, but States are free to include additional managed care plans as appropriate, and could even choose to include data on its FFS program in the MAC QRS. Furthermore, inclusion of additional plans (or even additional ratings or performance information) in a State's MAC QRS does not necessarily impact States' compliance with the CMS methodology established in § 438.515(b)(1) and (2), which establishes requirements related to the enrollees who must be included in quality ratings for the plan and the level at which the rating is assigned to the plan.

Comment: One commenter requested input on how low denominator sizes may impact the requirement to collect data necessary to calculate a measure, citing concerns about rating validity when there are low denominator sizes.

Response: Our minimum enrollment threshold policy at § 438.515(a)(1)(i) for Medicaid, and through a cross-reference at § 457.1240(d) for separate CHIP, requires States to collect data from contracted managed care plans that have 500 or more enrollees. Low denominator sizes do not impact the requirement to collect data from individual plans that meet the enrollment threshold but may impact whether a State reports a measure for a managed care plan if the measure's denominator size does not meet privacy, validity, or reliability standards. We noted in the proposed rule that we will follow data suppression policies for measure stewards in addition to the CMS Cell Size Suppression Policy such that if sample sizes are too small, we will not require States to publicly report data to avoid a potential violation of privacy. At present, CMS cell-size suppression policy for public reporting prohibits the direct reporting of beneficiary values from which users can derive values of 1 to 10, so CMS suppresses in its own release of data any cells with data within that range. We will also follow data suppression policies for measure stewards in addition to our Cell Size Suppression Policy. For instance, some measure stewards permit choosing not to publicly report a quality rating for a specific quality measure due to small numbers if the measure has a denominator that is less than 30. We will publish data suppression guidance in the technical resource manual based on validity or reliability concerns and intend to align this guidance with existing quality reporting practices to determine when a MAC QRS measure should be suppressed due to low denominator sizes to ensure validity of

the ratings and privacy of the included beneficiaries. Through their managed care contracts, States must ensure that Medicaid and CHIP managed care plans ensure the privacy of enrollee data pursuant to §§ 438.224 and 457.1233(e) respectively; States are also required to protect beneficiary confidentiality by Subpart F of part 431 of this chapter. In addition, the privacy and security requirements under HIPAA apply to Medicaid and CHIP. *See* 45 CFR part 164.

Comment: Many commenters requested technical assistance on how to obtain and use data from other sources without imposing an undue burden on the State, noting existing challenges in collecting Medicaid managed care data necessary to calculate quality measures from Medicaid data sources and ensuring that all data sources feed into a single point that will calculate ratings. A few commenters specifically requested that CMS provide a standardized data set of Medicare quality data to Medicaid agencies. Other commenters raised concerns about whether States could obtain Medicare data in a timely manner considering the proposed MAC QRS timelines. One commenter noted that some States have confidentiality clauses in managed care contracts that would forbid the exchange of any information pertaining to substance use disorder and HIV, which could affect data collection for the proposed Initiation and Engagement of SUD Treatment and the Follow-up After Hospitalization for Mental Illness measures.

Response: We appreciate the input on assistance that may be helpful to States in the collection and use of Medicaid FFS and Medicare data. We intend to provide both technical assistance and additional guidance on how best to meet this requirement, including the timely collection of Medicare data. We note that in the Medicare Program; Contract Year 2025 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; Health Information Technology Standards and Implementation Specifications proposed rule (referred to as the CY2025 Medicare Part C/D proposed rule), we have a solicitation for comment on "Use of MA Encounter Data to Support Required Medicaid Quality Reporting" to better understand how to balance considerations related to the timeliness of quality reporting with accuracy and

completeness of MA encounter data.²²⁵ [NOTE TO UPDATE IF THIS RELEASES BEFORE THIS FINAL RULE]. We note that in the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program final rule (referred to as the CMS Interoperability and Prior Authorization final rule), impacted payers—including States and MA plans—must implement and maintain a Payer-to-Payer API by January 1, 2027 to make available certain data to improve care continuity when a patient changes payers or between concurrent payers for those patients.²²⁶ States may be able to collect claims and encounter data from MA plans under a Payer-to-Payer API for those dually eligible individuals who opt-in to permit the data exchange. We will also consider whether additional resources, such as the requested Medicare data set, should be available through the State Data Resource Center to meet State needs related to the MAC QRS.

In response to the commenter's concern about data exchange of confidential information, we note that the feasibility criterion for including or adding a measure to the mandatory measure set takes into consideration whether States and health plans can access the data needed to calculate the measure. Furthermore, whether an undue burden exists is highly dependent on the circumstances within a specific State. We noted previously in this section that to identify whether an undue burden exists in a particular State may require considering the State's Medicaid agency administrative capacity, systems burden, and the general availability of data sources (among other consideration). As such, the answer to how to obtain and use data from sources other than a State's Medicaid managed care program without undue burden may share similarities and best practices, but will

often be unique in each State and for each data source. We will provide technical assistance to States to help them address their own unique barriers to collecting the necessary data and reporting measures, including State laws regarding exchange of health information, and intend to provide best practices where States may face similar challenges to obtain data. If States have data restrictions in place, the State may choose to have health plans calculate the measures.

Comment: Commenters generally supported our proposal to require that data be validated prior to the display of quality ratings to support the integrity of the ratings calculated and displayed as part of a State's MAC QRS. Commenters requested clarification on the role of External Quality Review Organizations (EQROs) in the calculation and validation of plan ratings. One commenter requested clarification about whether data collection and measure calculation must be done by a State, or if States would have flexibility to allow plans to calculate and report their own ratings to the State for certain measures (such as HEDIS measures). The commenter noted that relying on plan-submitted measures would avoid duplication of administrative work when plans have experience calculating measures included in the MAC QRS. Another commenter stated concern over how States would validate Medicare Advantage data, and recommended CMS provide a standard data set and technical assistance to support this process.

Response: We agree with commenters that validation of data is a critical aspect of generating trust in the information displayed on each State's MAC QRS. As noted in the proposed rule, States may use their EQRO to assist with quality ratings for the MAC QRS under the optional EQR activity at § 438.358(c)(6) for Medicaid, which applies to separate CHIP through an existing cross-reference at § 457.1250(a). Such assistance could include both calculation of performance measure rates and/or validation of the data used to calculate the rates. We agree with commenters that plans could collect the data necessary, calculate the performance rates themselves, and submit this information to the State (or EQRO) for data validation, and that allowing plans to submit measures could reduce duplication and burden on States. Therefore, we are modifying § 438.515(a) for Medicaid, and for separate CHIP by cross-reference at § 457.1240(d), in the final rule to use language that does not mandate that the State directly perform the necessary

data collection and measure calculation activities. Specifically, we are removing the terms "Must collect", "Must ensure that", "Must use" and "Must issue" from § 438.515(a)(1) through (4), respectively.

Under § 438.515(a)(1) and (3), as finalized, collecting necessary data and calculating performance rates may be performed by the State, the plan or an EQRO. This reporting structure aligns with the existing quality reporting regulations at §§ 438.330(c) and 438.358 for Medicaid, which apply to separate CHIP through an existing cross-reference at § 457.1250(a), whereby either the State or the plan can calculate the performance measures before they are validated. We do not believe plans are an appropriate entity to validate data collected pursuant to § 438.515(a)(2) because they are not free from bias. The definition of validation at § 438.500 of the final rule requires that the review be free from bias and § 438.515(a)(2) uses the defined term to ensure that the standards inherent in the definition apply. We are finalizing § 438.515(a)(2) with modification to codify this requirement by adding language to require that the validation of data must not be performed by any entity with a conflict of interest, including managed care plans.

We also note that for States planning to use the optional EQR activity at § 438.358(c) to carry out the validation or calculation of the performance rates, plans are prohibited from performing this external quality review activity. For the activity in § 438.515(a)(4) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), to issue the quality rating, we believe that it would not be appropriate for plans to issue ratings for themselves, and that this should be solely the State's responsibility. As noted in the proposed rule, States are in the best position to determine which quality ratings should be assigned to the plans within each of their Medicaid managed care programs, based on the services covered under that program. As such, the revisions to § 438.515(a)(4) include that the ratings be issued by the State (not the plan or an EQRO) for each managed care plan.

Finally, as previously discussed, we intend for the data collected and quality ratings issued for the MAC QRS to be as inclusive of all plan enrollees as possible (including dually eligible individuals), but we recognize that there are challenges to the collection, validation, and use of Medicare data necessary to include dually eligible individuals in the MAC QRS. Under finalized § 438.515(a)(2), States must

²²⁵ See 88 FR 78531, <https://www.govinfo.gov/content/pkg/FR-2023-11-15/pdf/2023-24118.pdf>.

²²⁶ See: <https://www.govinfo.gov/content/pkg/FR-2024-02-08/pdf/2024-00895.pdf>

ensure that all Medicare data collected per § 438.515(a)(1)(ii) is validated to the extent feasible without undue burden. (See earlier responses in this section about the standard “to the extent feasible without undue burden.”) As finalized, States will be afforded the flexibility to continue to work towards complete validation of available Medicare data used for the MAC QRS ratings and their ability to calculate quality ratings that are inclusive of dually eligible individuals enrolled in the State’s managed care program. Regarding the commenters’ concerns about Medicare Advantage data, including validation of the data, we intend to discuss methods of data collection and validation in the technical resource manual and will be available to provide States with any needed technical assistance. We also believe the provision at § 438.515(a)(1)(ii) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), that requires the use of non-Medicaid data to the extent feasible without undue burden, provides flexibility for States that cannot identify a pathway to collect this data without undue burden by the implementation date established in § 438.505(a)(2).

Comment: A few commenters stated concern about leaving the determination of whether a quality rating for a measure should be calculated and assigned to a given managed care plan to the State. Many commenters stated a concern that our proposal would require States to issue quality ratings for all mandatory measures to all managed care plans resulting in some plans being held responsible for measures for which they have no contractual or financial responsibility under a State managed care program.

Response: We disagree with commenters that proposed § 438.515(a)(3) and (a)(4) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), would hold managed care plans responsible for measures for which they have no contractual or financial responsibility under a State managed care program. Under the standard proposed and finalized in § 438.515(a)(3) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), whether a plan receives a quality rating for a given MAC QRS measure is dependent on whether the plan is contractually responsible for the service or action assessed by the measure under the managed care program in which it participates. We continue to believe that States should

determine which plans receive a quality rating because they are best situated to determine whether a given managed care program, and the plans within the program, cover a service or action assessed by a measure, and whether the program’s participating plans should be assigned a quality rating for the measure. Ultimately, this discretion allows States to determine whether it is fair to hold a plan accountable for a given measure based on the plan’s contractual relationship with the State. Further, the modifications finalized to § 438.510(a) at § 438.510(a)(1) about the scope of measures that must be included in each State’s MAC QRS also clarifies that measures are to be issued to reflect the services covered and activities performed by each managed care plan.

Comment: Many commenters noted that the proposal to require States to issue percentage quality ratings for each measure (meaning the measure performance rate) was an appropriate starting point for the MAC QRS. We received many comments supporting the future use of domain level ratings within the MAC QRS following additional input and rulemaking. Commenters noted that domain ratings would make it easier for beneficiaries to quickly evaluate differences across key services of relevance to them. Several commenters agreed that CMS should test domain level ratings with beneficiaries prior to proposing domain ratings. A few commenters requested that CMS identify the specific domains to be included, the measures included in each domain, and other technical details such as the methodology for calculating domain ratings. One commenter suggested that CMS attempt to align MAC QRS domain categories with existing Adult and Child Core Set domains. A few commenters, cautioned against the use of a single summary score for quality performance such as Medicare and Part D quality rating system ratings in the future, noting CMS’s Medicare and Part D quality rating system has been beset by questions about whether the ratings result in meaningful and equitable performance comparisons.

Response: We appreciate the support from commenters on our proposal to require the use of percentage ratings for the display of the MAC QRS measures. We will take commenters’ input into consideration in any future rulemaking regarding the use of domain ratings. We did not propose to require single summary scores in the proposed rule and the final rule similarly does not call for use of single summary scores for the MAC QRS. The informational preferences of users who participated in

our prototype testing is consistent with the commenters’ perspective that the MAC QRS users’ needs are best met by a mix of individual and domain level ratings scores.

Comment: Some commenters requested clarification on whether Medicare-covered services would be rated in the proposed MAC QRS, and whether MAC QRS ratings would be determined based on Medicaid-only services. A few commenters recommended that dually eligible individuals should only be included when they are enrolled to receive Medicare and Medicaid services through the same organization (such as through an integrated D–SNP). A couple of commenters stated concern about duplication between MAC QRS and the Medicare and Part C quality rating system, which could cause confusion. Many commenters requested technical assistance and additional guidance related to the inclusion of data for dually eligible beneficiaries in MAC QRS ratings, including how dually eligible individuals would be included in MAC QRS measures.

Response: We believe it is important for Medicaid managed care plans to support better health outcomes and access to care for the totality of an enrollee’s needs, not just those that fall within the covered benefits of a specific contract. While there are some services that are primarily covered by Medicare (such as preventive services) and some that are primarily covered by Medicaid (such as behavioral health and LTSS services), variation on this general rule exists across States. Furthermore, the factors that influence dually eligible enrollees’ health and well-being do not always completely align with either the services covered by their Medicaid managed care plan or with those covered by Medicare services. For example, while Medicare would primarily cover services associated with a chronic condition such as diabetes, meals provided to a dually eligible individual diagnosed with diabetes by an LTSS plan may also influence how well that individual’s A1c is controlled. Accounting for these complex relationships when rating the quality of an individual plan is an ongoing pursuit, and we continue to believe that our proposed policy balances the need to adequately reflect the quality of care experienced by dually eligible individuals with the challenges associated with care coordination and data sharing among States and both Medicare and Medicaid plans.

Therefore, we stress that when the service or action assessed by the measure is provided to the beneficiary

through *Medicare* and not the Medicaid managed care plan for which the rating is being calculated, we are not *requiring* States to include dually eligible individuals in quality ratings for MAC QRS measures.²²⁷ For example, we do not anticipate that States would include dually eligible individuals (that is, the data about dually eligible individuals) in MAC QRS quality ratings for measures of preventive health services such as Breast Cancer Screening because it is likely that States would determine that the services or actions assessed by this measure are covered by Medicare and not covered by the Medicaid managed care program. This is true even if the Medicaid managed care plan in which the dually eligible individual is enrolled is an integrated D-SNP (for example, a D-SNP offered by an organization that also has a Medicaid managed care contract to cover Medicaid benefits) or part of an integrated Medicare-Medicaid demonstration.

This final rule requires States to include dually eligible enrollees (that is, the data about dually eligible individuals) in quality ratings for a Medicaid managed care plan when the State determines, as described in § 438.515(a)(3), that the service or action assessed by the MAC QRS measure is covered by the Medicaid managed care plan's contract with the State. (See prior responses to public comments in this section about how the undue burden applies to this requirement). In determining whether a service or action assessed by the MAC QRS measure is covered by the Medicaid managed care plan's contract, the State may wish to consider whether the assessed service or action is, in fact, performed by the Medicaid managed care plan (in whole or in part), and whether the design of the State's Medicaid managed care program is such that the plan should be held accountable for the service or action assessed by the measure. For example, we anticipate that most States would include dually eligible enrollees in quality ratings for MAC QRS measures of behavioral health, such as IET, FUH and LTSS. Because these

measures are calculated using data for services that are commonly covered for dually eligible individuals through Medicaid as well as data for services covered by Medicare (such as hospital services), data for services provided by Medicare to dually eligible individuals also enrolled in a Medicaid managed care plan would often be necessary to calculate quality ratings for these measures that comply with § 438.515(b)(1). In such cases, the State would be required to collect, validate, and use the data necessary to calculate and issue quality ratings for the plan that include the plan's dually eligible enrollees, including the necessary Medicare data when available for collection without undue burden.

Having provided an overview of when a State would and would not be *required* to include dually eligible individuals in a managed care plan's quality ratings, we highlight that the requirement finalized at § 438.515(a)(3) would *not* prevent a State from determining that a Medicaid managed care plan should be issued a quality rating for a MAC QRS measure, even though the service or action assessed by the measure is not explicitly covered by the plan's contract with the State, if the State determines that the plan should be held accountable for the service or action. Using the example provided earlier, we note that a State would have the flexibility to choose to issue quality ratings for the MAC QRS measure Hemoglobin A1c Control for Patients with Diabetes (HBD) to its LTSS plans.

We disagree with commenters' suggestion that dually eligible enrollees should only be included when they are enrolled to receive Medicare and Medicaid services through the same organization. We believe that including dually eligible individuals who do not receive their care through an integrated product in MAC QRS ratings will be feasible for States for many measures and doing so is beneficial to dually eligible individuals who do not receive their care through an integrated product. Finally, we intend to provide additional guidance to assist States in determining how dually eligible individuals would be included in MAC QRS measures and also intend to provide technical assistance with integrating Medicare and Medicaid data to achieve this.

Comment: A few commenters requested additional guidance on the timeframe for including dually eligible individuals in MAC QRS ratings given the need to collect data from multiple sources.

Response: States must comply with the requirements of § 438.515(b)(1) by the implementation date identified in

§ 438.505(a)(2), that is, by December 31, 2028. However, as discussed in section I.B.6. of this final rule, we are finalizing the flexibility for States to request a one-time, one-year implementation extension for the MAC QRS methodology requirements described in § 438.515(b), which includes the inclusion of dually eligible individuals who are eligible for full Medicaid benefits that may be required under paragraph (b)(1), at new § 438.515(d). If a State submits an extension request for its compliance with § 438.515(b)(1) to have an additional year to fully comply with the requirement by including dually eligible individuals in their MAC QRS, and CMS approves the request, the State would have until December 31, 2029 to collect and utilize the data necessary to calculate and issue quality ratings that include dually eligible individuals. For instance, a State may have access to the data necessary to include dually eligible individuals in a managed care plan's quality ratings through the State's contracts with its D-SNPs. However, the State may need additional time to integrate this data with Medicaid managed care data to produce quality ratings that include the dually eligible individuals in plan ratings for certain measures. We note, however, that where inclusion of dually eligible individuals in a plan's quality rating is based on use of Medicare data, calculation of the measure using that Medicare data is contingent on the extent to which the Medicare data necessary to calculate the quality rating is available to the State without undue burden.

Comment: Several commenters supported assigning MAC QRS ratings at the plan level by managed care program, noting that this approach would provide beneficiaries with information that is more tailored to their specific needs and would allow managed care plans, States, and CMS to effectively measure and manage all Medicaid programs. One commenter encouraged CMS to define "managed care programs" as based on the population they enroll, which would allow for transparent measurement of the performance of MCOs that serve different populations, such as in States that operate more than one D-SNP-based Medicaid managed care program for dually eligible individuals, one for individuals under 65 and another for individuals 65 and over.

Response: We appreciate commenters' support for our proposal and the commenter's request to provide a definition for "managed care program." We decline to provide a more detailed definition for the term managed care

²²⁷ See § 438.515(a)(3) requiring States to "calculate 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" and § 438.515(b)(1) requiring States to ensure that the quality ratings issued to a managed care plan under (a)(3) 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 (1)(1)(ii).

program in this final rule than what is currently defined in § 438.2 for Medicaid. Per that definition, a managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act. This definition broadly covers Medicaid managed care delivery systems and Medicaid managed care plans that are available to Medicaid beneficiaries through a managed care program. For separate CHIP, we do not define the term “managed care program” in part 457 but we believe that it is clear from the context that the term means a managed care delivery system through which managed care entities have contracts to cover CHIP beneficiaries. We intend to address this as well in the technical resource manual, aligning with how “managed care program” is defined in § 438.2 and used in subregulatory guidance for other Medicaid reporting requirements, such as through §§ 438.66(e) and 438.207(d); these other guidance documents generally refer to managed care programs as having a distinct set of benefits and eligibility criteria that is articulated in a contract between the State and managed care plans.^{228 229} In line with these existing reporting requirements, we intend to provide guidance on how States distinguish among their managed care programs in issuing MAC QRS ratings in the technical resource manual or guidance which will align with existing guidance on managed care programs provided for reporting through §§ 438.66(e) and 438.207(d). The provisions at § 438.207(d) also apply to separate CHIP through an existing cross-reference at § 457.1230(b).

Comment: A few commenters stated concern about the ability of States and managed care plans to comply with the MAC QRS methodology requirements proposed at § 438.515(b) by the implementation deadline. Some commenters noted general challenges with the collection of data that is required to comply with the data collection and measure calculation and reporting requirements for each managed care plan in each program while distinguishing between performance in different managed care programs when the same plan has multiple contracts or contracts to participate in multiple managed care programs. Another commenter stated

that States may experience data integration issues that could make it challenging for States to comply with these requirements by the implementation date. One commenter stated interest in allowing a voluntary performance year prior to mandating the implementation of the proposed MAC QRS to ensure that States and managed care plans have appropriate time to identify and resolve challenges.

Response: Under § 438.515(b) as proposed and finalized, States must ensure that all enrollees who receive coverage through a managed care plan are included in the MAC QRS ratings issued for that plan and States must issue ratings at the plan level, by managed care program. Based on commenters feedback that States may need additional time beyond the implementation timeline finalized in § 438.505(a)(2) to obtain necessary data or develop a system to house and utilize the data necessary to meet these requirements in this final rule, we are finalizing in § 438.515(d) that States will have the ability to submit a request for a one-time, one-year extension for the methodology requirements in § 438.515(b), as discussed in section I.B.6.d. of this final rule. We believe that this one-year extension is sufficient as we already proposed, and are finalizing, an additional year for implementation beyond the date previously codified at § 438.334. This additional year was proposed in response to State concerns identified prior to rulemaking requesting that CMS consider State current workload and resources when establishing the MAC QRS implementation timeline. Considering the totality of comments we received on the proposals in this final rule, we have considered how we may further stagger implementation deadlines across the board, and believe that the MAC QRS implementation date is one way to reduce State burden and address these continued concerns.

We are finalizing the information that States must submit with their extension request at § 438.515(d)(1), the deadline for submitting an extension request in § 438.515(d)(2), and the conditions under which CMS will grant a requested extension at § 438.515(d)(3). As finalized, States will need to include four things in their extension request. We describe here an example of how a State may meet these requirements when requesting an extension of a requirement under § 438.515(b). First, the State must identify the specific requirement(s) for which it is requesting an extension. When identifying the specific requirement for which a State is requesting an extension, the State

should be as specific as possible. For example, we will consider how a State may submit an extension request if it has collected the necessary Medicare data to include dually eligible individuals in quality ratings for its managed care plans that enroll dually eligible individuals, but will need additional time to address technical issues that prevent the State from completing the infrastructure that will allow the collected Medicare data to be integrated with Medicaid managed care data to produce plan quality ratings for MAC QRS measures that require Medicare data to include dually eligible individuals and comply with § 438.515(b)(1). In this example, the State should not request an extension for § 438.515(b)(1) as a whole. Instead, the State should specify the specific requirement under (b)(1) that it will not be able to meet, which in this case would be the inclusion of dually eligible individuals in quality ratings for a subset of the mandatory measures that require data from both Medicaid and Medicare. If the State’s extension request was granted, the State would still be required to issue quality ratings for MAC QRS measures by the implementation date finalized in § 438.505(a)(3), but the ratings for any subset of mandatory measures that require Medicare data to incorporate dually eligible individuals would not yet include dually eligible individuals.

Second, the State must include a description of the steps the State has taken to meet the requirement. Continuing with our previous example, the State should describe the steps it has taken to date to establish the infrastructure necessary to integrate Medicare data so that they can be used to calculate MAC QRS quality ratings for managed care plan. States should include sufficient detail to allow CMS to assess whether the State has made a good faith effort to meet the requirement by the implementation date. Third, the State must explain why the State will be unable to comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement by the implementation date identified by CMS. Again, the State should provide sufficient detail to allow CMS to understand why the State will be unable to fully comply with the requirement by the implementation date. The State in this example may describe technical issues it has experienced with its data infrastructure that require the State to solicit a contractor to fix before it can complete

²²⁸ See Managed Care Program Annual Report template at <https://www.medicaid.gov/media/124631>.

²²⁹ See Network Adequacy and Access Assurances Report template at <https://www.medicaid.gov/media/140906>.

the work necessary to integrate the Medicare data and may provide information showing that the required work will extend past the implementation deadline. Finally, the State must include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, how the State will address the identified implementation barrier. Continuing the example, the State could include an assessment of the work that must be done to allow the State to use the collected data, identify the steps needed to fix the data infrastructure issue and a detailed explanation of how long each step will take and how the State plans to ensure the steps are completed successfully before the end of the one-year extension.

We are finalizing a deadline of September 1 of the fourth calendar year following the effective date of the final rule for requests for a one-year extension to be submitted to CMS. We believe that this is the appropriate date because it provides more than 4 years for States to determine that they need an extension but gives CMS enough time to review and approve the request prior to the implementation deadline of December 31, 2028. Finally, we are also finalizing the standards that CMS will apply in evaluating and determining whether to approve a request for extension of the deadline for collecting data, calculating ratings, and issuing ratings in § 438.515(d)(3). Those standards are discussed and noted in section I.B.6.d of this final rule.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to public comments, we are finalizing § 438.515 generally as proposed but with several modifications. First, we are finalizing § 438.515(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), with modifications to clarify when a State may or may not delegate to a separate party the actions described in § 438.515(a). Second, we are modifying paragraph (a)(4) to require that quality ratings are issued by the State “for” each managed care plan instead of “to” each managed care plan. We believe this language aligns better with our proposal because the ratings are publicly posted, not just issued to the plan itself. Additionally, we are including the standard for identifying measures that must be included in a State’s MAC QRS for each health plan described in paragraph (a)(3) (measures which assesses a service or action covered by the plans’ contract with the State, as determined by the State) to (a)(4) instead of including only a reference to

the standard. We believe that this change also more clearly reflects our proposed and finalized policy. We are not finalizing the requirement that enrollment as of July 1 of the measurement year be used to determine which managed care plans are subject to the MAC QRS ratings in § 438.515(a)(1)(i) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d) and will instead provide additional detail on how to determine if a plan has 500 or more enrollees through subregulatory guidance. We are finalizing § 438.515(a)(1)(i) to specify that the enrollment threshold of 500 will be calculated as described by CMS in the technical resource manual. We are also modifying § 438.515(a)(1)(ii), (a)(2), (a)(3) to clarify the circumstances in which the undue burden standard may be used to exclude Medicaid FFS or Medicare data from a MAC QRS quality rating, along with minor language updates throughout § 438.515 to implement this change, including removing reference to § 438.515(a)(1) in § 438.515(b)(1), which is no longer necessary due to the modifications made to § 438.515(a)(1)(ii), (a)(2), and (a)(3). We are also modifying § 438.515(a)(2) by adding language to require that the validation of data used to calculate performance rates for MAC QRS measures must not be performed by any entity with a conflict of interest, including managed care plans. We are also adopting a new paragraph (d) to provide an opportunity for States to request one-time one-year extension of the deadline by which the first quality ratings must be issued. Furthermore, we are making minor language updates throughout § 438.515 to better align with how we describe managed care contracts in other sections of Subpart G. Finally, as discussed in section I.B.6.h. of this final rule, we are finalizing the provisions on State alternative methodologies proposed at § 438.525 to § 438.515(c); as part of this final rule, proposed § 438.515(c) regarding potential domain level ratings is finalized as paragraph (e).

g. MAC QRS Website Display (§§ 438.334(e), 438.520(a), 428.520(b), 457.1240(d))

Current regulations at § 438.334(e), which will be redesignated at § 438.520(a) of this final rule, require States to prominently display the quality ratings 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 proposed to 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 through a cross-reference in the CHIP regulations at § 457.1240(d).

(1) Navigational and Orienting Information (§§ 438.334(e), 438.520(a)(1) and (5), 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 were 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. Therefore, we proposed 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 understood 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 final rule may require more technology-intensive implementation, such as the interactive features that allow users to tailor displayed information. Therefore, we proposed 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 could 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 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 sought comment on which requirements should be phased in, as well as how much time will be needed.

Given the visual nature of the website display, we provided with the proposed rule a link to two sample MAC QRS prototypes to illustrate our proposal; a simple website (Prototype A) that represents the information we were considering to require by the proposed implementation date in § 438.505(a)(2) and a more complex 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 were meant to show our overall vision for the proposed progression of the website display. In addition to the two prototypes, we indicated our intent to release a MAC QRS design guide following the final rule, which would 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 indicated our intent for the design guide to include several components, including but not limited to desirable features and content that States could 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.

We summarize and respond to public comments received on MAC QRS website Display (§§ 438.334(e), 438.520(a), 457.1240(d)) below.

Comment: Almost all commenters supported our decision to include a website display with clearly defined components identified by CMS in the framework for the MAC QRS. Many commenters supported our upfront engagement with States, plans, beneficiaries, and other interested parties in the identification of the MAC QRS website display requirements, as well as our proposal to consult with these parties in the future to continue to evaluate MAC QRS website display requirements for continued alignment with beneficiary preferences and values. Several commenters were especially supportive of requirements meant to assist dually eligible individuals in the selection of a Medicaid managed care plan. Some commenters supported the MAC QRS website display requirements but stated concern about the resources required to develop the website with each of the components identified by CMS, even with our proposal to implement the mandatory MAC QRS website in 2 phases. One commenter noted that enhanced FFP and technical assistance for the website would be vital to successful website development. A couple of commenters requested that we consider providing an exemption from the MAC QRS website display requirements for States with a small number of managed care plans or with a managed care program(s) that offers a single plan. A couple of commenters requested that we clarify whether States will be required to provide an alternative way to access the MAC QRS for enrollees who do not have access to the internet. A few commenters sought clarification on whether it would be acceptable to house the required website display on a State website that requires a login, such as where the State has developed a member portal accessible to those who have already enrolled in Medicaid and are at the stage of choosing their managed care plan(s).

Response: We agree with commenters that the MAC QRS website will require additional State resources to implement. Enhanced Federal match (FFP funding) may be available for the planning, design, implementation, and maintenance of the State's MAC QRS website, and the data infrastructure that supports it, when necessary to comply with the new MAC QRS website requirements we are finalizing in

§ 438.520, as part of FFP available for the State's Medicaid Enterprise System (MES). See State Medicaid Director Letter #22-001 for more information. We encourage States to meet with their MES State Officer for technical assistance on which operational elements of their MAC QRS implementation may be eligible for enhanced FFP.

We understand that technical assistance will be needed to help States successfully implement the MAC QRS website display requirements. To support States, we intend to issue a MAC QRS website design manual with additional guidance, and we intend to provide technical assistance for the design and implementation of the MAC QRS website. The design manual will include CMS developed resources (for example, plain language descriptions of the importance and impact of mandatory measures and metrics), the prototypes for phases 1 and 2 described in the proposed rule, and additional visual resources for how States could choose to display MAC QRS display requirements.

We considered commenters' requests to exclude certain States from the MAC QRS website display requirements, such as smaller States or those in which beneficiaries do not have a choice of managed care plan. After reviewing each of the proposed website display requirements in § 438.520(a), in conjunction with the comments, we believe that each requirement is important to achieve our stated goals for the MAC QRS, discussed in section I.6.B.a of the proposed rule, regardless of State size or number of managed care plans with two exceptions. Specifically, proposed § 438.520(a)(6)(i) and (ii) for Medicaid, applied to separate CHIPs by cross-reference through a proposed amendment at § 457.1240(d), would require States to implement search tools that enable users to identify available managed care plans that provide coverage for a drug identified by the user and plans that include a provider identified by the user in the plan's network of providers. The utility of these search tools is applicable only to programs with two or more plans offering different drug formularies and provider networks. Therefore, we are finalizing § 438.520(a)(6)(i) and (ii) with modifications to require these search tools only for managed care programs with more than one plan. As with all of the MAC QRS regulations in §§ 438.500 through 438.535, the requirements apply to separate CHIP by cross reference adopted in an amendment to § 457.1240(d), subject to specific exclusions for 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.

Regarding the commenter's questions about whether States will be required to provide an additional way to access the MAC QRS for enrollees who do not have access to the internet, we decline to require States to provide the MAC QRS in another format other than the website display in this rule. However, we expect States will make interested parties who counsel beneficiaries on the selection of a managed care plan, such as enrollment brokers, aware of the MAC QRS as a resource, and these interested parties would be available to assist individuals who lack internet access by communicating the information displayed on the website. In addition, independent obligations for States to furnish information (such as in § 438.10) that may be duplicative of information in the MAC QRS website display are not revised here so States may be responsible for making information available in alternative formats or languages under those other rules. We note that the language and format requirements in § 438.10(d) do apply to the MAC QRS website display requirements per § 438.525(a).

Finally, we considered whether it may be acceptable for a State to comply with the website display requirements, or a portion of the website display requirements, using a website that is accessible only to individuals who are enrolled in a managed care program. Though this approach could allow States to better tailor the website display information to the user, we believe our goal of empowering beneficiaries with useful information about the managed care plans available to them is only achievable if the MAC QRS website is available to the public, including caregivers or organizations that counsel or assist individuals with enrollment. States interested in maintaining a log-in only interface could consider allowing beneficiaries to log-in to access a more tailored and detailed version of the MAC QRS website, so long as it is also possible to view the required website display information as a member of the public or as a guest who is not currently enrolled in a managed care program.

While we believe that the requirement to prominently display the requirements on the State's Medicaid website implies that the information must be immediately and easily available to the public, we are modifying § 438.520(a) to further clarify our policy. We are therefore revising § 438.520(a) to include language establishing that the

requirements described in § 438.520(a) must be both prominently displayed *and* accessible to the public on the website required under § 438.10(c)(3). Additionally, we are modifying § 438.520(a)(1)(iii) to avoid implying that States may require users to provide log-in credentials prior to using or accessing a State's QRS. Under finalized § 438.520(a)(1)(iii), if users are requested to input user-specific information, including the information described in paragraph (2)(i) of this section, the State must provide an explanation of why the information is requested, how it will be used, and whether it is optional or required to access a QRS feature or type of information. We intend to provide States with technical assistance on how a State could achieve such a site, or modify an existing site, with minimal duplication.

Comment: Many commenters made recommendations for additional website display requirements. These display recommendations included requiring a fair method for the order of health plans displayed on the website, inclusion of State or national benchmarks for displayed measures to provide additional context to beneficiaries when reviewing quality ratings, and an explanation of the benefits and advantages of integrated care products for dually eligible individuals.

Response: We appreciate commenters' enthusiasm to ensure that the MAC QRS website display is helpful to beneficiaries and includes information that supports beneficiaries in identifying a plan that best fits their individual needs. We considered the additional requirements proposed by commenters and are declining to finalize additional website display requirements. To balance the preferences identified during our user testing with the State burden of website development, we included the most desirable information and features shared by testing participants in our requirements at § 438.520(a), which is applicable to separate CHIP under the proposal, through a cross-reference at § 457.1240(d). While the additional information proposed by commenters aligns with many of the beneficiary preferences we identified, a main consideration for our proposal was to establish minimum content and interactive function standards for the MAC QRS to be a usable and meaningful tool to users without overburdening States.

Furthermore, in new § 438.505(a)(1)(ii)—discussed in section I.6.d of this final rule—we are clarifying the State's ability to include website features in addition to those

required under § 438.520, including additional measures as described in § 438.520(b). To support States in the development of additional, optional display elements that will further assist MAC QRS users, we will consider providing guidance in our design guide on those elements recommended by commenters that overlap with preferences we identified in user testing to assist those States that wish to include additional display features, such as suggested language to use to describe the benefits and advantages of integrated products for those who are dually eligible. While we are not finalizing additional website display features in this final rule, additional mandatory website display features may be added (or existing required features removed) over time through rulemaking to reflect evolving beneficiary preferences and values identified through our obligation, proposed at § 438.520(c) and finalized at § 438.520(d), to periodically consult with interested parties to evaluate the website display requirements for continued alignment with beneficiary preferences and values.

Lastly, while we agree with commenters that including State or national benchmarks could help users interpret displayed quality ratings, we did not test the use of benchmarks in our user testing or consult with States, plans, or other interested parties on their use, nor did we propose to require display of such benchmarks in the proposed rule. We will consider requiring benchmarking of the quality ratings in future rulemaking after consulting with beneficiaries, States, and other interested parties. While not required, States have the flexibility to include benchmarks as part of their MAC QRS website display as we would consider the display of benchmarks to be an additional website display feature, which are permitted under § 438.520(c).

Comment: As we discussed in sections I.B.6. and I.B.6.d. of this final rule, many commenters provided feedback on the overall implementation timeline for the MAC QRS and the mandatory MAC QRS website display. Several of these commenters stated concern about the ability of States to comply with the MAC QRS website display requirements proposed at § 438.520 by the implementation deadlines, citing the time and resources necessary to implement a website display meeting the proposed requirements. Commenters most frequently stated concern with their ability to display quality ratings stratified as required by proposed § 438.520(a)(2)(v) and (a)(6)(iii), and to

implement the more technology-intensive requirements in § 438.520(a)(6).

Response: As discussed in section I.B.6.d. in this final rule, we are finalizing in § 438.520(b) that States will have the ability to submit a request for a one-time, one-year extension for the website display requirements specified at § 438.520(a)(2)(v) and (a)(6), which were the features most commonly characterized as challenging by States and plans both during pre-rulemaking engagement and by commenters in response to our proposed rule. Specifically, States will be able to request a one-year extension to comply with the requirements at § 438.520(a)(2)(v), which requires States to display quality ratings for each managed care plan for mandatory measures stratified by dual eligibility status, race and ethnicity, and sex and § 438.520(a)(6), which requires States to (1) implement interactive search tools that enable users to identify available managed care plans that provide coverage for a drug identified or include a provider identified by the user and (2) to stratify quality ratings by certain additional factors identified by CMS. States will not be able to request an extension for implementing the display requirements, at § 438.520(a)(1), that States include information necessary for beneficiaries to understand and navigate the MAC QRS website; at § 438.520(a)(2)(i) through (iv), that States include information that allows beneficiaries to identify managed care plans available to them that align with their coverage needs and preferences; at § 438.520(a)(3), that States provide standardized information identified by CMS that allows users to compare available managed care plans and programs; at § 438.520(a)(4), that information on quality ratings be displayed in a manner that promotes beneficiary understanding of and trust in the ratings; and at § 438.520(a)(5), that the QRS website include information or hyperlinks directing beneficiaries to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan. In our view, States currently should have easy access to the information required to comply with these provisions.

We also discussed in I.B.6.d. and I.B.6.f. of this rule that we are finalizing authority for States to request and CMS to grant one-time, one-year extensions for calculating and issuing MAC QRS quality ratings that fully comply with the methodology described in § 438.515(b) (§ 438.515(d)) and for implementing certain MAC QRS website display requirements (§ 438.520(b))

using the same requirements for what must be included in the request and what standards CMS will use to decide whether to grant an extension. We are finalizing at § 438.520(b)(1) that an extension request for a requirement under § 438.520 must also include the information described in § 438.515(d)(1) and will be assessed by CMS using the same standards and conditions finalized at § 438.515(d)(3).

Finally, at § 438.520(b)(2), we are finalizing the deadlines by which a State must submit an extension request for a website display requirement, based on whether the requirement must be implemented in phase 1 or phase 2 of the website display implementation. For extensions of the requirements specified in paragraph (a)(2)(v), the extension request must be submitted to CMS no later than September 1 of the fourth calendar year following the effective date of the final rule (that is, September 1, 2028). For extensions of the website requirements specified in paragraph (a)(6) of this section, the extension request must be submitted to CMS no later than four months prior to the implementation date specified by CMS pursuant to paragraph (a)(6) for those requirements. We have chosen this deadline as it maximizes the amount of time that a State has to identify that an extension may be necessary but leaves enough time for CMS to review and provide a determination for the extension request prior to the implementation date.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.520(a) and 457.1240(d) as proposed except we are modifying § 438.520(a) to require that States must prominently display *and make accessible to the public* on the State's Medicaid website required under § 438.10(c)(3) the display requirements in § 438.520(a).

(2) Navigational and Orienting Information (§§ 438.334(e), 438.520(a)(1) and (5), 457.1240(d))

Throughout our pre-rulemaking engagement activities, beneficiaries consistently stated the expectation that State Medicaid websites and the online plan selection processes will be difficult to navigate, and many users shared that they previously had been confused and overwhelmed during the process of selecting a managed care plan. When shown an initial draft MAC QRS prototype, some beneficiaries reported struggling to understand the purpose of the prototype and how and when the information could be useful.

Considering 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 will 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 will be used, users became more comfortable providing personal information.

Based on these findings from user testing, we proposed certain navigational requirements for the MAC QRS website display requirements in proposed § 438.520(a)(1). Specifically, we proposed 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 Medicaid, CHIP, and Medicare, and an overview of how the MAC QRS website

can be used to select a managed care plan. We proposed 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 (described in section I.B.6.d. of this final rule). Since beneficiary support systems are not currently required for separate CHIPs, our proposed amendment to § 457.1240(d) excludes references to this requirement. We solicited comments on whether beneficiary supports like 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 CHIPs by cross-reference through a proposed amendment at § 457.1240(d), States would be required to explain why user-specific information is requested, inform users of how any information they provide would be used, and whether it is optional or required. 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 would ensure that users can easily navigate to the next steps in the plan selection process after reviewing the MAC QRS website.

We noted in the proposed rule that we believe that States could implement these features by relying on information already posted on their websites or expanding current requirements. For instance, States are required to have a beneficiary support system at § 438.71 in place and could train staff who support this system to provide similar support to individuals on navigating 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, we noted that as part of the MAC QRS design guide, we intend to provide plain language descriptions of the information that States would be required to provide under the final rule—for example an

overview of how to use the MAC QRS to select a quality managed care plan). We noted that States would be able to use or tailor these CMS-developed descriptions for their MAC QRS websites.

We did not receive any comments on the proposed regulations relating to navigational and orienting information required for the MAC QRS (§§ 438.334(e), 438.520(a)(1) and (5). For the reasons outlined in the proposed rule we are finalizing §§ 438.334(e), 438.520(a)(1) and (5), and 457.1240(d)) as proposed. As discussed in this final rule in Section I.B.6.g, we are finalizing § 438.520(a)(1)(iii) with modification to avoid implying that States may require users to provide log-in credentials prior to using or accessing a State's QRS. This modification aligns with finalized § 438.510(a) establishing that the requirements described in § 438.520(a) must be both prominently displayed *and* accessible to the public on the website required under § 438.10(c)(3).

(3) Tailoring of MAC QRS Display Content (§§ 438.334(e), 438.520(a)(2), 438.520(a)(6) and 457.1240(d))

In conducting user testing to inform development of the proposed rule, we 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). However, we also found that testing participants were reluctant to provide information, such as their age, needed for such features unless their privacy concerns were addressed. Providing information on how and why such data would be used generally addressed such privacy concerns. Beneficiaries noted 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 proposed at § 438.520(a)(2)(i) for Medicaid, and for separate CHIPs 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 users may be eligible based on their age, geographic location, and dual eligibility status, as well as other demographic data identified by CMS 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 could 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 could 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 features to help beneficiaries identify plans available to them. We believe this requirement would support the MAC QRS website being a one-stop-shop where beneficiaries could select a plan based on their characteristics or needs. Therefore, we proposed to require the development and use of the MAC QRS website in this manner, which we believe both would support the beneficiary enrollment and disenrollment protections established in section 1932(a)(4)(A) of the Act and would be necessary for the proper and efficient operation of State Medicaid plans, consistent with section 1902(a)(4) of the Act. Based on our testing, we believe that the additional health plan information would be 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. Note that in § 438.505(b), we have extended the requirements in section 1932(a)(5)(C) of the Act to PIHPs and PAHPs, as well as MCOs, under the 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 will be covered under a plan prior to navigating to other details about the plan.

Therefore, we proposed 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 drug coverage and provider directory 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 under the proposed rule by the general implementation date proposed under § 438.505(a)(2).

As previously mentioned, user-testing participants preferred an integrated search feature that allows 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 will require them to conduct multiple searches to identify the plans that cover their prescriptions and providers. When consulted during the pre-rulemaking process, States were supportive of the display requirements we ultimately proposed 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,²³⁰ 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). Therefore, we believe that burden on managed care

²³⁰ 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).), which appeared 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>).

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); States could compile and leverage this existing data to offer the search functionality we proposed. However, we agreed with States that they will need additional time to implement dynamic, interactive website display features. Therefore, we proposed, 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 would allow users to identify plans that cover certain providers and prescriptions (see Prototype B). We solicited comment on this phased-in approach and a reasonable timeline for the second phase. In addition, we sought comment on the display requirements and technical assistance needs.

Proposed § 438.520(a)(6)(iii) and (iv) also included the display of stratified quality ratings. In this second phase, States would be required to implement an interactive display that allows beneficiaries to view and filter quality ratings for specific mandatory measures (to be identified by CMS). The factors by which the quality ratings would be filtered include the stratification factors already required in phase one under proposed § 438.520(a)(2)(v) (that is, dual eligibility status, race and ethnicity, and sex) plus additional factors identified by CMS for the second implementation phase under § 438.520(a)(6)(iii) 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 addressed 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.

Like our proposal to phase-in interactive plan provider directory and formulary tools, we proposed 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 proposed a first phase of implementation for this information that will 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 proposed to permit States to report 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.²³¹ Measuring health plan performance and making quality ratings available 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 aligns with the CMS Strategic Priorities. In the first phase of implementation that we proposed for the MAC QRS website display, 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). We noted that this requirement would be consistent with current efforts among measure stewards and other Federal reporting programs, such as the Child and Adult Core Sets, to stratify data by various demographic factors to ensure that disparities in health outcomes are identified and addressed (See Core Set proposed rule, 87 FR 51313). We proposed selecting the same factors required for the Core Sets as our initial stratification factors, as we believe this information would be most likely to be collected as compared to our other potential 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. Under the proposed rule, States would be required to display this information by the general MAC QRS implementation date proposed under § 438.505(a)(2). We sought comment on the feasibility of the proposed factors for stratifying quality ratings by the initial implementation date for the first phase of the website display requirements, and whether certain mandatory measures may be more feasible to stratify by these factors than others. We proposed that the interactive tools required under the proposed rule would need to be available no earlier than 2 years after the general MAC QRS implementation date. We requested 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 quality ratings should be stratified.

We summarize and respond to public comments received on tailoring the MAC QRS website display content (§§ 438.334(e), 438.520(a)(2) and (a)(6), and 457.1240(d)) below.

Comment: Several commenters supported our proposal to require that display of quality ratings for mandatory measures be stratified by factors identified by CMS. Many commenters shared current challenges related to capturing and reporting high-quality, reliable data that can be used to stratify quality measures and requested that CMS continue to work with States and other interested parties to improve collection of this data, with many requesting that CMS enhance current guidance to standardize data collection for race, ethnicity and language, sexual orientation and gender identity (SOGI), and Social Determinants of Health information so that these data can be stratified. Many commenters requested that we require age, language and rural/urban status be implemented as stratification factors in phase 1 instead of phase 2, because they thought that this information is easily accessible to plans and the State. Several commenters requested that we clarify that we would require States to display quality ratings for mandatory measures stratified by all the factors listed in § 438.520(a)(6)(iii) in the second phase of MAC QRS website implementation. Many commenters requested that we add to or

modify our proposed stratification factors to include SOGI and that we stratify not by disability as proposed, but by disability type. One commenter requested that we include pregnancy as a stratification factor.

Response: We recognize that stratification of measures is an evolving area and CMS will continue to provide guidance and technical assistance to support States and plans in the collection of data necessary to implement CMS required stratification factors. We are declining to finalize changes to the stratification factors implemented in phase 1, as we continue to believe that data on dual eligibility status, race and ethnicity, and sex are most accessible to States and likely to be collected as compared to the other stratification factors that are identified in proposed § 438.520 for Medicaid and through a cross-reference at revised § 457.1240(d) for separate CHIP. We are also declining to identify a definitive list of stratification factors for phase two, though we encourage States to include additional stratification factors in either phase if they have the data to do so. We agree that the stratification factors proposed by commenters are important in highlighting areas of inequity and we intend to consider SOGI, pregnancy, and disability type as stratification factors for phase two of website implementation. When issuing guidance on stratification of mandatory measures, we will consider whether stratification is currently required by the measure steward or other CMS programs and by which factors, in accordance with our finalized provisions at § 438.530(b) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d).

Comment: Most commenters supported the additional website components proposed in § 438.520(a)(6) for phase two, including the searchable formulary and provider directories and an interactive tool that allows user to view plan ratings stratified by factors identified by CMS. A couple of commenters questioned the utility of the phase 2 requirements and whether they would provide beneficiaries with tools and information that are important to beneficiaries.

Response: We appreciate the support commenters gave to the additional website components and disagree with commenters that questioned the utility and desirability of the tools and information required in phase 2 of the MAC QRS website display. These features were identified as desirable to MAC QRS users through the extensive user testing described in section I.B.6.g

²³¹ See Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting, 87 FR 51303 page 51328 (finalized at 42 CFR 437.10(b)(7) in 88 FR 60278) and Medicaid Program; Ensuring Access to Medicaid Services, 88 FR 27960 page 28084.

of the proposed rule. The formulary and provider search tools were developed directly from beneficiary input that they often have several prescribed medications, several providers, or both and searching each available plan's formulary or provider directory to determine coverage of a drug and their current provider(s) is time-consuming and unrealistic. Once we presented a website prototype that included these tools, they were consistently identified among the most desirable features. As noted previously, the provider directory and preferred drug list data available through the MAC QRS 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 leverage this existing data to offer the required search functionality. Additionally, our proposal to display stratified quality ratings was based on initial conversations with beneficiaries during which participants frequently shared their own experience with health inequities and, once stratified ratings were included in the prototype, we consistently received positive feedback from users who found it meaningful to understand the quality of care provided to "people like them" who are enrolled in a health plan.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.520(a)(2) and 457.1240(d), including the redesignation of the requirements about the availability of MAC QRS information from § 438.334(e) as proposed. We are also finalizing § 438.520(a)(6) with modification to narrow the scope of the requirements proposed in § 438.520(a)(6)(i) and (ii) that States would be required to display a search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user and a search tool that enables users to identify available managed care plans that include a specific provider in the plan's network. In this final rule we are applying these requirements only to managed care plans that participate in managed care programs with two or more participating plans.

(4) Plan Comparison Information (§§ 438.334(e), 438.520(a)(3) and 457.1240(d))

Our prototype testing showed that 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 prescription drug coverage) and health plan metrics (such as average time spent waiting for care, weekend and evening hours, and appointment wait times). When all this information was compiled into a standardized display along with quality ratings in our website prototype, participants responded positively. They 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 proposed 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 would allow users to compare available managed care plans and programs, including the name, website, and customer service telephone hot line for the 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 a summary of benefits including differences 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 that providing comparative information of this type is consistent with the information disclosure requirements in section 1932(a)(5) of the Act. These requirements were illustrated in Prototypes A and B.

Under proposed § 438.520(a)(3)(v), States would also be required to provide on their MAC QRS website certain metrics of managed care plan performance that States must make available to the public under part 438, subparts B and D of the Medicaid regulations, including certain data most recently reported to CMS on each managed care program under § 438.66(e) (Medicaid only) and the results of a secret shopper survey proposed at § 438.68(f). Proposed paragraph (a)(3)(v) would authorize CMS to specify the

metrics that would be required to be displayed. States already report information related to grievances, appeals, availability, and accessibility of covered services under § 438.66(e) and we believe that providing some of this information on the MAC QRS website 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. Under the proposed rule, States could integrate these metrics into the display of MAC QRS measures on the MAC QRS website or, as illustrated in Prototypes A and B, they could provide a hyperlink to an existing page with the identified information in the MAC QRS web page. We noted that these proposed requirements also would 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 plan selection. We sought comment on the inclusion of metrics to be specified by CMS, and whether we should consider phasing in certain metrics first before others.

Lastly, at § 438.530(a)(3)(vi), we proposed 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 42 CFR 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 sought comment on these requirements and requested feedback on the feasibility of providing this information on plan integration and MA and Part D ratings by the date initial implementation date.

We summarize and respond to public comments received on the proposed requirements for the MAC QRS website to include plan comparison information (§§ 438.334(e), 438.520(a)(3), and 457.1240(d)) below.

Comment: A couple of commenters recommended including additional plan comparison information about the accessibility of covered benefits, such as an indication of the services and drugs that require prior authorization by the plan and appointment wait times.

Response: We agree that including information on the extent to which a covered service is accessible to beneficiaries (such as whether prior authorization is required and appointment wait times) is desirable and helpful to beneficiaries. Our proposed regulations give CMS discretion to include information about prior authorization requirements related to drug coverage as “other similar information” under § 438.520(a)(2)(ii), which requires States to provide a description of the drug coverage of each managed care plan, including the formulary information specified in § 438.10(i) and other similar information as specified by CMS. To respond to requests to provide prior authorization information for both drugs and services, and to align with § 438.520(a)(2)(ii), we are modifying § 438.520(a)(3)(iv) to add discretion for CMS to specify, in addition to requiring that the MAC QRS website display a summary of benefits including differences in benefits among available managed care plans within a single program, other similar information on benefits to be included on the website such as whether access to the benefit requires prior authorization from the plan. This modification also aligns with § 438.520(a)(3)(v), which provides CMS with the discretion to require States to display in their MAC QRS metrics of existing managed care performance that States already report to CMS under subparts B and D of this part. We intend to include access metrics from these sources, including the Access Standards Report required in § 438.207(d) through (f), which include new requirements to establish and report on standards for appointment wait times finalized in this final rule at § 438.207(f).

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing §§ 438.520(a)(3) and 457.1240(d) as proposed and with a modification at § 438.520(a)(3)(iv) to add discretion for CMS to require States to include on the MAC QRS website, in addition to displaying a summary of benefits including differences in benefits among available managed care plans within a single program, other similar information on benefits such as whether access to the benefit requires prior authorization from the plan. We are also finalizing the proposed changes to § 438.334.

(5) Information on Quality Ratings (§§ 438.334(e), 438.520(a)(4), 438.520(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 proposed that States will 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 will 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 the 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 will 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 proposed 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 proposed that States must provide on the MAC QRS website when, how, and by whom quality

ratings have been validated. Under our proposal, 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 solicited comments 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 proposed 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.

We did not receive any comments in response to our proposals for the MAC QRS website to include certain information about the published quality ratings and, for the reasons outlined in the proposed rule, we are finalizing §§ 438.520(a)(4) and (c), and 457.1240(d) as proposed along with the proposed changes to § 438.334.

(6) Display of Additional Measures Not on The Mandatory Measure Set (§§ 438.334(e), 438.520(c) and 457.1240(d))

Section § 438.510(a), as proposed and finalized at § 438.510(a)(2), provides that States will 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) (finalized at § 438.520(c)(2)(i) and (ii))

are met. The same standards will apply to separate CHIP as proposed in § 457.1240(d) by cross-referencing part 438, subpart G.

The first requirement, proposed in § 438.520(b)(1), would require a State that chooses to display quality ratings for additional measures not included in the mandatory measures set described in § 438.510(a), 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 both the proposed rule and this final 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.

The second requirement, proposed at § 438.520(b)(2), would require 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 also proposed 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 will be considered additional measures and will 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.

We did not receive any comments in response to our proposals authorizing display of additional measures not on the mandatory measure list, subject to requirements for States to obtain and document input on the additional measures. For the reasons outlined in the proposed rule, we are finalizing the provisions proposed at §§ 438.520(b) and 457.1240(d) largely as proposed and the proposed changes to § 438.334(e), except that we are finalizing these

provisions at § 438.520(c)(2) to address the addition of new paragraph § 438.520(b) finalizing an implementation extension for certain website requirements. Furthermore, we are modifying paragraph (c) to clearly establish that States may implement additional website features not described in § 438.520(a) in their MAC QRS (to align with modifications to § 438.505(a)(1)(ii) establishing the same), including the display of additional measures not included in the mandatory measure set.

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 proposed to redesignate § 438.334(c) at § 438.525 for Medicaid and to modify the current policy by narrowing the changes that would require our approval. We proposed to apply the same requirements for both Medicaid and separate CHIP managed care programs by revising § 457.1240(d) to require States to comply with § 438.525.

First, we proposed to remove the requirement in current § 438.334(c)(1) that CMS must approve use of "different performance measures" as part of CMS's approval of an alternative QRS prior to a State's use of the different measures. 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 included in the mandatory measure set creates unnecessary administrative burden for both States and CMS. Under the proposed regulation, instead of requiring approval of different measures, we proposed that States would be required to include all measures in the mandatory measure set identified by CMS in their MAC QRS, but that they would have the flexibility to add additional measures without prior approval from CMS.

We highlighted that the measure specifications established by measure stewards for measures in the mandatory

measure set established by CMS under proposed § 438.510(a) are not considered part of the methodology described in proposed § 438.515, and therefore, States would not have an option to request changes to mandatory measure technical specifications under our proposal at § 438.525. We stated that modifications to measure specifications that are approved by the measure steward would not require a State to request approval of an alternative QRS in order to use the steward-approved modifications. These steward-approved modifications could include allowable adjustments to a measure's specifications published by the measure steward or measure specification adjustments requested from and approved by the measure's steward. However, we noted in the proposed rule that we would consider quality ratings calculated for a mandatory measure to be ratings for a different measure if the modifications have not been approved by the measure steward. We believe that this policy provides flexibility to States while ensuring that ratings for mandatory measures remain comparable among States because measure specification modifications approved by a measure steward have been reviewed and subjected to the measure steward's own process to ensure that modified specifications allow for comparisons across health plans.

Second, we proposed to further define the criteria and process for determining if an alternative methodology is substantially comparable to the MAC QRS methodology described in proposed § 438.515. The current regulations at § 438.334(c)(4) provide that we would issue guidance on the criteria and process for determining if an alternative QRS meets the substantial comparability standard in § 438.334(c)(1)(ii). We proposed to eliminate § 438.334(c)(4) and redesignate the requirements for an alternative QRS methodology as proposed § 438.525(c)(2)(i) through (iii). We also proposed at § 438.525(c)(2)(iv) that States would be responsible for submitting documents and evidence that demonstrates compliance with the substantial comparability standard. We believe eliminating § 438.334(c)(4) was 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.

We indicated in the proposed rule that we intend to issue future 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 for a new or modifications of an existing alternative QRS made after the proposed implementation date, we indicated we would consider accepting rolling requests instead of specifying certain dates or times of year when we would accept such requests. We believe this would be necessary given that States may have different contract cycles with managed care plans. We solicited 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 proposed to redesignate and revise § 438.334(c)(2) 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 will yield information regarding managed care plan performance that is substantially comparable to that yielded by the MAC QRS methodology developed by CMS and described in proposed § 438.515(b). 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 yields ratings that are substantially comparable to the ratings produced using the methodology required under § 438.515(b).

We solicited comments on these proposals, in particular, the described process and documentation for assessing whether a proposed alternative QRS framework is substantially comparable, by when States will need alternative QRS guidance, and by when States will need to receive approval of an alternative QRS request to implement the alternative by the implementation date specified in proposed § 438.505(a)(2).

We summarize and respond to public comments received on the alternative quality rating system section (§§ 438.334(c), proposed 438.525, and 457.1240(d)) below.

Comment: We received comments both in support of the flexibility provided for use by a State of an alternative QRS, as well as some concerns about how it would reduce standardization. Those commenters in support appreciated the flexibility that an alternative QRS would provide and requested timely approvals of alternative QRS requests by CMS (that is, within 1 year of the final rule) and technical assistance on the substantial comparability standard. Many commenters emphasized the importance of both a standardized set of measures and a standardized methodology for

calculating those measures. These commenters raised concerns that the alternative QRS may reduce alignment with other quality rating systems and that substituting mandatory measures or calculating quality ratings for mandatory measures without the CMS methodology or the measure steward's technical specifications would create unnecessary complexity for plans and undermine the ability to make inter-State comparisons among MAC QRS plans.

Response: We agree with commenters about the importance of alignment and standardization for the MAC QRS for the methodology for calculating quality ratings for mandatory measures and the mandatory measure set and believe that our proposal has sufficient guardrails to address these concerns. Regarding concerns related to the standardization of mandatory measures, we do not agree with commenters that the flexibility to use an approved alternative rating methodology will impact the standardization of the mandatory measures set as this flexibility does not permit a State to substitute a mandatory measure with another measure that is "substantially comparable." Regardless of whether a State applies the CMS methodology or an approved alternative methodology, per finalized § 438.510(a), all States must include the mandatory measures that are applicable to the State's managed care program in their QRS.

In response to the concerns stated by commenters related to the standardization of quality ratings produced using the CMS methodology versus an approved alternative rating methodology, we believe that standardization of the MAC QRS quality ratings will be maintained due to the limitations on the scope of the alternative methodology flexibility and the substantial comparability standard proposed at § 438.525(a)(2) and finalized at § 438.515(c)(1)(i). As we discussed in section I.B.6 of the final rule, the policy we proposed and are finalizing permits a State to request approval to use an alternative rating methodology to the methodology finalized at § 438.515(b) for Medicaid, and in separate CHIP by cross-reference through a proposed amendment at § 457.1240(d). Subject to the undue burden standard finalized at § 438.515(a)(1)(ii), (2), and (3), all States must ensure that MAC QRS quality ratings comply with the requirements related to data collection, data validation, performance rate calculation, and issuance of quality ratings finalized in § 438.515(a). Additionally, prior to approval, a State must demonstrate that

any alternative methodology generates ratings that yield information on plan performance that is "substantially comparable" to information yielded by the CMS methodology (that is, the methodology required by § 438.515(b)).

In response to concerns related to the calculation of MAC QRS quality ratings that do not align with the measure steward's technical specification, as we discussed in section I.B.6.h. of the proposed rule and in section I.B.6.f. of this final rule, the measure steward specifications for a mandatory measure are not part of the methodology identified in § 438.515(b) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d). Those specifications are inherently part of the mandatory minimum measure set that all States must use when the State's managed care program covers the service or action assessed by the measure. Per finalized § 438.510(a)(1), States must display applicable mandatory measures as described by CMS in the technical resource manual, which will include the measure steward specifications for measures in the mandatory set as well as guidance on calculating and issuing quality ratings. As discussed in section I.B.6.f. of the proposed rule, such technical specifications could include allowable adjustments identified by the measure steward as well as adjustments approved by the measure steward for an individual State. As such, regardless of whether a State applies the CMS methodology or an alternative methodology, a State must calculate quality ratings for applicable mandatory measures using technical specifications approved by the measure steward. Furthermore, as required under § 438.535(a)(6) and discussed in section I.B.6.j. of the proposed rule, CMS will require States to report the use of any technical specification adjustments to mandatory measures that are outside the measure steward's allowable adjustments, which the measure steward has approved for use by the State or a plan within the State. This will allow CMS to better understand if the flexibility to use such adjustments impact plan-to-plan comparability or comparability within and among States.

In combination, we believe that quality ratings for mandatory measure produced in line with these policies, whether calculated using the CMS methodology or an approved alternative rating methodology, will be sufficiently standardized and allow ratings that are comparable among States. To ensure that these guardrails remain sufficient, CMS will monitor the use of alternative rating methodologies among States to

determine if additional guardrails are necessary to maintain alignment and standardization of the MAC QRS mandatory measure set and methodology. In response to commenters' concerns about maintaining the ability to make inter-State comparisons of MAC QRS measures, we believe that the guardrails that maintain alignment and standardization also ensure the ability to make these inter-State comparisons.

Comment: One commenter recommended we update the reference to the MCAC in § 438.525(b)(1) to align with proposed changes to § 431.12, renaming the MCAC as the Medicaid Advisory Group, and creating a new Beneficiary Advisory Group.

Response: As described in section I.B.6.a. of this rule, we received many comments noting a general concern about the administrative complexity and the time and resources needed to implement the MAC QRS in light of other Medicaid requirements established in the proposed rule. In that section we also outline several changes that we are finalizing in this rule after considering how to reduce the overall implementation burden of the MAC QRS. One of these changes is the removal of the requirement that States obtain input from their Medical Care Advisory Committee and provide an opportunity for public comment on the State's proposed alternative rating system or modification to an approved alternative rating system. We believe that eliminating these consultation and public notice and comment requirements will reduce burden on States to implement an alternative QRS methodology with minimal impact on the availability of desirable information. While the MCAC plays an important role in providing feedback within State Medicaid programs, we believe that it could be overly burdensome for States to present methodology changes, many of which may be highly technical and nuanced, in a way that will elicit actionable feedback through the MCAC and a public comment process. In response to the suggestion that we rename the MCAC, as noted, we are removing reference to the MCAC in the final rule.

Comment: Several commenters believed that the alternative methodology would provide a pathway for States to substitute mandatory measures with alternative measures or substitute website display requirement for alternative website display features or to exempt them from some website display features altogether.

Response: As proposed and finalized, the ability of a State to use an

alternative methodology does not include authority to modify either the mandatory measure set or the minimum website display requirements in § 438.520. We are finalizing this proposal in this final rule largely as proposed, but we are modifying how the alternative QRS requirements are described and organized in this final rule to address the confusion stated by commenters.

To address the confusion from commenters on the scope of the of the alternative methodology, we are finalizing modifications to the proposed regulation. First, as described in section I.B.6.g.4 of the proposed rule, we proposed to modify current regulations at § 438.334(c)(1) to no longer require States to obtain CMS approval if they wished to include measures different than those included in the mandatory measure set identified by CMS because we believe that requiring approval of additional, different measures not required in the mandatory measure set creates unnecessary burden for States and CMS. To implement this change, we also proposed at § 438.520(b) (finalized at § 438.520(c)) that States would have the flexibility to add measures that are not mandatory measures without prior approval from CMS. Under our proposal, States could add additional measures beyond those identified by CMS without CMS approval, but neither the current regulations at § 438.334(c), nor our proposal, would have allowed States to substitute mandatory measures with different measures. This final rule also does not permit States to substitute mandatory measures with different measures. Ratings for the mandatory measures must always be published when the mandatory measures are applicable to the State's managed care program (see section I.B.6.f. for additional detail). How those ratings are calculated under the State's MAC QRS may be changed using an alternative methodology, subject to CMS approval.

As the proposed alternative QRS provision in § 438.525 provides States with the flexibility to request to apply an alternative methodology only, we are removing references to "alternative MAC QRS" throughout this subpart and using instead the term "alternative QRS methodology" in the regulation text. Throughout this final rule, we use the terms "alternative QRS methodology," "alternative methodology," or "alternative rating methodology" to focus on the limits of what type of alternative is available to States. We proposed at § 438.525 and are finalizing at § 438.515(c) the requirements to receive approval to apply an alternative QRS methodology in part 438. (As

discussed in a prior response to a public comment, we are not retaining the requirement that the State consult with the MCAC or engage in a public notice and comment process before seeking approval from CMS of the State's alternative QRS methodology). As § 438.515(b) codifies the requirements for the MAC QRS methodology, we believe that codifying the authority and parameters for State use of an alternative QRS methodology in the same section addresses the confusion around the scope of the authority for States to have an alternative rating methodology. We also believe that including the alternative methodology provisions in § 438.515, where the CMS methodology is codified, is more consistent with the MAC QRS framework definition in § 438.500, which, as finalized, describes the MAC QRS methodology as either the CMS methodology or an alternative methodology approved by CMS. We are also finalizing a conforming modification at § 438.505(a)(1)(i) to reflect the new location of the alternative QRS methodology provisions.

Second, we are finalizing a new provision, at § 438.515(c)(3), to further establish the scope of the flexibility to implement an alternative methodology. As finalized, (c)(3) establishes that CMS will not review or approve requests to implement a MAC QRS that does not comply with the requirements to include mandatory measures established in § 438.510(a)(1), the general requirements for calculating quality ratings established in § 438.515(a)(1) through (4), or the requirement to include the website features identified in § 438.520(a)(1) through (6). We are also finalizing that CMS will not review or approve requests to implement additional measures or website features as these are permitted, without CMS review or approval, as established in § 438.520(c). Lastly, we are finalizing that CMS will not review or approve requests to include plans that do not meet the threshold established in 483.515(a)(1)(i), which State may choose to do as appropriate as discussed in section I.B.6.f. We believe that new paragraph (c)(3) gives States clarity in the requests to use an alternative methodology that may be submitted to CMS under § 438.515(c) while also reducing burden on States to ensure that they do not design a MAC QRS that does not comply with the general rule in § 438.505(a).

Thirdly, we are not finalizing § 438.525(a)(1), which proposed that an alternative QRS includes the mandatory

measures identified by CMS under § 438.510(a). This provision is duplicative of finalized § 438.510(a)(1), which requires States to include applicable mandatory measures in their MAC QRS, regardless of whether the State uses the CMS or an alternative methodology.

Finally, we are addressing technical errors in the proposed rule. We are modifying proposed § 438.525(a) (moved to § 438.515(c)(1) in the final rule), which permits States to implement a MAC QRS that applies an alternative methodology from that described in § 438.510(a)(3). Proposed § 438.525(a) should have cited § 438.515(b), which describes the MAC QRS methodology established by CMS instead of § 438.510(a)(3) (there is no paragraph (a)(3) proposed in § 438.510). The purpose of the cross reference was to make clear that requests to implement an alternative methodology may be requested and approved for the methodology requirements in § 438.515(b). At § 438.515(a)(3) we proposed to require States to “use the methodology described in paragraph (b)” of § 438.515. Additionally, we proposed that the methodology requirements in § 438.515(b) were subject to the flexibility to implement an alternative methodology in § 438.525 and finalized at § 438.515(c)(1). These two proposals show our intention to establish § 438.515(b) as the CMS methodology and to require States to implement those requirements unless the State received CMS approval to apply an alternative methodology under flexibility proposed in § 438.525 and finalized at § 438.515(c). We are also making conforming technical changes to the provision proposed at § 438.525(a)(2), which is moved to § 438.515(c)(i) in the final rule, by citing specifically to § 438.515(b) describing the CMS methodology instead of more broadly to § 438.515. These technical changes apply equally to separate CHIP by cross-reference through an amendment at § 457.1240(d).

i. Annual Technical Resource Manual (§§ 438.334, 438.530 and 457.1240(d))

We proposed at §§ 438.530(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS would 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 will include information needed by States and managed care plans to calculate and issue quality ratings for all mandatory measures that States will be required to report under this final 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. We proposed 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 did 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 that would be issued by CMS. As described in § 438.530(a)(1), we proposed 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.

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 proposed 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 (6)(iii). We discuss the rationale for inclusion of stratification in section I.B.6.g.2. of this final rule.

- How to use the methodology described in § 438.515 to calculate quality ratings for managed care plans. We sought 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 measure stewards. We believe this information will 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, the MA and Part D quality rating system, and the QHP quality rating system.

Lastly, at § 438.530(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), we proposed a general rule that CMS consider 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. We stated that we plan to implement a phased-in approach that would increase over time the total number of mandatory measures for which data must be stratified. We also proposed to phase-in the factors by which data would be stratified. We stated our intent to align with the stratification schedule 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 will minimize State and health plan burden to report stratified measures. For any MAC QRS measures that are not Core Set measures, we will consider, and align where appropriate, with the stratification policies for the associated measure steward or other CMS reporting programs. We described additional information regarding MAC QRS stratification requirements in section I.B.6.g.2. of the proposed rule.

Based on feedback we received through listening sessions with interested parties, we considered releasing an updated technical resource manual at least 5 months prior to the measurement period for which the technical resource manual will apply. This aligned with the proposed date for the first technical resource manual of August 1, 2025, for a 2026 measurement year, and ensured 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 will align with those used by other measure stewards (for example, NCQA for HEDIS measures) and will 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 sought 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.

We summarize and respond to public comments received on our proposals related to the annual technical resource manual (§§ 438.334, 438.530, and 457.1240(d)) below.

Comment: We received comments related to our proposed date for releasing the initial technical resource manual, and comments pertaining to future release dates. In general, these comments requested that we release the technical resource manual information earlier than 5 months prior to the measurement year, including requests for releasing the manual at least 9 months or 12 months before the start of the measurement year. Additionally, some commenters urged us to better align the timing of the release of the annual technical resource manual with the timeline used by measure stewards to update their measure specifications.

Response: Based on commenter's feedback, we are modifying how the technical resource manual information identified in § 438.530(a) will be released. We considered whether we could release a technical resource manual 9 to 12 months prior to the measurement year as a couple of commenters requested and still include all the information identified in § 438.530(a). We found that this timeline is not feasible because we cannot guarantee that the information identified in § 438.530(a) will exist 9 to 12 months prior to the measurement year to which the technical resource manual applies. For example, under § 438.530(a)(1)(ii) and (a)(4), CMS must include the list of measures newly added or removed from the prior year's mandatory measure set and the summary of interested party engagement and public comments. At 9 to 12 months prior to the measurement year, CMS will likely still be engaged in the subregulatory process proposed in § 438.510(b) and unable to publish a

manual with the final decision from that process.

Though it is not feasible to release the technical resource manual 9 to 12 months prior to the measurement year, we believe that we can get the information identified in § 438.530(a) to States as early as reasonably possible by releasing the information in installments as the content of the manual is available throughout the year (as opposed to releasing all such information at the same time and in one document, as proposed). Therefore, we are finalizing at § 438.530(a) that CMS may publish the technical resource manual information identified in § 438.530(a) in installments throughout the year to give CMS the flexibility to publish the individual pieces of information identified in § 438.530(a) as they are available. For instance, as finalized CMS can release an updated list of mandatory measures, as required under § 438.530(a)(1)(ii), and the summary of the subregulatory process used to identify the updated mandatory measure set, as required under § 438.530(a)(4), prior to releasing the technical specifications, as required under § 438.530(a)(3).

We have also determined a need to modify the release date of the first complete technical resource manual from August 1, 2025 to CY 2027. We arrived at this determination after considering a commenter's input that our proposed release date could align more closely with when the measure stewards update their specifications. We reviewed schedules for measure stewards' annual updates and found that the technical specifications for measurement year 2026 will not be available by the proposed technical resource manual release date in CY 2025. For example, NCQA, which is the measure steward for 12 of the measures in the initial mandatory set, currently finalizes their technical specifications in the second quarter of the measurement year in which the technical specifications apply. To ensure that the technical specifications for the initial measurement year in 2026 align with the measure steward technical specifications for the same year, CMS can release those technical specifications no earlier than CY 2027. States will then be able to use this information as they calculate quality ratings for MY 2026 in CY 2027. As States and health plans are accustomed to receiving technical specifications in the measurement year to which they apply, after data collection has begun, we believe that receiving the specification soon after the measurement ends will not impact

State's ability to collect the data necessary to calculate quality ratings for mandatory measures.

Furthermore, because the guidance on the application of the methodology used to calculate and issue quality ratings required under § 438.530(a)(2) is related to the technical specifications, the release date for this information would need to be pushed back as well. Additionally, the summary of information of the subregulatory process that must be included in the technical resource manual under § 438.530(a)(4) will not be available by August 1, 2025 as proposed. In section I.B.6.e.3 of the proposed rule, we discussed options for when we could begin implementing the subregulatory process to update the mandatory measure set finalized at § 438.510(b). Due to commenters support for our proposal to update the mandatory measure set no less than every 2 years, we intend to implement the subregulatory process by which these updates will be made no less than two years after the final rule, so beginning in CY 2026. (See section I.B.6.e.3 for a discussion of the final policy to engage in the public consultation process to evaluate the mandatory measure set every 2 years.)

Therefore, we are finalizing that CMS will begin annual publication of the complete technical resource manual in CY 2027. In combination with our modification to allow the technical resource information to be released in increments throughout the year to account for instances when certain components described in § 438.530(a) can be released sooner than others, we believe this approach is responsive to both commenters who requested we release information as soon as possible and those who requested that we more closely align with the release of measure steward technical specifications. To implement these changes, we are finalizing, with modifications, the policy at § 438.530(a) for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), to use the new date and authorize the incremental release of the technical resource manual. We did not propose and, therefore, are not finalizing the schedule for the annual technical resource manual beyond 2027. We will continue to balance recommendations from commenters in setting future release dates for the technical resource manual and to align closely with the publication of the Annual Core Set technical specifications.

Finally, based on our pre-rulemaking consultations with States, we understand that States will need the MAC QRS measure information

identified in § 438.530(a)(1) prior to the initial measurement year of CY 2026. Unlike the information in § 438.530(a)(2) through (4), the measure information will be available for CMS to release prior to CY 2027. Therefore, we are modifying § 438.530 to add a paragraph (c), which retains the requirement for CMS to publish the information specified in paragraph § 438.530(a)(1) no later than August 1, 2025. As finalized, this will require CMS to provide, no later than August 1, 2025, the initial list of mandatory measures finalized in this rule, any measures removed from the initial mandatory measure set before August 2025 by CMS following the final rule as permitted under § 438.510(d)(2)–(4), and the subset of initial mandatory measures that must be stratified and by which stratification factors. We note that, regarding the identification of measures newly added or removed from the prior year's mandatory measure set as required under § 438.530(a)(1)(ii), CMS cannot add additional measures to the mandatory measure set for the initial measurement year published with this final rule. However, it is possible that CMS may remove measures from the set published in this rule if changes made to the measure that meet the removal criteria finalized in § 438.515(d)(2) through (4) occur after CMS finalizes this rule. This includes instances where the measure steward retires or stops maintaining a measure or CMS determines either that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes or that the measure shows low statistical reliability under the standard identified in §§ 422.164(e) and 423.184(e). Per § 438.510(a), the MAC QRS implemented by the State must include the measures in this list released under § 438.530(c).

Comment: We received some comments on the contents of the annual technical resource manual, including requests that the manual include resources on data collection and validation, free source coding materials, and a clear process with timelines that States should follow. A few commenters noted it would be challenging if CMS deviated from the measure specifications of the measure steward.

Response: We thank commenters for the recommendation to include information on data collection and validation. We intend to provide additional detail on the requirements finalized in § 438.515 for Medicaid, and for separate CHIP by cross-reference through an amendment at § 457.1240(d),

related to data collection, validation, and calculation of quality ratings for mandatory measures through two resources: the annual technical resource manual and the external quality review protocols associated with the optional activity for the MAC QRS at § 438.358(c)(6), which would allow States to use an EQRO if desired to assist with the quality ratings. We appreciate the recommendation to include free source coding materials in the technical resource manual and intend to align with the current approach used in the Core Set technical specifications whereby we include links to available free source code sets in the manual. We agree that including a clear process and timeline to follow for each measurement year and display year, relative to the release of the measure list and measure technical specifications, will be helpful to detail for States in the technical resource manual. In response to the concern about deviations from measure specifications, we agree with commenters that any deviations in measure specifications could result in complications and discrepancies across programs and quality reporting systems, and CMS works closely with measure stewards in developing reporting guidance to make as few adaptations to the technical specifications as possible.

After reviewing the public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing § 438.530, and for separate CHIP by cross-reference through an amendment at § 457.1240(d), with modifications. We are finalizing § 438.530(a) with modifications to change the date for the first annual technical resource manual to no later than CY 2027. We are adding § 438.530(c) to indicate that the measure list in § 438.530(a)(1)(i) and subset of measures that must be stratified, and by which factors, in and § 438.530(a)(1)(iii) will be released no later than August 1, 2025. We are also making a technical change to § 438.530(a)(4) to indicate that a summary of public comments would be included in the technical resource manual only in the years when the engagement with interested parties occurs.

j. Reporting (§§ 438.334, 438.535 and 457.1240(d))

We proposed 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 proposed any request for reporting by States would be no more frequently than annually. We proposed 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, which CMS could use 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 proposed § 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, which will enable CMS to ensure the MAC QRS ratings are current; and

- The use of any technical specification adjustments to MAC QRS mandatory measures that 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 the 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 (meaning alternative methodology) approved by CMS, including the effective dates (the period during which the alternative QRS was, has been, or will be applied by the State) for each approved alternative QRS.

We proposed 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 proposed in § 438.535(a) the report would 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 proposed that States would be given a minimum of 90 days’ notice to provide such a report. We sought comment on whether States prefer one annual reporting date or a date that is relative to their MAC QRS updates. We summarize and respond to public comments received on the proposed reporting requirements (§§ 438.535 and 457.1240(d)) below.

Comment: Two commenters supported the use of one annual reporting date versus a State-specific date that is relative to MAC QRS updates.

Response: We will take the comments regarding timing into account when finalizing our guidance related to annual reporting. However, we are finalizing that reports will be required no more frequently than annually, and that CMS will provide no less than 90 days of notice that a report is due.

After reviewing public comments and for the reasons outlined in this rulemaking, we are finalizing these provisions largely as proposed but with modifications. We are finalizing § 438.535(a)(1) with modifications, which will also apply to separate CHIP, to add content to the required report: (1) identification of mandatory measures that are not included in their MAC QRS because they are not applicable to the State’s Medicaid managed care program; (2) for any measures identified as inapplicable to the State’s managed care program, a brief explanation of why the State determined that the measure is inapplicable; and (3) for any measure identified as applicable to the State’s managed care program, the managed care programs to which the measure is applicable. This modification aligns with revisions we are also finalizing in § 438.510(a), which are discussed in section I.B.6.e. of the final rule. We are also adding new paragraph (a)(8) to include additional reporting requirements related to Medicare and Medicaid data that is not included in MAC QRS quality ratings, as discussed in section I.B.6.f of this final rule. In addition, we are finalizing minor changes in references to other regulations to take into account changes made in this final rule compared to the proposal (for example, codifying the rules for a State to use an alternative QRS methodology at § 438.515(c)).

k. Technical Changes (§§ 438.334, 438 Subpart G, 438.358 and 457.1240(d))

We proposed several technical changes to conform our regulations with other parts of our proposed rule, which included:

- Redesignating the regulations under current § 438.334(a) to part 438, subpart G, § 438.505 with changes in policy and modifications to take into account new subpart G provisions, as discussed throughout section I.B.6 of this final rule; and

- 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 redesignation of § 438.334 § 438.

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.

In our May 3, 2023 (88 FR 28092) proposed rule (CMS–2439–P; RIN 0938–AU99) we solicited public comment on each of the aforementioned issues for the following sections of the rule that contained information collection requirements. One comment is noted below that addresses the overall burden of the entire rule. Additionally, ICR #4 (Rate Certification Submission) and #16 (Program Integrity Requirements Under the Contract) also received public comment and a summary of the comment and response can be found below under the applicable ICR section.

Comment: A few commenters opined on the overall level of burden imposed by this rule. (Individual comments on burden are addressed in the respective topic areas of this final rule.)

Commenters stated that the numerous, interrelated, and overlapping obligations that Medicaid agencies will have to undertake if all of the elements of this rule are adopted as proposed will cost exponentially more than CMS has estimated, require extensive new Medicaid agency staffing and large-scale vendor contracts, intersect with numerous systems obligations that are already in the pipeline, as well as those that are anticipated under various pieces of Federal legislation, and require staging and more time than is anticipated by CMS’s proposed implementation deadlines.

Response: We acknowledged commenters’ concerns and have reviewed our burden estimates and made revisions when appropriate. We recognize that many factors impact the burden associated with each provision and we attempt to address them appropriately. We also gave careful consideration to the level of burden associated with each provision and selected applicability dates for each one that provided time for activities necessary to implement. The burden estimates in this rule are incorporated into and comply with the Paperwork Reduction Act and will be reviewed and revised as required.

Comment: One commenter stated support for CMS’s proposals to make all Medicaid proposals generally applicable to CHIP plans except where provisions are not relevant, which helps to ensure equal protections for CHIP recipients, promotes consistency between Federal programs, and reduces burden on States and providers.

Response: We appreciate the support for the alignment of most CHIP provisions in this final rule with those finalized for Medicaid. We agree that alignment promotes consistency between Medicaid and separate CHIP managed care programs. When appropriate, we made exceptions for situations in which separate CHIP differs from Medicaid and considered implications for managed care plans that serve smaller separate CHIP populations. We also agree with the commenter that alignment between programs provides equity for beneficiaries, promotes operational and administrative efficiencies, and reduces financial burden on States, plans, and providers.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational

Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/2022/may/oes_nat.htm). Table 4 presents BLS' mean hourly wage, our

estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE 4: National Occupational Employment and Wage Estimates

| Occupation Title | Occupation Code | Mean Hourly Wage (\$/hr) | Fringe Benefits and Other Indirect Costs (\$/hr) | Adjusted Hourly Wage (\$/hr) |
|---|-----------------|--------------------------|--|------------------------------|
| All Occupations | 00-0000 | 29.76 | n/a | n/a |
| Accountant | 13-2011 | 41.70 | 41.70 | 83.40 |
| Actuary | 15-2011 | 61.34 | 61.34 | 122.68 |
| Business Operations Specialist, All Other | 13-1199 | 39.75 | 39.75 | 79.50 |
| Database Administrator | 15-1242 | 49.29 | 49.29 | 98.58 |
| General and Operations Manager | 11-1021 | 59.07 | 59.07 | 118.14 |
| Medical Records Specialist | 29-2072 | 24.56 | 24.56 | 49.12 |
| Office Clerk, General | 43-9061 | 19.78 | 19.78 | 39.56 |
| Registered Nurse | 29-1141 | 42.80 | 42.80 | 85.60 |
| Software and web developers, programmers, and testers | 15-1250 | 60.07 | 60.07 | 120.14 |
| Statistician | 15-2041 | 50.73 | 50.73 | 101.46 |
| Web Developer | 15-1254 | 42.11 | 42.11 | 84.22 |

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 other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believed that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

After reviewing the public comments, we are updating the specific occupation title and code for 15–1251. In error, the proposed rule listed the occupation code 15–1251 for “computer programmer.” However, the occupation code 15–1250 “Software and web developers, programmers, and testers” encompasses a larger pool of work types for information technology related tasks.

Beneficiaries: To derive average costs for beneficiaries we believed that the burden will be addressed under All Occupations (BLS occupation code 00–0000) at \$29.76/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

B. 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 2021.²³² The enrollment data reflected 67,655,060 enrollees in MCOs, 36,285,592 enrollees in PIHPs or PAHPs, and 5,326,968 enrollees in PCCMs, and a total of 77,211,654 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.²³³ 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 changes to § 438.3 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1203 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.3(i) and 457.1203(f) will require that MCOs, PIHPs, and PAHPs report provider incentive payments based on standard metrics for provider performance. Amendments to § 438.8(e)(2) will 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 will require modification to reflect these changes. For the contract modifications, we estimate it will take 2 hours at \$79.50/hr for a business operations

²³² <https://www.medicaid.gov/medicaid/managed-care/enrollment-report/index.html>.

²³³ Data source: Statistical Enrollment Data System (SEDS) Form 21E, Children Enrolled in

Separate CHIP, and Form 64.21E, Children enrolled in Medicaid expansion CHIP.

specialist and 1 hour at \$118.14/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 × 3 hr) at a cost of \$87,299 [315 contracts × ((2 hr × \$79.50/hr) + (1 hr × \$118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 315 hours (945 hr/3 yr) and \$29,100 (\$87,299/3 yr). The annualization divides our estimates by 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 × 3 hr) at a cost of \$27,714 [100 contracts × ((2 hr × \$79.50/hr) + (1 hr × \$118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 100 hours (300 hr/3 yr) and \$9,238 (\$27,714/3 yr). The annualization divides our estimates by 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 will need to select standard metrics, develop appropriate payment arrangements, and then modify the affected providers' contracts. We estimate it will take 120 hours consisting of 80 hours × \$79.50/hr for a business operations specialist and 40 hours × \$118.14/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 × 120 hr) at a cost of \$3,491,964 [315 contracts × ((80 hr × \$79.50/hr) + (40 hr × \$118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 12,600 hours and \$1,163,988. The annualization divides our estimates by 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 × 120 hr) at a cost of \$1,108,560 [100 contracts × ((80 hr × \$79.50/hr) + (40 hr × \$118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 4,000 hours (12,000hr/3 yr) and \$369,520 (\$1,108,560/3 yr). The annualization divides our estimates by 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 did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

2. ICRs Regarding Special Contract Provisions Related to Payment (§ 438.6)

The following changes will be submitted to OMB for approval under control number 0938–1453 (CMS–10856).

Amendments to § 438.6(c)(2) will 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 final rule) must be submitted and have written approval by CMS prior to implementation.

We estimate that 38 States will submit 50 new SDP proposals for minimum/maximum fee schedules, value-based payment, or uniform fee increases. To complete a new preprint, we estimate that it will take 2 hours at \$122.68/hr for an actuary, 6 hours at \$79.50/hr for a business operations specialist, and 2 hours at \$118.14/hr for a general and operations manager for development and submission. We estimate an annual State burden of 500 hours (50 proposals × 10 hr) at a cost of \$47,932 [50 proposals × ((2 hr × \$122.68/hr) + (6 hr × \$79.50/hr) + (2 hr × \$118.14/hr))].

We estimate that 38 States will submit 150 renewals of existing SDPs or amendments to existing SDPs per year. To make revisions to an existing preprint, we estimate it will take 1 hour at \$79.50/hr for a business operations specialist, 1 hour at \$122.68/hr for an actuary, and 1 hour at \$118.14/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 × 3 hr) and \$48,048 [150 renewal/amendment proposals × ((1 hr × \$79.50/hr) + (1 hr × \$118.14/hr) + (1 hr × \$122.68/hr))].

The amendments to § 438.6(c)(2)(iii) will 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

will take 6 hours at \$122.68/hr for an actuary, 3 hours at \$118.14/hr for a general and operations manager, and 6 hours at \$120.14/hr for a software and web developers, programmers and testers for each analysis. In aggregate we estimate a one-time State burden of 900 hours (60 SDPs × 15 hr) and a cost of \$108,680 [60 certifications × ((6 hr × \$122.68/hr) + (3 hr × \$118.14/hr) + (6 hr × \$120.14/hr))]. As this will be a requirement to update once every 3 years, we annualize our time and cost estimates to 300 hours and \$36,227. The annualization divides our estimates by 3 years to reflect OMB's likely approval period.

Section 438.6(c)(2)(iv) will require that States that use 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 will submit 50 written evaluation plans for new proposals. We also estimate it will take 5 hours at \$120.14/hour for a software and web developers, programmers and testers, 2.5 hours at \$118.14/hr for a general and operations manager, and 2.5 hours at \$79.50/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 × 10 hr) and a cost of \$54,741 [50 evaluation plans × ((5 hr × \$120.14/hr) + (2.5 hr × \$118.14) + (2.5 hr × \$79.50/hr))].

We estimate that 38 States will prepare and submit 150 written evaluation plans for amendment and renewal of existing proposals. We also estimate it will take 2 hours at \$120.14/hr for a software and web developers, programmers and testers, 2 hours at \$118.14/hr for a general and operations manager and 2 hours at \$79.50/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 × 6 hr) at a cost of \$95,334 [150 evaluation plans × ((2 hr × \$120.14/hr) + (2 hr × \$118.14) + (2 hr × \$79.50/hr))].

Section 438.6(c)(2)(v) will 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. Section 438.6(c)(2)(ii)(F) also requires that States provide evaluation reports to CMS, upon request, that 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 57 evaluation reports. We also estimate it will take 3 hours at \$120.14/hr for a software and web developers, programmers, and testers, 1 hour at \$118.14/hour for a general and operations manager, and 2 hours at \$79.50/hr for a business operations specialist for each report. In aggregate we estimate an annual State burden of 342 hours (57 reports \times 6 hr) at a cost of \$36,341 [57reports \times ((3 hr \times \$120.14/hr) + (1 hr \times \$118.14/hr) + (2 hr \times \$79.50hr)].

The provision at § 438.6(c)(7) will 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 will need: 5 hours at \$122.68/hr for an actuary, 5 hours at \$120.14/hr for a software and web developers, programmers and testers, and 7 hours at \$79.50/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 170 hours (17 hr \times 10 States) at a cost of \$17,706 (10 States \times [(5 hr \times \$122.68/hr) + (5 hr \times \$120.14/hr) + (7 hr \times \$79.50/hr)]. We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

3. ICRs Regarding Special Contract Provisions Related to Payment—Attestations (§ 438.6(c)(2)(ii)(H))

The following changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10856). Upon approval, it will be folded into 0938–1453 (CMS–10856).

Amendments to § 438.6(c)(2)(ii)(H) will require all States with managed care delivery systems to collect attestations from providers who would receive an SDP attesting that they do not participate in any hold harmless arrangements. The paperwork burdens associated with this requirement include the following for States: developing instructions and communication for providers/plans; recordkeeping; and reporting to CMS when requested. For providers, the burden associated with this requirement

relates to reviewing and signing the attestations. Although States will have the flexibility to delegate work of collecting attestations to managed care plans, we cannot predict how many States will elect this option. As such, we are not accounting for that burden separately in these estimates.

States: We estimate that 44 States with MCOs, PIHPs and PAHPs will need to develop an attestation process and prepare attestations and communicate with providers. For each State, we estimate on a one-time basis it will take 200 hours at \$79.50/hr for a business operations specialist to plan the data collection process and develop the attestations and communications providers, and 200 hours at \$120.14/hr for a software and web developers, programmers, and testers to program an ingest and recordkeeping process for the attestations. In total, we estimate a one-time burden of \$1,756,832 and 17,600 hours (44 States \times [(200 \times \$79.50/hr) + (200 \times \$120.14/hr)]), or \$39,928 per State. Taking into account the 50 percent Federal administrative match, we estimate one time cost per State of \$19,964 [(\$15,900 + \$24,028) \times 0.5].

On an ongoing basis, we estimate that annually, it will take 200 hours at \$79.50/hr for a business operations specialist to manage the data collection process and 232 hours at \$39.56/hr for an office clerk to input the attestations. On an annual, national basis, we estimate States will submit 55 SDPs across 44 States with MCOs, PIHPs, and PAHPs for which they would need to provide attestations at CMS's request. We estimate at each instance it will take a general and operations manager 2 hours at \$118.14/hr for to prepare the submission and any necessary explanations, or 110 hours annually across all States. In total, we estimate an annual burden of \$1,116,424 and 19,118 hours [(44 States \times [(200 \times \$79.50) + (232 \times \$39.56)] + (55 SDPs \times (2 \times \$118.14)], or \$25,373 per State. Taking into account the 50 percent Federal administrative match, we estimate ongoing costs per State of \$12,687 (\$25,373 \times 0.5).

Providers: For the purposes of these estimates, we are using a provider estimate of 1,088,050 providers enrolled with MCOs, PIHPs, and PAHPs, based on T–MSIS Analytic Files (also known as TAF) data, that will need to submit an attestation to the State. We are further assuming for the purposes of these estimates that these collections will occur on an annual basis, one per provider, but want to note States may elect different timing or number of attestations per provider that would increase or decrease these estimates. We

estimate it will take a healthcare administrator at a provider 6 minutes to review and sign the attestation at \$93.04/hr. In total, we estimate an annual burden of \$10,123,217 and 108,805 hours (1,088,050 providers \times (\$93.04/hr \times 0.1)).

4. ICRs Regarding Rate Certification Submission (§ 438.7)

The following changes will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). One public comment was received. It is summarized and responded to under this ICR section.

Amendments to § 438.7 set out revisions to the submission and documentation requirements for all managed care actuarial rate certifications. The certification will 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 believed these requirements are consistent with actuarial standards of practice and previous Medicaid managed care rules.

We estimate that 44 States would develop 253 certifications at 250 hours for each certification. Of the 250 hours, we estimate that it will take 110 hours at \$122.68/hr for an actuary, 15 hours at \$118.14/hr for a general and operations manager, 53 hours at \$120.14/hr for a software and web developers, programmers and testers, 52 hours at \$79.50/hr for a business operations specialist, and 20 hours at \$39.56/hr for an office and administrative support worker. In aggregate we estimate an annual State burden of 63,250 hours (250 hr \times 253 certifications) at a cost of \$6,719,559 [253 certifications \times ((110 hr \times \$122.68/hr) + (15 hr \times \$118.14/hr) + (53 hr \times \$120.14/hr) + (52 hr \times \$79.50/hr) + (20 hr \times \$39.56/hr)]. We solicited public comment on these issues. We summarize and respond to public comments below:

Comment: One commenter stated that the provisions at § 438.7(c)(4) and (5) could increase State administrative burden if a revised rate certification would be required when there is a programmatic change for ILOSs and SDPs.

Response: We agree with the commenter that the provisions at § 438.7(c)(4) could increase State administrative burden. The commenter did not provide an estimate on the potential administrative burden. We believe it would be reasonable to increase the ICR by approximately 2 percent (that is, 5 rate certifications) to account for any revised rate certifications necessary for ILOS

changes and to increase the ICR by approximately 10 percent (23 certifications) to account for any revised rate certifications for SDP changes. This increases the total number of rate certifications for the ICR from 225 certifications to 253 rate certifications.

After reviewing the public comments, we are finalizing the ICRs with revision to account for a total of 253 rate certifications rather than 225 certifications while all ICR estimates on the total number of hours remains unchanged. In aggregate, we estimate an annual State burden of 63,250 hours at a cost of \$6,719,559 as reflected in the estimate above.

5. ICRs Regarding Medical Loss Ratio Standards (§§ 438.8, 438.74, and 457.1203)

The following changes to §§ 438.8 and 438.74 will be submitted to OMB for approval under control number 0938-1453 (CMS-10856). The following changes to § 457.1203 will be submitted to OMB for approval under control number 0938-1282 (CMS-10554).

Amendments to §§ 438.8 and 457.1203 will 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.

Amendments to §§ 438.8(k)(1)(vii) and 457.1203(f) will require that MCOs, PIHPs, and PAHPs develop their annual MLR reports compliant with the expense allocation methodology.²³⁴ To meet this requirement we anticipate it will take: 1 hr at \$83.40/hr for an accountant, 1 hr at \$79.50/hr for a business operations specialist, and 1 hr at \$118.14/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 × 3 hr) at a cost of \$176,775 [629 contracts × ((1 hr × \$83.40/hr) + (1 hr × \$79.50/hr) + (1 hr × \$118.14/hr))]. In aggregate for CHIP for § 457.1203(f), we estimate an annual private sector burden of 597 hours (199 contracts × 3 hr) at a cost of \$55,927

[199 contracts × ((1 hr × \$83.40/hr) + (1 hr × \$79.50/hr) + (1 hr × \$118.14/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 will take 1 hour at \$79.50/hr for a business operations specialist. In aggregate for Medicaid we estimate an annual private sector burden of 315 hours (315 contracts × 1 hr) at a cost of \$25,043 (315 contracts × 1 hr × \$79.50/hr). In aggregate for CHIP for § 457.1203(f), we estimate an annual private sector burden of 100 hours (100 contracts × 1 hr) and \$7,950 (100 contracts × 1 hr × \$79.50/hr).

Amendments to §§ 438.74 and 457.1203(e) will require States to comply with data aggregation requirements for their annual reports to CMS. We estimate that only 5 States will need to resubmit MLR reports to comply with the data aggregation changes. We anticipate that it will take 5 hours × \$79.50/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 × 5 hr) at a cost of \$1,988 (5 States × 5 hr × \$79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 8 hours (25 hr/3 yr) and \$663 (\$1,988/3 yr).

In aggregate for CHIP for § 457.1203(e) we estimate a one-time State burden of 25 hours (5 States × 5 hr) at a cost of \$1,988 (5 States × 5 hr × \$79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates for CHIP to 8 hours (25 hr/3 yr) and \$663 (\$1,988/3 yr).

The annualization divides our estimates by 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 did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

6. ICRs Regarding Information Requirements (§§ 438.10 and 457.1207)

The following changes to § 438.10 will be submitted to OMB for approval under control number 0938-1453 (CMS-10856). The following changes to § 457.1207 will be submitted to OMB for approval under control number 0938-1282 (CMS-10554).

Amendments to §§ 438.10(c)(3) and 457.1207 will require States to operate a website that provides the information

required in § 438.10(f). We are estimating 45 States will need to operate the website. We are finalizing that States must include required information on one page, use clear labeling, and verify correct functioning and accurate content at least quarterly. We anticipate it will take 20 hours at \$120.14/hr once for a software and web developers, programmers, and testers 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 × 20 hr) at a cost of \$108,126 (900 hr × \$120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 300 hours and \$36,042.

In aggregate for CHIP for § 457.1207, we estimate a one-time State burden of 640 hours (32 States × 20 hr) at a cost of \$76,890 (640 hr × \$120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 213 hours and \$25,630.

The annualization divides our estimates by 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 will take 40 hours at \$120.14/hr for a software and web developers, programmers, and testers to periodically add content and verify the function of the site at least quarterly (10 hours/quarter).

In aggregate for Medicaid, we estimate an annual State burden of 1,800 hours (45 States × 40 hr) at a cost of \$216,252 (1,800 hr × \$120.14/hr).

Due to the additional finalized requirement 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 \$120.14/hr for a software and web developers, programmers, and testers 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 × 41 hr) at a cost of \$157,624 (1,312 hr × \$120.14/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

7. ICRs Regarding ILOS Contract and Supporting Documentation Requirements (§§ 438.16 and 457.1201)

The following changes to § 438.16 will be submitted to OMB for approval

²³⁴ Methodology(ies) for allocation of expenditures as described at 45 CFR 158.170(b).

under control number 0938–1453 (CMS–10856). The following changes to § 457.1201 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

The provisions at §§ 438.16 and 457.1201 will 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 believed 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 estimated 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 provision at § 438.16(c)(4)(i) will require States to submit a projected ILOS cost percentage to CMS as part of the rate certification. The burden for this provision is accounted for in ICR #2 (above) for § 438.7 Rate Certifications.

The provision at § 438.16(c)(5)(ii) will 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 anticipated that 22 States will need: 5 hours at \$122.68/hr for an actuary, 5 hours at \$120.14/hr for a software and web developers, programmers and testers, and 7 hours at \$79.50/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 374 hours (17 hr × 22 States) at a cost of \$38,953 (22 States × [(5 hr × \$122.68/hr) + (5 hr × \$120.14/hr) + (7 hr × \$79.50/hr)]).

Provisions at §§ 438.16(d)(1) and 457.1201(e) will 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 will need 1 hour at \$79.50/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 estimated an annual State burden of 327 hours (327 contracts × 1 hr) at a cost of \$25,997 (327 hr × \$79.50/hr). In aggregate for CHIP for § 457.1201(e) we estimated an annual State burden of 100 hours (100 contracts × 1 hr) at a cost of \$7,950 (100 hr × \$79.50/hr).

Provisions at §§ 438.16(d)(2) and 457.1201(e) will 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 will be required for States with a projected ILOS cost percentage greater than 1.5 percent. We anticipated that approximately 5 States may be required to submit this additional documentation. We estimated it will take 2 hours at \$79.50/hr for a business operations specialist to provide this documentation. In aggregate for Medicaid for § 438.16(d)(2), we estimated an annual State burden of 10 hours (5 States × 2 hr) at a cost of \$795 (10 hr × \$79.50/hr). In aggregate for CHIP for § 457.1201(e) we estimate the same annual State burden of 10 hours (5 States × 2 hr) at a cost of \$795 (10 hr × \$79.50/hr).

Provisions at §§ 438.16(e)(1) and 457.1201(e) will require States with a final ILOS cost percentage greater than 1.5 percent to submit an evaluation for ILOSs to CMS. We anticipated that approximately 5 States may be required to develop and submit an evaluation. We estimated it will take 25 hours at \$79.50/hr for a business operations specialist. In aggregate for Medicaid for § 438.16(e)(1), we estimated an annual State burden of 125 hours (5 States × 25 hr) at a cost of \$9,938 (125 hr × \$79.50/hr). In aggregate for CHIP for § 457.1201(e), we estimated the same annual State burden of 125 hours (5 States × 25 hr) at a cost of \$9,938 (125 hr × \$79.50/hr).

An ILOS may be terminated by either a State, a managed care plan, or by CMS. Provisions at §§ 438.16(e)(2)(iii) and 457.1201(e) will require States to develop an ILOS transition of care policy. We believed all States with non-IMD ILOSs should proactively prepare a transition of care policy in case an ILOS is terminated. We estimated both a one-time burden and an annual burden for these provisions. We believed there is a higher one-time burden as all States that currently provide non-IMD ILOSs will need to comply with this requirement by the applicability date, and an annual burden is estimated for States on an ongoing basis. We estimated for a one-time burden, it will take: 2 hours at \$120.14/hr for a software and web developers, programmers and testers and 2 hours at \$79.50/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 × 4 hr) at a cost of \$8,784 (22 States × [(2 hr × \$120.14/hr) + (2 hr × \$79.50/hr)]). As this will be a

one-time requirement, we annualized our time and cost estimates to 30 hours and \$2,928. In aggregate for CHIP for § 457.1201(e), we estimated a one-time State burden 64 hours (16 States × 4 hr) at a cost of \$6,389 (16 States × [(2 hr × \$120.14/hr) + (2 hr × \$79.50/hr)]). As this will be a one-time requirement, we annualized our time and cost estimates to 21 hours and \$2,130. The annualization divides our estimates by 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 estimated that this ILOS transition of care policy will have an annual burden of 1 hour at \$79.50/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 × 1 hr) at a cost of \$1,749 (22 hr × \$79.50/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual State burden of 16 hours (16 States × 1 hr) at a cost of \$1,272 (16 hr × \$79.50/hr).

For MCOs, PIHPs, or PAHPs that will 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 estimated an annual managed care plan burden of 2 hours at \$79.50/hr for a business operations specialist to implement the policy. In aggregate for Medicaid for § 438.16(e)(2)(iii)(B), we estimated an annual burden of 130 hours (65 plans × 2 hr) at a cost of \$10,335 (130 hr × \$79.50/hr). In aggregate for CHIP for § 457.1201(e), we estimate an annual burden of 80 hours (40 plans × 2 hr) at a cost of \$6,360 (80 hr × \$79.50/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

8. ICRs Regarding State Monitoring Requirements (§ 438.66)

The following changes will be submitted to OMB for approval under control number 0938–1453 (CMS–10856).

Amendments to § 438.66(c) will require States to conduct, or contract for, an enrollee experience survey annually. We believed 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 \$79.50/hr for a business operations specialist and 25 hours at \$118.14/hr for general operations manager. In aggregate for § 438.66(c), we estimate a one-time State burden of 5,390 hours (49 States × 110 hr) at a cost of \$475,840 (49 States × [(85 hr × \$79.50/hr) + (25 hr × \$118.14)]). As this will be a one-time requirement, we annualize our time and cost estimates to 1,796 hours and \$158,614. The annualization divides our estimates by 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 estimated 50 hours at \$79.50/hr for a business operations specialist and 15 hours at \$118.14/hr for general operations manager. In aggregate, we estimated an annual State burden of 3,185 hr (49 States × 65 hr) at a cost of \$281,608 (49 States × [(50 hr × \$79.50/hr) + (15 hr × \$118.14/hr)]).

Amendments to § 438.66(e)(1) and (2) will 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 in § 438.16, will be used to complete the report. We anticipate it will take 80 hours at \$79.50/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 × 80 hr) at a cost of \$311,640 (3,920 hr × \$79.50/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

9. ICRs Regarding Network Adequacy Standards (§§ 438.68 and 457.1218)

The following changes to § 438.68 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1218 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Sections 438.68(e) and 457.1218 will require States with MCOs, PIHPs, or PAHPs to develop appointment wait time standards for four provider types. We anticipate it will take: 20 hours at \$79.50/hr for a business operations specialist for development and 10 hours at \$79.50/hr for 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 × 20 hr) at a cost of \$69,960 (880 hr × \$79.50/hr). As this will be a one-time requirement, we annualize our one-time burden estimates to 293 hours and \$23,320. The annualization divides our one-time by 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.

Additionally, § 438.68(e) has an annual State burden. We anticipate it will take: 10 hours at \$79.50/hr for a business operations specialist for development. In aggregate for Medicaid for § 438.68(e), we anticipate an annual State burden of 440 hours (44 States × 10 hr) at a cost of \$34,980 (440 hr × \$79.50/hr).

In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 640 hours (32 States × 20 hr) at a cost of \$50,880 (640 hr × \$79.50/hr) for States to develop appointment wait time standards for four provider types and an annual State burden of 320 hours (32 States × 10 hr) at a cost of \$25,440 (320 hr × \$79.50/hr) for enforcement of all network adequacy standards. As the development of appointment wait time standards will be a one-time requirement, we annualize our one-time burden estimates to 213 hours (640hr/3yr) and \$16,960 (50,880/3yr). The annualization divides our one-time estimates by 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 will 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 will take: 85 hours at \$79.50/hr for a business operations specialist and 25 hours at \$118.14/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 × 110 hr) at a cost of \$427,284 (44 States × [(85 hr × \$79.50/hr) + (25 hr × \$118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 1,614 hours and \$142,428. In aggregate for CHIP for § 457.1218, we estimate a one-time State burden of 3,520 hours (32 States × 110 hr) at a cost of \$310,752 (32 States × [(85

hr × \$79.50/hr) + (25 hr × \$118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 1,173 hours and \$103,584. The annualization divides our estimates by 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 will take 50 hours at \$79.50/hr for a business operations specialist and 15 hours at \$118.14/hr for general operations manager. In aggregate for Medicaid for § 438.68(f), we estimate an annual State burden of 2,860 hours (44 States × 65 hr) at a cost of \$252,872 (44 States × [(50 hr × \$79.50/hr) + (15 hr × \$118.14)]).

In aggregate for CHIP for § 457.1218 we estimate an annual State burden of 2,080 hours (32 States × 65 hr) at a cost of \$183,907 (32 States × [(50 hr × \$79.50/hr) + (15 hr × \$118.14/hr)]).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

10. ICRs Regarding Assurance of Adequate Capacity and Services (§§ 438.207 and 457.1230)

The following changes to § 438.207 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1230 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.207(b) and 457.1230(b) will require MCOs, PIHPs, and PAHPs to submit documentation to the State of their compliance with § 438.207(a). As we finalized 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 \$79.50/hr for a business operations specialist, 20 hours at \$118.14/hr for a general operations manager, and 80 hours at \$120.14/hr for software and web developers, programmers and testers. 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 × 150 hr) at a cost of \$10,031,921 (629 MCOs, PIHPs, and PAHPs × [(50 hr × \$79.50/hr) + (20 hr × \$118.14/hr) + (80 hr × \$120.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 31,449 hours and \$3,343,974. The annualization divides our estimates by 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 × 150 hr) at a cost of \$3,173,851 (199 MCOs, PIHPs, and PAHPs × [(50 hr × \$79.50/hr) + (20 hr × \$118.14/hr) + (80 hr × \$120.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 9,950 hours and \$1,057,950. The annualization divides our estimates by 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 will be required by amendments to § 438.207(b), we estimate it will take: 20 hours at \$79.50/hr for a business operations specialist, 5 hours at \$118.14/hr for a general operations manager, and 20 hours at \$120.14/hr for software and web developers, programmers and testers. In aggregate for Medicaid, we estimate a one-time private sector burden of 28,305 hours (629 MCO, PIHPs, and PAHPs × 45 hr) at a cost of \$2,883,021 (629 MCO, PIHPs, and PAHPs × [(20 hr × \$79.50/hr) + (5 hr × \$118.14/hr) + (20 hr × \$120.14/hr)]).

In aggregate for CHIP, we estimate a one-time private sector burden of 8,955 hours (199 MCO, PIHPs, and PAHPs × 45 hr) at a cost of \$912,117 (199 MCO, PIHPs, and PAHPs × [(20 hr × \$79.50/hr) + (5 hr × \$118.14/hr) + (20 hr × \$120.14/hr)]).

Amendments to §§ 438.207(d) and 457.1230(b) will 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. By including the requirements in this rule at §§ 438.68(f) and 438.208(b)(3), we anticipate it will take 40 hours at \$79.50/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 believed these submissions will be infrequent and require minimal updating to the template; therefore, the burden estimated here is inclusive of occasional revisions. In aggregate for Medicaid, we estimate an annual State

burden of 1,760 hours (44 States × 40 hr) at a cost of \$139,920 (1,760 hr × \$79.50/hr).

Due to the additional finalized requirement to include enrollee experience survey results in the State's separate CHIP analysis of network adequacy, we anticipate an additional 4 hours at \$79.50/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 × 44 hr) at a cost of \$111,936 (1,408 hr × \$79.50/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

11. ICRs Regarding External Quality Review Results (§§ 438.364 and 457.1250)

The following changes to § 438.364 and § 438.360 will be submitted to OMB for approval under control number 0938-0786 (CMS-R-305), and the changes to § 457.1250 will be submitted to OMB for approval under control number 0938-1282 (CMS-10554).

Amendments to § 438.360(a)(1) will 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 will simplify the plan accreditation process. We assume that States will apply the non-duplication provision to 10 percent of MCOs, PIHPs, and PAHPs, we anticipate that this provision will 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). To develop the burden reduction estimate, we applied the currently approved estimates in CMS-R-305, which quantifies the burden for § 438.358(b)(1)(i) through (iii). The existing burden estimate assumes for the first mandatory EQR-related activity that each MCO, PIHP, or PAHP will conduct 2 PIPs at 65 hours per PIP for a total of 130 hours (65 hr × 2 PIP validations). For the next two mandatory activities, we estimate that each MCO, PIHP, PAHP, or PCCM entity will calculate 3 performance measures each year at 53 hours per performance measure. A compliance review will also occur every three years and burden is annualized. This totals 279.33 hours [(53 hours × 3 performance measures) + [361 hours/3 years compliance review]]. In total, for one entity we estimate 409.33 hours

(130 + 279.33) to conduct the mandatory EQR activities. All activities are conducted by a business operations specialist at \$79.50/hr for a total cost per entity of \$32,541.74 (409.33 × \$79.50/hr). Therefore, for § 438.358(b)(1)(i) through (iii), we estimate an aggregated offset of annual State burden of minus 26,606 hours [(-65 MCOs, PIHPs × 409.33 hr)] and minus \$2,115,213 (-26,606.45 hr × \$79.50/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, will (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(a)(2)(iii), 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 will take 1 hour at \$79.50/hr for a business operations specialist to describe the data and results from quantitative assessments and 30 minutes at \$39.56/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 \$64,929 (654 reports × [(1 hr × \$79.50/hr) + (0.5 hr × \$39.56/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 \$19,757 (199 reports × [(1 hr × \$79.50/hr) + (0.5 hr × \$39.56/hr)]).

Amendments to § 438.364(c)(2)(i) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, will 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 will take 30 minutes at \$79.50/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 \$1,749 (22 hr × \$79.50/hr). In aggregate for CHIP, we estimate an annual State burden of 16 hours (32

States \times 0.5 hr) at a cost of \$1,272 (16 hr \times \$79.50/hr).

Amendments to § 438.364(c)(2)(iii) for Medicaid, and through an existing cross-reference at § 457.1250(a) for separate CHIP, will 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 will take 5 minutes (0.0833 hr) at \$79.50/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 \times 0.75 \times 5 years \times 0.0833 hr) at a cost of \$16,218 (204 hr \times \$79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 68 hours and \$5,406. In aggregate for CHIP for § 457.1250(a), we estimate a one-time burden of 62 hours [(199 MCOs, PIHPs, and PAHPs yearly reports \times 0.75 \times 5 years \times 0.0833/hr) at a cost of \$4,929 (62 hr \times \$79.50/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 21 hours and \$1,643. The annualization divides our estimates by 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.

Based on the public comments received on our proposed change to 438.364(c)(1) to the annual due date of the EQR technical reports, we decided not to finalize this change, and therefore, have removed the associated burden. The associated burden was based on an estimate of 1 hour at \$79.50/hr for a business operations specialist and 30 minutes at \$118.14/hr for a general operations manager to amend vendor contracts to reflect the new reporting date. In aggregate for Medicaid, we estimated an annual State burden of 981 hours (654 MCOs, PIHPs, and PAHPs yearly reports \times 1.5 hr) at a cost of \$90,625 (654 contracts [(1 hr \times \$79.50/hr) + (0.5 hr \times \$118.14/hr)]). This change is discussed in more detail in section I.B.5.c. of this final rule.

12. ICRs Regarding Requirements for PCCMs and New Optional EQR Activity (§§ 438.310(c)(2), 438.350, 438.358, and 457.1250)

The following changes to § 438.310(c)(2) and § 438.350 will be submitted to OMB for approval under

control number 0938–0786 (CMS–R–305). The following changes to § 457.1250 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.310(c)(2), 438.350, and 457.1250(a) will 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 will take 53 hours at \$79.50/hr for a business operations specialist to complete each performance measure validation and 361 hours at \$79.50/hr for a business operations specialist to conduct a compliance review. Alleviating this burden will result in an annual State Medicaid savings of minus 2,793 hours (10 PCCM entities \times [(53 hr/validation \times 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus \$222,044 (– 2,793 hr \times \$79.50/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 2,196 hours (7 PCCM entities \times [(53 hr/validation \times 3 performance measure validations) + (361 hr/3 years compliance review)]) and minus \$174,582 (– 2,196 hr \times \$79.50/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 (approximately 1 PCCM) will be subject to each of the optional EQR-related activities. To conduct the optional activities we estimate it will take: 250 hours at \$120.14/hr for a software and web developers, programmers and testers to program and synthesize the data; 549 hours at \$79.50/hr for a business operations specialist to collect data and administer surveys; and 200 hours at \$118.14/hr for general and operations manager to oversee and manage the process. Alleviating this burden will result in an annual state Medicaid savings of minus 999 hours (250 hr + 549 hr + 200hr) and minus \$97,309 [(250 hr \times \$120.14/hr) + [549 hr \times \$79.50/hr] + [200 hr \times \$118.14)]. Adjusting for 7 PCCMs for CHIP for

§ 457.1250(a), we estimate annual State savings of minus 650 hours (– 228 hr – 49 hr – 16 hr – 103 hr – 127 hr – 127 hr) and minus \$63,302 [(– 650 hr \times 0.20 \times \$118.14/hr) + (– 650 hr \times 0.25 \times \$120.14/hr) + (– 650 hr \times 0.55 \times \$79.50/hr)].

Per § 438.364(c)(2)(ii), each State agency will provide copies of technical reports, 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. This change will 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 \$39.56/hr for an office clerk to disclose the reports (per request), and that a State will receive five requests per PCCM entity. Alleviating this burden, for § 438.310(c)(2) and § 438.350, will result in an annual Medicaid State savings of minus 4 hours (10 PCCM entities \times 5 requests \times 0.0833/hr) and minus \$158 (– 4 hr \times \$39.56/hr). For CHIP for § 457.1250(a), we estimate an annual State savings of minus 3 hours (7 PCCM entities \times 5 requests \times 0.0833/hr) and minus \$119 (– 3 hr \times \$39.56/hr).

For the mandatory and optional EQR activities, in aggregate for Medicaid, for § 438.310(c)(2) and § 438.350, we estimate an annual State savings of minus 3,796 hours (– 2,793 hr + – 999 hr + – 4 hr) and minus \$319,495 [(222,044 + \$97,309 + \$158)]. Similarly, in aggregate for CHIP for § 457.1250(a), we estimate an annual State savings of minus 2,849 (– 2,196 hr – 650 hr – 3 hr) and minus \$238,003 (– \$174,582 – \$63,302 – \$119).

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. The currently approved burden estimate in CMS–305 assumes 200 hr for a MCO, PIHP, or PAHP to prepare the information for all mandatory EQR 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 will take half the time (or 100 hr) to prepare the documentation for these 2 activities, half (50 hr) at \$79.50/hr by a business operations specialist and half (50 hr) at \$39.56/hr by an office clerk. In aggregate for Medicaid, we estimate an annual private sector savings of minus 1,000 hours (10 PCCM entities \times 100 hr) and minus \$59,530 [(– 500 hr \times \$79.50/hr) +

(– 500 hr × \$39.56/hr)]. In aggregate for CHIP for § 457.1250(a), we estimate an annual private sector savings of minus 200 hours (2 PCCM entities × 100 hr) and minus \$11,906 [(– 100 hr × \$79.50/hr) + (– 100 hr × \$39.56/hr)].

Amendments to §§ 438.358(c)(7) and 457.1250(a) add a new optional EQR activity to assist in evaluations for ILOSs, quality strategies and SDPs 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 it will take 80 hours for a mix of professionals will work on each optional EQR-related activity: 16 hours for a general and operations manager at \$118.14/hr; 20 hours for software and web developers, programmers and testers at \$120.14/hr; and 44 hours for a business operations specialist at \$79.50/hr. In aggregate for Medicaid, the annual State burden to assist in evaluations is 4,640 hours (58 MCOs, PIHPs and PAHPs × 80 hr) at a cost of \$451,880 [(58 MCOs, PIHPs and PAHPs × 16 hr × \$118.14/hr) + (58 MCOs, PIHPs and PAHPs × 20 hr × \$120.14/hr) + (58 MCOs, PIHPs and PAHPs × 44 hr × \$79.50/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 × 80 hr) at a cost of \$155,821 [(1,600 hr × 0.20 × \$118.14/hr) + (1,600 hr × 0.25 × \$120.14/hr) + (1,600 hr × 0.55 × \$79.50/hr)].

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

13. ICRs Regarding Quality Rating System Measure Collection (§§ 438.515 and 457.1240)

The following changes to § 438.515 will be submitted to OMB for approval under control number 0938–1281 (CMS–10553). The following changes to § 457.1240 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.515(a)(1) and 457.1240(d) will 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 will calculate and issue an annual quality rating to each managed care

plan. The State will also collect data from Medicare and the State's FFS 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 will be required to collect data using the framework of a mandatory QRS Measure Set. We used the mandatory measure set, found in Table 2 of this final rule, as the basis for the measure collection burden estimate. The mandatory measure set consists of 16 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 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 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 will take: 680 hours at \$120.14/hr for a software and web developers, programmers and testers to program and synthesize the data; 212 hours at \$79.50/hr for a business operations specialist to manage the data collection process; 232 hours at \$39.56/hr for an office clerk to input the data; 300 hours at \$85.60/hr for a registered nurse to review medical records for data collection; and 300 hours at \$49.12/hr for medical records and health information analyst to compile and process medical records. For Medicaid, for § 438.515(a)(1) 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 \$148,143 [(680 hr × \$120.14/hr) + [212 hr × \$79.50/hr] + [232 hr × \$39.56/hr] + [300 hr × \$85.60/hr] + [300 hr × \$49.12/hr)].

For Medicaid, we also estimate that conducting the QRS survey measures comprised of the CAHPS survey will take: 20 hours at \$79.50/hr for a

business operations specialist to manage the data collection process; 40 hours at \$39.56/hr for an office clerk to input the data; and 32 hours at \$101.46/hr for a statistician to conduct data sampling. For 438.515(a)(1), 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 \$6,419 [(20 hr × \$79.50/hr) + [40 hr × \$39.56/hr] + [32 hr × \$101.46)].

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 \$154,562 (\$148,143 + \$6,419). In aggregate, for Medicaid, for 438.515(a)(1), we estimate an annual private sector burden of 1,142,264 hours (629 Medicaid MCOs, PIHPs and PAHPs × 1,816 hours) and \$97,219,498 (629 Medicaid MCOs, PIHPs and PAHPs × \$154,562).

For CHIP for § 457.1240(d), we expect reporting non-survey QRS measures will take: 400 hours at \$120.14/hr for a software and web developers, programmers and testers to program and synthesize the data; 148 hours at \$79.50/hr for a business operations specialist to manage the data collection process; 152 hours at \$39.56/hr for an office clerk to input the data; 60 hours at \$85.60/hr for a registered nurse to review medical records for data collection; and 60 hours at \$49.12/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 \$68,782 [(400 hr × \$120.14/hr) + [148 hr × \$79.50/hr] + [152 hr × \$39.56/hr] + [60 hr × \$85.60/hr] + [60 hr × \$49.12/hr)].

For CHIP for § 457.1240(d), we also estimate that conducting the survey measures (comprised of the CAHPS survey and secret shopper) will take: 20 hours at \$79.50/hr for a business operations specialist to manage the data collection process; 56 hours at \$39.56/hr for an office clerk to input the data; and 32 hours at \$101.46/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 \$7,052 [(20 hr × \$79.50/hr) + [56 hr × \$39.56/hr] + [32 hr × \$101.46)].

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 \$80,970 (\$73,918 + \$7,052). 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 \times 928hr) and \$16,113,110 (199 CHIP MCOs, PIHPs and PAHPs \times \$80,970).

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 will be conducted twice, once for children and once for adults. We estimate it will take 20 minutes (0.33 hr) at \$29.76/hr for a Medicaid beneficiary to complete the CAHPS Health Plan Survey. For Medicaid, in aggregate, we estimate a new beneficiary burden of 170,623 hours (629 MCOs, PIHPs and PAHPs \times 0.33 hr per survey response \times 822 beneficiary responses) at a cost of \$5,077,727 (170,623 hr \times \$29.76/hr). Since it is not a new requirement for States to complete CAHPS surveys for CHIP beneficiaries, no new burden estimates are provided CHIP.

Additionally, amendments to § 438.515(a)(1)(i) that require reporting of QRS measures will require States to update existing managed care contracts. We estimate it will take 1 hour at \$79.50/hr for a business operations specialist and 30 minutes at \$118.14/hr for 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 \times 1.5 hours) at a cost of \$87,161 (629 contracts \times [(1 hr \times \$79.50/hr) + (0.5 hr \times \$118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 315 hours and \$29,054. The annualization divides our estimates by 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 \times 1.5 hours) at a cost of \$27,575 (199 contracts \times [(1 hr \times \$79.50/hr) + (0.5 hr \times \$118.14/hr)]). As this will be a one-time requirement, we annualize our time and cost estimates to 99 hours and \$9,192. The annualization divides our estimates by 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 FFS 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 that subset of States will need to collect Medicare data or State Medicaid FFS data to report the mandatory quality measures. We assume that plans have access to Medicare data for their enrollees and have included this burden in the cost of data collection described above. However, we assume Medicaid FFS data will need to be provided and that this requirement will impact 5 States. For a State to collect the FFS data needed for QRS reporting, we expect it will take: 120 hours at \$120.14/hr for a software and web developers, programmers and testers to program and synthesize the data and 20 hours at \$79.50/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 \times [120 hr + 20 hr]) at a cost of \$80,034 (5 States \times [(120 hr \times \$120.14/hr) + (20 hr \times \$79.50/hr)]).

Amendments to §§ 438.515(a)(2) and 457.1240(d) require the QRS measure data to be validated. We estimate it will take 16 hours at \$79.50/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 \times 16 hr) at a cost of \$800,088 (10,064 hr \times \$79.50/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 \times 16 hr) at a cost of \$253,128 (3,184 hr \times \$79.50/hr).

Amendments to §§ 438.515(d)(2) and 457.1240(d) allow the State to request a one-year extension on the implementation of certain methodology requirements outlined in § 438.515. The extension request must: identify the specific requirement(s) for which the extension is requested; describe the barriers to the requirement's implementation; demonstrate that, despite making good-faith efforts to identify and begin executing an implementation strategy, the State has good reason to believe that it will be unable to meet the specified requirement(s) by the implementation date identified by CMS in this subpart. The request must also include a detailed plan to implement the requirement(s) by the end of the extension including, but not limited to, the operational steps the

State will take to address any identified implementation barrier(s). We assume that a small subset of States (7 States) will be unable to meet the QRS methodology requirements, and therefore, will submit an extension request. We estimate it will take 24 hours at \$118.14/hr for a general operations manager to draft and submit the extension request. In aggregate for Medicaid, we estimate an annual private sector burden of 168 hours (7 States \times 24 hr) at a cost of \$19,848 (168 hr \times \$118.14/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed except modifications to reflect the inclusion of the option to submit a MAC QRS extension request in the final rule, discussed in more detail in section I.B.6.d. of this final rule and finalized at §§ 438.515(d) and 438.520(b). We have updated our burden calculations to reflect the inclusion of the option to submit a MAC QRS extension request.

14. ICRs Regarding Requirements for QRS Website Display (§§ 438.520(a) and 457.1240)

The following changes to § 438.520(a) will be submitted to OMB for approval under control number 0938–1281 (CMS–10553). The following changes to § 457.1240 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

The amendments to §§ 438.520(a) and 457.1240(d) will 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 will need to maintain the display by populating the display with data collected from the mandatory QRS measure set established in this final rule. The final 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 result in an overestimate during the initial phase of the website display but believed the estimate is representative of the longer-term burden associated with the QRS website display requirements.

To develop the initial display, we estimate it will take: 600 hours at

\$120.14/hr for a software and web developers, programmers and testers to create and test code; 600 hours at \$84.22/hr for a web developer to create the user interface; 80 hours at \$79.50/hr for a business operations specialist to manage the display technical development process; and 450 hours at \$98.58/hr for a database administrator 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 \$173,337 [(600 hr × \$120.14/hr) + (600 hr × \$84.22/hr) + (80 hr × \$79.50/hr) + (450 hr × \$98.58/hr)]. In aggregate for Medicaid, we estimate a one-time State burden of 76,120 hours (44 States × 1,730 hr) at a cost of \$7,626,828 (44 States × \$173,337). As this will be a one-time requirement, we annualize our Medicaid burden estimates to 25,373 hours and \$2,542,276. In aggregate for CHIP for § 457.1240(d), we estimate a one-time State burden of 55,360 hours (32 States × 1,730 hr) and \$5,546,784 (32 States × \$173,337). As this will be a one-time requirement, we annualize our time and cost estimates for CHIP to 18,453 hours and \$1,848,928. The annualization divides our estimates by 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 will take: 384 hours at \$120.14/hr for a software and web developers, programmers and testers to modify and test code; 256 hours at \$84.22/hr for a web developer to update and maintain the user interface; 120 hours at \$79.50/hr for a business operations specialist to manage the daily operations of the display; and 384 hours at \$98.58/hr for a database administrator 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 \$115,089 [(384 hr × \$120.14/hr) + (256 hr × \$84.22/hr) + (120 hr × \$79.50/hr) + (384 hr × \$98.58/hr)]. In aggregate for Medicaid, we estimate an annual State burden of 50,336 hours (1,144 hours × 44 States) at a cost of \$5,063,916 (\$115,089 × 44 States). In aggregate for CHIP for § 457.1240(d), we estimate an annual State burden of 36,608 hours (1,144 hr × 32 States) at a cost of \$3,682,842 (\$115,089 × 32 States).

Amendments to §§ 438.520(a)(2)(iv) and 457.1240(d) will require the display

to include quality ratings for mandatory measures which may be stratified by factors determined by CMS. We estimate it will take 24 hours at \$120.14/hr for a software and web developers, programmers, and testers 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 × 24 hr) at a cost of \$1,813,633, (15,096 hr × \$120.14/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 × 24 hr) at a cost of \$573,789 (4,776 hr × \$120.14/hr).

Amendments to § 438.520(a)(3)(v) will 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 will complete the secret shopper independent of the QRS requirements. To meet QRS requirements, States will 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 will take 16 hours at \$39.56/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 × 16 hr) at a cost of \$398,132 (10,064 hr × \$39.56/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 × 16 hr) at a cost of \$125,959 (3,184 hr × \$39.56/hr).

Amendments to §§ 438.520(b)(1) and 457.1240(d) allow the State to request a one-year extension on the implementation of certain website display requirements outlined in §§ 438.520(a). The extension request must: identify the specific requirement(s) for which the extension is requested; describe the barriers to the requirement's implementation; demonstrate that, despite making good-faith efforts to identify and begin executing an implementation strategy, the State has good reason to believe that it will be unable to meet the specified requirement(s) by the implementation date identified by CMS in this subpart.

The request must also include a detailed plan to implement the requirement(s) by the end of the extension including, but not limited to, the operational steps the State will take to address any identified implementation barrier(s). We assume that a small subset of States (11 States) will be unable to meet the QRS website requirements, and therefore, will submit an extension request. We estimate it will take 24 hours at \$118.14/hr for a general operations manager to draft and submit the extension request. In aggregate for Medicaid, we estimate an annual private sector burden of 264 hours (11 States × 24 hr) at a cost of \$31,189 (264 hr × \$118.14/hr).

We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

15. ICRs Regarding QRS Annual Reporting Requirements (Part 438 Subpart G and §§ 438.520(a) and 457.1240)

The following changes will be submitted to OMB for approval under control number 0938–1281 (CMS–10553). The following changes to § 457.1240 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.535(a) and 457.1240(b) will 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 will take 24 hours at \$79.50/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 × 24 hr) at a cost of \$83,952 (1,056 hr × \$79.50/hr). In aggregate for CHIP for § 457.1240(b), we estimate an annual State burden of 768 hours (32 States × 24 hr) at a cost of \$61,056 (768 hr × \$79.50/hr).

The addition of part 438, subpart G for Medicaid, and through an amendment at § 457.1240(d) for separate CHIP, will revise the quality rating system requirements and associated burden previously issued 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.

To implement an alternative Medicaid managed care QRS, we estimate it will take: 5 hours at \$39.56/hr for an office and administrative support worker, 25 hours at \$79.50/hr for a business operations specialist to complete the public comment process, and 5 additional hours at \$79.50/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 3 years.

Therefore, alleviating this burden will result in an annual Medicaid State reduction of minus 116.7 hours [(10 States \times 35 hr)/3 years] and minus \$8,609 (10 States \times [(5 hr \times \$39.56/hr) + (30 \times \$79.50/hr)]/3 years). Similarly, we estimate an annual CHIP State savings of minus 117 hours [(10 States \times 35 hr)/3 years] and minus \$8,609 [(10 States \times [(5 hr \times \$39.56/hr) + (30 \times \$79.50/hr)]/3 years)]. We did not receive any public comments on the aforementioned collection of information requirements and burden estimates and are finalizing them as proposed.

16. ICRs Regarding Program Integrity Requirements Under the Contract (§§ 438.608 and 457.1285)

The following changes to § 438.608 will be submitted to OMB for approval under control number 0938–1453 (CMS–10856). The following changes to § 457.1285 will be submitted to OMB for approval under control number 0938–1282 (CMS–10554).

Amendments to §§ 438.608 and 457.1285 will require States to update

all MCO, PIHP, and PAHP contracts to require managed care plans to report overpayments to the State within 30 calendar days of identifying or recovering an overpayment. We estimate that the changes to the timing of overpayment reporting (from timeframes that varied by State to 30 calendar days for all States) will apply to all MCO, PIHP, and PAHP contracts, excluding contracts for NEMT, that is, a total of 629 contracts for Medicaid, and 199 contracts for CHIP. We estimate it will take: 2 hours at \$79.50/hr for a business operations specialist and 1 hour at \$118.14/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 1,887 hours (629 contracts \times 3 hr) at a cost of \$174,321 [629 contracts \times ((2 hr \times \$79.50/hr) + (1 hr \times \$118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 629 hours and \$58,107.

In aggregate for CHIP for § 457.1285, we estimate a one-time State burden of 597 hours (199 contracts \times 3 hr) at a cost of \$55,151 [199 contracts \times ((2 hr \times \$79.50/hr) + (1 hr \times \$118.14/hr))]. As this will be a one-time requirement, we annualize our time and cost estimates to 199 hours and \$18,384. The annualization divides our estimates by 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 will take MCOs, PIHPs, and PAHPs 1 hour at \$120.14/hr for software and web

developers, programmers, and testers 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 629 hours (629 contracts \times 1 hr) at a cost of \$75,568 (629 hr \times \$120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 210 hours and \$25,189. In aggregate for CHIP for § 457.1285, we estimate a one-time private sector burden of 199 hours (199 contracts \times 1 hr) at a cost of \$23,908 (199 contracts \times \$120.14/hr). As this will be a one-time requirement, we annualize our time and cost estimates to 66 hours and \$7,969. The annualization divides our estimates by 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.

One public comment was received with regard to program integrity requirements under the contract (§§ 438.608 and 457.1285). A summary of the comment and our response follows:

Comment: One commenter noted that CMS should clarify if the proposed changes applied to NEMT PAHPs.

Response: We note that the proposed changes to overpayment reporting (from 10 calendar days to 30 calendar days) do not apply to NEMT PAHPs. We have updated the applicable number of contracts in these estimates to exclude NEMT contracts.

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TABLE 5: Summary of 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) contract modifications | 0938-1453 (CMS-10856) | 315 Medicaid contracts | 315 | 3 | 945 | Varies | 87,299 | Once | 315 | 29,100 |
| 438.3(i) provider incentive payment reporting | 0938-1453 (CMS-10856) | 315 Medicaid contracts | 315 | 120 | 37,800 | Varies | 3,491,964 | Once | 12,600 | 1,163,988 |
| 438.3(i) annual reconciliation | 0938-1453 (CMS-10856) | 315 Medicaid contracts | 315 | 3 | 945 | Varies | 87,299 | Once | 4,200 | 29,100 |
| 438.6(c)(2)(ii) New SDP submissions | 0938-1453 (CMS-10856) | 38 States | 50 | 10 | 500 | Varies | 47,932 | Annual | n/a | n/a |
| 438.6(c)(2)(ii) Renewal/Amend. SDP submissions | 0938-1453 (CMS-10856) | 38 States | 150 | 3 | 450 | Varies | 48,048 | Annual | n/a | n/a |
| 438.6(c)(2)(ii)(H) SDP Attestations | 0938-TBD (CMS-10856) | 44 States | 44 | 400 | 17,600 | Varies | 1,756,832 | Once | 133 | 585,611 |
| 438.6(c)(2)(ii)(H) SDP Attestations | 0938-TBD (CMS-10856) | 44 States | 44 | 434 | 19,118 | Varies | 1,116,424 | Annual | n/a | n/a |
| 438.6(c)(2)(ii)(H) SDP Attestations | 0938-TBD (CMS-10856) | 1,088,050 Providers | 1,088,050 | 0.1 | 108,805 | Varies | 10,123,217 | Annual | n/a | n/a |
| 438.6(c)(2)(iii) specific SDPs and ACR rate | 0938-1453 (CMS-10856) | 38 States | 60 | 15 | 900 | Varies | 108,680 | Once | 300 | 36,227 |
| 438.6(c)(2)(iv) SDP written eval plan | 0938-1453 (CMS-10856) | 38 States | 50 | 10 | 500 | Varies | 54,741 | Annual | n/a | n/a |
| 438.6(c)(2)(iv) eval plan for amendment and renewal | 0938-1453 (CMS-10856) | 38 States | 150 | 6 | 900 | Varies | 95,334 | Annual | n/a | n/a |
| 438.6(c)(2)(v) eval report spending greater than 1.5 percent and 438.6(c)(2)(ii)(f) – evaluation reports | 0938-1453 (CMS-10856) | 38 States | 57 | 6 | 282 | Varies | 36,341 | Annual | n/a | n/a |
| 438.6(c)(7) final SDP cost percentage actuarial report with rate certification | 0938-1453 (CMS-10856) | 10 States | 10 | 17 | 170 | Varies | 17,706 | Annual | n/a | n/a |
| 438.7(b) actuarial | 0938-1453 | 44 States | 253 | 250 | 63,250 | Varies | 6,719,558 | 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 (\$) |
|--|---------------------------------|--------------------------|----------------------|---------------------------|--------------------|--------------------|-----------------|-----------|-------------------------|-----------------------|
| rate submission | (CMS-10856) | | | | | | | | | |
| 438.8(k) annual MLR reports | 0938-0920 (CMS-10856) | 629 Medicaid contracts | 629 | 3 | 1887 | Varies | 176,775 | Annual | n/a | n/a |
| 438.10(c)(3) website | 0938-1453 (CMS-10856) | 45 States | 45 | 20 | 900 | 120.14 | 108,126 | Once | 300 | 36,042 |
| 438.10(c)(3) periodic update to website | 0938-1453 (CMS-10856) | 45 States | 45 | 40 | 1,800 | 120.14 | 216,252 | Annual | n/a | n/a |
| 438.16(c)(5)(ii) ILOS reporting | 0938-1453 (CMS-10856) | 22 States | 22 | 17 | 374 | Varies | 38,953 | Annual | n/a | n/a |
| 438.16(d)(1) documentation for ILOS in contract | 0938-1453 (CMS-10856) | 22 States | 327 | 1 | 327 | 79.50 | 25,997 | Annual | n/a | n/a |
| 438.16(d)(2) ILOS additional documentation | 0938-1453 (CMS-10856) | 5 States | 5 | 2 | 10 | 79.50 | 795 | Annual | n/a | n/a |
| 438.16(e)(1) ILOS evaluation | 0938-1453 (CMS-10856) | 5 States | 5 | 25 | 125 | 79.50 | 9,938 | Annual | n/a | n/a |
| 438.16(e)(2)(iii) ILOS transition of care policy | 0938-1453 (CMS-10856) | 22 States | 22 | 4 | 88 | varies | 8,784 | Once | 30 | 2928 |
| 438.16(e)(2)(iii) updates to ILOS policy | 0938-1453 (CMS-10856) | 22 States | 22 | 1 | 22 | 79.50 | 1,749 | Annual | n/a | n/a |
| 438.16(e)(2)(iii) ILOS termination transition policy | 0938-1453 (CMS-10856) | 65 MCOS, PIHPs and PAHPs | 65 | 2 | 130 | 79.50 | 10,335 | Annual | n/a | n/a |
| 438.66(c) enrollee experience survey – first year | 0938-1453 (CMS-10856) | 49 States | 49 | 110 | 5390 | Varies | 475,840 | Once | 1,796 | 158,614 |
| 438.66(c) conduct experience surveys | 0938-1453 (CMS-10856) | 49 States | 49 | 65 | 3185 | Varies | 281,608 | Annual | n/a | n/a |
| 438.66(e) annual program assessment report | 0938-1453 (CMS-10856) | 49 States | 49 | 80 | 3,920 | 79.50 | 311,640 | Annual | n/a | n/a |
| 438.68(e) network adequacy standards | 0938-1453 (CMS-10856) | 44 States | 44 | 20 | 880 | 79.50 | 69,960 | Once | 293 | 23,320 |
| 438.68(e) – network adequacy standards | 0938-1453 (CMS-10856) | 44 States | 44 | 10 | 440 | 79.50 | 34,980 | Annual | n/a | n/a |
| 438.68(f) secret shopper survey vendor | 0938-1453 (CMS-10856) | 44 States | 44 | 110 | 4840 | Varies | 427,284 | Once | 1,614 | 142,428 |

| 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 (\$) |
|--|---------------------------------|---------------------------|----------------------|---------------------------|--------------------|--------------------|-----------------|-----------|-------------------------|-----------------------|
| 438.68(f) contract management and analysis of results | 0938-1453 (CMS-10856) | 44 States | 44 | 65 | 2,860 | Varies | 252,872 | Annual | n/a | n/a |
| 438.74 Data aggregation for MLR reporting | 0938-1453 (CMS-10856) | 5 States | 5 | 5 | 25 | 79.50 | 1,988 | Once | 8 | 663 |
| 438.207(b)(3) payment analysis | 0938-1453 (CMS-10856) | 629 MCOS, PHIPs and PAHPs | 629 | 150 | 94,350 | Varies | 10,031,921 | Once | 31,449 | 3,343,974 |
| 438.207(b)(3) payment analysis | 0938-1453 (CMS-10856) | 629 MCOS, PHIPs and PAHPs | 629 | 45 | 28,305 | Varies | 2,883,021 | Annual | n/a | n/a |
| 438.207(d) assurance of compliance | 0938-1453 (CMS-10856) | 44 States | 44 | 40 | 1,760 | 79.50 | 139,920 | Annual | n/a | n/a |
| 438.310(c)(2), 438.350 removing PCCM EQR requirements | 0938-0786 (CMS-R-305) | 10 States | 10 | 379.6 | -3,796 | varies | -319,510 | Annual | n/a | n/a |
| 438.334(c)(1)(a) Alternative QRS | 0938-0786 (CMS-R-305) | 10 States | -10 | -35 | -117 | varies | -8,609 | Annual | n/a | n/a |
| 438.358(b)(2) PCCM EQR data preparation | 0938-0786 (CMS-R-305) | 10 PCCMs | -10 | -100 | -1,000 | varies | -59,530 | Annual | n/a | n/a |
| 438.358(c)(7) New optional EQR activity | 0938-0786 (CMS-R-305) | 58 MCOS, PHIPs and PAHPs | 58 | 80 | 4,640 | Varies | 451,880 | Annual | n/a | n/a |
| 438.360(a)(1) EQR plan accreditation requirements | 0938-0786 (CMS-R-305) | 65 MCOS, PHIPs and PAHPs | -65 | -409.33 | -26,606 | 79.50 | -2,115,177 | Annual | n/a | n/a |
| 438.364(a)(2)(iii) adding outcome data to EQR reports | 0938-0786 (CMS-R-305) | 654 MCOS, PHIPs and PAHPs | 654 | 1.5 | 981 | varies | 64,929 | Annual | n/a | n/a |
| 438.364(c)(2)(i) Notification of EQR report publishing | 0938-0786 (CMS-R-305) | 44 States | 44 | 0.5 | 22 | 79.50 | 1,749 | Annual | n/a | n/a |
| 438.364(c)(2)(iii) Archiving EQR reports for 5 years | 0938-0786 (CMS-R-305) | 44 States | 2452.5 | 0.0833 | 204 | 79.50 | 16,218 | Once | 68 | 5,406 |
| 438.515(a)(1) QRS measure collection | 0938-1282 (CMS-10553) | 629 MCOS, PHIPs and PAHPs | 629 | 1816 | 1,142,264 | Varies | 97,219,498 | 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 (\$) |
|---|---------------------------------|----------------------------|----------------------|---------------------------|--------------------|--------------------|-----------------|-----------|-------------------------|-----------------------|
| 438.515(a)(1)(i) QRS vendor contract updates | 0938-1282 (CMS-10553) | 44 States | 629 | 1.5 | 944 | Varies | 87,161 | Once | 315 | 29,054 |
| 438.515(a)(1)(ii) QRS FFS data collection | 0938-1282 (CMS-10553) | 5 States | 5 | 140 | 700 | varies | 80,034 | Annual | n/a | n/a |
| 438.515(a)(2) QRS measure validation | 0938-1282 (CMS-10553) | 629 MCOS, PHIPs and PAHPs | 629 | 16 | 10,064 | 79.50 | 800,088 | Annual | n/a | n/a |
| 438.515(d)(2) QRS optional methodology implementation extension | 0938-1282 (CMS-10553) | 7 States | 7 | 24 | 168 | 118.14 | 19,848 | Annual | n/a | n/a |
| 438.520(a) QRS website display creation | 0938-1282 (CMS-10553) | 44 States | 44 | 1730 | 76,120 | varies | 7,626,828 | Once | 25,373 | 2,542,276 |
| 438.520(a) QRS website display yearly maintenance | 0938-1282 (CMS-10553) | 44 States | 44 | 1,144 | 50,336 | varies | 5,063,916 | Annual | n/a | n/a |
| 438.520(a)(2)(iv) QRS measure stratification | 0938-1282 (CMS-10553) | 629 MCOS, PHIPs and PAHPs | 629 | 24 | 15,096 | 120.14 | 1,813,633 | Annual | n/a | n/a |
| 438.520(a)(3)(v) QRS secret shopper survey data entry | 0938-1282 (CMS-10553) | 629 MCOS, PHIPs and PAHPs | 629 | 16 | 10,064 | 39.56 | 398,132 | Annual | n/a | n/a |
| 438.520(b)(1) QRS optional website implementation extension | 0938-1282 (CMS-10553) | 11 States | 11 | 24 | 264 | 118.14 | 31,189 | Annual | n/a | n/a |
| 438.535(a) QRS annual reporting | 0938-1282 (CMS-10553) | 44 States | 44 | 24 | 1056 | 79.50 | 83,952 | Annual | n/a | n/a |
| 438.608(a)(2) – contract modifications | 0938–1453 (CMS–10856) | 629 Medicaid contracts | 629 | 3 | 1887 | Varies | 174,321 | Once | 629 | 58,107 |
| 438.608(a)(2) system updates | 0938–1453 (CMS–10856) | 629 MCOs, PIHPs, and PAHPs | 629 | 1 | 629 | 120.14 | 75,568 | Once | 210 | 25,189 |
| Total | | Varies | 18,956 | Varies | 1,529,955 | Varies | 136,346,234 | Varies | 75,213 | 7,130,225 |

TABLE 6: Summary of 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) additional documentation for ILOs in contract | 0938-1282 (CMS-10554) | 16 States | 100 | 1 | 100 | 79.50 | 7,950 | Annual | n/a | n/a |
| 457.1201(e) ILOS additional documentation | 0938-1282 (CMS-10554) | 5 States | 5 | 2 | 10 | 79.50 | 795 | Annual | n/a | n/a |
| 457.1201(e) ILOS evaluation | 0938-1282 (CMS-10554) | 5 States | 5 | 25 | 125 | 79.50 | 9,938 | Annual | n/a | n/a |
| 457.1201(e) ILOS transition of care policy | 0938-1282 (CMS-10554) | 16 States | 16 | 4 | 64 | Varies | 6,389 | Once | 21 | 2,130 |
| 457.1201(e) updates to ILOS policy | 0938-1282 (CMS-10554) | 16 States | 16 | 1 | 16 | 79.50 | 1,272 | Annual | n/a | n/a |
| 457.1201(e) ILOS termination transition policy | 0938-1282 (CMS-10554) | 40 CHIP contracts | 40 | 2 | 80 | 79.50 | 6,360 | Annual | n/a | n/a |
| 457.1203(f) contract modifications | 0938-1282 (CMS-10554) | 100 CHIP contracts | 100 | 3 | 300 | Varies | 27,714 | Once | 100 | 9,238 |
| 457.1203(f) provider incentive payment reporting | 0938-1282 (CMS-10554) | 100 CHIP contracts | 100 | 120 | 12,000 | Varies | 1,108,560 | Once | 4,000 | 369,520 |
| 457.1203(f) annual reconciliation | 0938-1282 (CMS-10554) | 100 CHIP contracts | 100 | 1 | 100 | 79.50 | 7,950 | Annual | n/a | n/a |
| 457.1203(f) annual MLR reports | 0938-1282 (CMS-10554) | 199 CHIP contracts | 199 | 3 | 597 | Varies | 55,927 | Annual | n/a | n/a |
| 457.1203(e) Data aggregation for MLR reporting | 0938-1282 (CMS-10554) | 5 CHIP contracts | 5 | 5 | 25 | 79.50 | 1,988 | Once | 8 | 663 |
| 457.1207 website | 0938-1282 (CMS-10554) | 32 States | 32 | 20 | 640 | 120.14 | 76,890 | Once | 213 | 25,630 |

| 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 (\$) |
|---|---------------------------------|---------------------------|----------------------|---------------------------|--------------------|--------------------|-----------------|-----------|-------------------------|----------------------|
| 457.1207 periodic updates to website | 0938-1282 (CMS-10554) | 32 States | 32 | 41 | 1,312 | 120.14 | 157,624 | Annual | n/a | n/a |
| 457.1218 network adequacy standards | 0938-1282 (CMS-10554) | 32 States | 32 | 20 | 640 | 79.50 | 50,880 | Once | 213 | 16,960 |
| 457.1218 network adequacy standards | 0938-1282 (CMS-10554) | 32 States | 32 | 10 | 320 | 79.50 | 25,440 | Annual | n/a | n/a |
| 457.1218 vendor for secret shopper | 0938-1282 (CMS-10554) | 32 States | 32 | 110 | 3,520 | Varies | 310,752 | Once | 1173 | 103,584 |
| 457.1218 contract management and analysis of results | 0938-1282 (CMS-10554) | 32 States | 32 | 65 | 2,080 | Varies | 183,907 | Annual | n/a | n/a |
| 457.1230(b) reimbursement analysis | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 150 | 29,850 | Varies | 3,173,851 | Once | 9,950 | 1,057,950 |
| 457.1230(b) analysis for amendments | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 45 | 8,955 | Varies | 912,117 | Once | 2,985 | 304,039 |
| 457.1230(b) assurance of compliance and posting survey summaries | 0938-1282 (CMS-10554) | 32 States | 32 | 44 | 1,408 | 79.50 | 111,936 | Annual | n/a | n/a |
| 457.1240(d) QRS measure collection | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 928 | 184,672 | Varies | 16,113,110 | Annual | n/a | n/a |
| 457.1240(d) QRS vendor contract updates | 0938-1282 (CMS-10554) | 32 States | 199 | 1.5 | 299 | Varies | 27,575 | Once | 99 | 9,192 |
| 457.1240(d) QRS measure validation | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 16 | 3,184 | 79.50 | 253,128 | Annual | n/a | n/a |
| 457.1240(d) QRS website | 0938-1282 (CMS-10554) | 32 States | 32 | 1,730 | 55,360 | Varies | 5,546,784 | Once | 18,453 | 1,848,928 |

| 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 (\$) |
|--|---------------------------------|---------------------------|----------------------|---------------------------|--------------------|--------------------|-----------------|-----------|-------------------------|----------------------|
| display creation | | | | | | | | | | |
| 457.1240(d) QRS website display yearly maintenance | 0938-1282 (CMS-10554) | 32 States | 32 | 1,144 | 36,608 | Varies | 3,682,842 | Annual | n/a | n/a |
| 457.1240(d) QRS measure stratification | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 24 | 4,776 | 120.14 | 573,789 | Annual | n/a | n/a |
| 457.1240(d) QRS secret shopper survey data entry | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 16 | 3,184 | 39.56 | 125,959 | Annual | n/a | n/a |
| 457.1240(d) QRS annual reporting | 0938-1282 (CMS-10554) | 32 States | 32 | 24 | 768 | 79.50 | 61,056 | Annual | n/a | n/a |
| 457.1240(d) Alternative QRS | 0938-1282 (CMS-10554) | (10 States) | (10) | (35) | (117) | Varies | (8,609) | Annual | n/a | n/a |
| 457.1250(a) adding outcome data to EQR reports | 0938-1282 (CMS-10554) | 199 MCOs, PIHPs and PAHPs | 199 | 1.5 | 299 | Varies | 19,757 | Annual | n/a | n/a |
| 457.1250(a) Notification of EQR report publishing | 0938-1282 (CMS-10554) | 32 States | 32 | .5 | 16 | 79.50 | 1,272 | Annual | n/a | n/a |
| 457.1250(a) Archiving EQR reports for 5 years | 0938-1282 (CMS-10554) | 32 States | 746 | .0833 | 62 | 79.50 | 4,929 | Once | 21 | 1,643 |
| 457.1250(a) removing PCCM EQR requirements | 0938-1282 (CMS-10554) | (7 States) | (7) | (407) | (2,849) | Varies | (238,003) | Annual | n/a | n/a |
| 457.1250(a) PCCM EQR data preparation | 0938-1282 (CMS-10554) | (2 PCCMs) | (2) | (100) | (200) | Varies | (11,906) | Annual | n/a | n/a |
| 457.1250(a) New optional EQR activity | 0938-1282 (CMS-10554) | 20 MCOs, PIHPs and PAHPs | 20 | 80 | 1600 | Varies | 155,821 | Annual | n/a | n/a |
| 457.1285 contract | 0938-1282 (CMS-10554) | 199 CHIP contracts | 199 | 3 | 597 | Varies | 55,151 | Once | 199 | 18,384 |

| 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 (\$) |
|--|--|-------------------------|-----------------------------|----------------------------------|---------------------------|---------------------------|------------------------|------------------|--------------------------------|-----------------------------|
| modifications | | | | | | | | | | |
| Total | | Varies | 3,576 | Varies | 350,401 | Varies | 32,600,895 | Varies | 37,435 | 3,767,861 |

TABLE 7: Summary of Medicaid and CHIP Requirements and Burden

| | 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 (\$) |
|----------|--|------------------|----------------------|---------------------------|--------------------|--------------------|-----------------|-----------|-------------------------|----------------------|
| Medicaid | 0938–1453(CMS–10856) 0786 (CMS-R-305) 1282 (CMS-10553) | Varies | 18,956 | Varies | 1,529,955 | Varies | 136,346,234 | Varies | 75,213 | 7,130,225 |
| CHIP | 0938-1282 (CMS-10554) | Varies | 3,576 | Varies | 350,401 | Varies | 32,600,895 | Varies | 37,435 | 3,767,861 |
| Total | | Varies | 22,532 | Varies | 1,880,356 | Varies | 168,947,129 | Varies | 112,648 | 10,898,086 |

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III. Regulatory Impact Analysis

A. Statement of Need

This final rule will advance CMS's efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and CHIP managed care enrollees. The final rule will 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 will apply when States use ILOSs to promote effective utilization and identify the scope and nature of ILOS, specify MLR requirements, and establish a 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 will meaningfully further the President's priorities or the

principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant under Section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), OMB's Office of Information and Regulatory Affairs has determined that this final rule does meet the criteria set forth in 5 U.S.C. 804(2). 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 final rule are expected to minimally or moderately increase administrative burden and associated costs as we note in the COI (see section II. of this final rule). Aside from our analysis on burden in the COI, we believed that certain provisions in this final 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 and 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 CY 2017, CMS received 36 preprints for our review and approval from 15 States; in CY 2021, CMS received 223 preprints from 39 States. For CY 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 MACPAC reported that CMS approved SDPs in 37 States, with spending exceeding more than \$25 billion.²³⁵ The U.S. Government Accountability Office 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.²³⁶

We have tracked SDP spending trends as well. Using the total spending captured for each SDP through the end of 2023, we calculate that SDP payments in 2022 were \$52.2 billion and that such payments were \$78.1 billion in 2023. We note that 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.

²³⁵ 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.

²³⁶ 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>.

We estimate that SDP spending comprises approximately 15.6 percent of total managed care payments in 2023 (\$499.8 billion) and 9.0 percent of total Medicaid benefit expenditures (\$869.7 billion). SDP spending varies widely across States. Thirty-nine (39) States reported the use of one or more SDPs in 2022 and/or 2023. In 2022, the percentage of Medicaid managed care spending paid through SDPs ranged from 1 percent to 58 percent across these States, 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. (Data for 2023 is not yet available.)

From 2016 through 2023, SDPs were a significant factor in Medicaid expenditure growth. Total benefit spending increased at an average annual rate of 6.8 percent per year from 2016 through 2023; excluding SDPs, benefit spending grew at an average rate of 5.4 percent. Managed care payments grew 9.6 percent on average over 2016 to 2023, but excluding SDPs, the average growth rate was 6.9 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 2023 we expect that much of this is new spending.

In 2023, we estimate that about 70 percent of SDP spending went to hospitals for inpatient and outpatient services, and another 4 percent went to academic medical centers. 10 percent of SDP spending was reported for multiple provider types, which mostly were hospitals and academic medical centers. The remaining 16 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 FFS 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 believed much of the earlier SDP spending was largely existing Medicaid spending that was transitioned to managed care SDPs. However, in more recent years, we believed that most SDP spending reflects new expenditures. For context, States reported \$6.7 billion in pass-through payments after the 2016 final rule.²³⁷ States also have reported only a small decrease in FFS supplemental payments since 2016 (from \$28.7 billion in 2016 to \$27.5 billion in 2022).²³⁸ SDP spending in 2023 significantly exceeds the originally reported pass-through payments and the changes in FFS 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 final 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 \$15 billion to \$20 billion of SDPs in 2023 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 will be near the ACR. These will include SDPs with effective payment rates of 150 percent or more of the Medicare rate (with several over 200 percent).

Under current policy, we project that SDP spending will increase from \$78 billion in 2023 (or 15.6 percent of managed care spending) to about \$99 billion by 2029 (or 16.5 percent of managed care spending).

TABLE 8: Projected Medicaid Managed Care and State Directed Spending Under Current Policy, FY 2022-2029 (\$ Billions)

| | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 |
|------------------------------|-------|-------|--------|--------|--------|--------|--------|--------|
| Managed care spending | \$442 | \$488 | \$457 | \$467 | \$498 | \$530 | \$565 | \$602 |
| SDP spending | \$52 | \$78 | \$74 | \$76 | \$82 | \$88 | \$93 | \$99 |
| SDP as share of managed care | 11.8% | 16.0% | 16.2 % | 16.4 % | 16.4 % | 16.5 % | 16.5 % | 16.5 % |

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

²³⁷ Our data reflects documentation provided from 15 States with pass-through payments in rating periods beginning from July 1, 2017 through June 30, 2018.

²³⁸ CMS-64. <https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbesches/index.html>.

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 will 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 will 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.

Fourth, how states finance these arrangements may also have some effect on the increase in spending through SDPs. The final rule requires states to obtain provider attestations of compliance with Federal restrictions on hold harmless arrangements no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028. We acknowledge that States may be motivated to submit SDP preprints at a higher than usual rate prior to the effective date of these provisions.

For these reasons, we believe it is prudent to provide a range of estimated impacts for this section of the final rule. The following estimates reflect a reasonable expectation of the impacts of this final rule on Medicaid expenditures, but do not necessarily include all possible outcomes.

The estimate of the upper end of the range is based on the expectation that the provisions of the final rule will prompt States to increase SDP spending. We believed 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. The high end of the range also reflects possible short-term increases of SDPs prior to the effective date of the hold harmless requirements.

For the high scenario, we assumed that Medicaid SDP spending will increase at a faster rate than projected under current law. Under current law, Medicaid SDP spending is projected to reach 16.5 percent of managed care spending by 2027. We assumed in the

high scenario that SDP spending will reach about 22.8 percent of managed care spending in 2027, and then decrease to 21.5 percent in 2028 as the financing requirements go into effect. Under this scenario, SDP spending will increase by approximately 49 percent by 2027 (or about \$43 billion). From 2025 through 2027, SDP spending will increase somewhat faster than assumed under current law to reach those levels. This increase will include additional spending from current SDPs increasing payment rates to the ACR and may also include new or expanded SDPs. We also expected that this will 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. We project that SDPs would increase by \$129.6 billion over 2024 through 2028 in the high case.

In the proposed rule, we estimated that the low end of the range of impacts for the changes to SDPs would be 0. However, we have updated our estimates in the final rule for the low end of the range to reflect an increase in expenditures. In particular, some States have already indicated that they would increase SDPs with the clarification that CMS would allow effective payment rates up to ACR. As a result, we believe that it is more accurate to estimate for the low case that there are some increases in spending. We estimate that the low end of the range of impacts for these provisions in the final rule would be half of the impact of the high end of the range. We project that SDPs would increase by \$27.0 billion over 2024 through 2028 in the low case.

The median estimates of these two cases are the middle scenario. The estimated impacts are provided in Table 9.

TABLE 9: Projected Medicaid State Directed Payment Spending Under Final Rule, High, Middle, and Low Scenarios, FY 2024-2028 (\$ Billions)

| | 2024 | 2025 | 2026 | 2027 | 2028 | 2024-2028 |
|------------------------|--------|--------|---------|---------|---------|-----------|
| Current law | \$74.2 | \$76.4 | \$81.8 | \$87.5 | \$93.2 | \$413.1 |
| High scenario | \$75.4 | \$90.6 | \$117.2 | \$130.5 | \$129.0 | \$542.7 |
| High scenario impact | \$1.2 | \$14.2 | \$35.4 | \$43.0 | \$35.8 | \$129.6 |
| Middle scenario | \$74.9 | \$86.0 | \$102.6 | \$112.8 | \$115.1 | \$491.4 |
| Middle scenario impact | \$0.7 | \$9.6 | \$20.8 | \$25.3 | \$21.9 | \$78.3 |
| Low scenario | \$74.4 | \$81.4 | \$88.0 | \$95.1 | \$101.2 | \$440.1 |
| Low scenario impact | \$0.2 | \$5.0 | \$6.2 | \$7.6 | \$8.0 | \$27.0 |

Note: The impact represents the difference between the projected SDP spending under each scenario and the current law projections.

In Table 10, we provide estimates of the impacts on the Federal government and on States.

TABLE 10: Projected Medicaid State Directed Payment Spending Under Final Rule by Payer, High, Middle, and Low Scenarios, FY 2024-2028 (\$ Billions)

| | 2024 | 2025 | 2026 | 2027 | 2028 | 2024-2028 |
|------------------------|-------|--------|--------|--------|--------|-----------|
| <i>High Scenario</i> | | | | | | |
| Total Impact | \$1.2 | \$14.2 | \$35.4 | \$43.0 | \$35.8 | \$129.6 |
| Federal Impact | \$0.8 | \$9.2 | \$23.0 | \$27.9 | \$23.0 | \$83.9 |
| State Impact | \$0.4 | \$5.0 | \$12.4 | \$15.1 | \$12.8 | \$45.7 |
| <i>Middle Scenario</i> | | | | | | |
| Total Impact | \$0.7 | \$9.6 | \$20.8 | \$25.3 | \$21.9 | \$78.3 |
| Federal Impact | \$0.5 | \$6.2 | \$13.5 | \$16.4 | \$14.1 | \$50.7 |
| State Impact | \$0.2 | \$3.4 | \$7.3 | \$8.9 | \$7.8 | \$27.6 |
| <i>Low Scenario</i> | | | | | | |
| Total Impact | \$0.2 | \$5.0 | \$6.2 | \$7.6 | \$8.0 | \$27.0 |
| Federal Impact | \$0.1 | \$3.3 | \$4.1 | \$4.9 | \$5.2 | \$17.6 |
| State Impact | \$0.1 | \$1.7 | \$2.1 | \$2.7 | \$2.8 | \$9.4 |

Under the high scenario, we project that Federal spending would increase \$83.9 billion over 2024 through 2028, and States spending would increase by \$45.7 billion. For the middle scenario, projected Federal spending would be \$50.7 billion higher from 2024 through 2028, and projected State spending would be \$27.6 billion higher over these 5 years. In the low scenario, we project the Federal impact would be \$17.6 billion over the next 5 years, and the impact on the States would be \$9.4 billion over that time period. We note that the States will 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 certain financing provisions are not effective in this final rule until 2028, 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 final 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 believed 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 did not have quantitative data to analyze the impact of these provisions. However, based on a qualitative analysis of our work with States, we believed these regulatory changes will 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 anticipated 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 anticipated this will change the types of SDPs States seek, encouraging them to pursue VBP models, that will 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 did 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, the elimination of the use of separate payment terms, and eliminating States' ability to use reconciliation processes. We expect that these provisions will not have any significant effect on Medicaid expenditures.

Aside from spending, we believe many of the proposals in section I.B.2. of this final rule will 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 final 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 final rule) should remove unnecessary barriers for States implementing VBP initiative. 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 final rule) to require specific information in managed care plan contracts will 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 believed our SDP related proposals in this rule will enable us to ensure that SDPs will 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 will provide a more robust set of regulations for SDPs and are informed by 6 years of experience reviewing and approving SDP preprints. We believe the resulting regulations will enable more efficient and effective use of Medicaid managed care funds.

We summarize and respond to public comments received on detailed economic analysis below.

Comment: Several commenters were critical of the analysis in the proposed rule. Some commenters were critical of the analysis because they claimed that the provisions in the rule would reduce payments and access to care and harm beneficiaries. Some requested analyses on the impact by individual hospital, by population, and by State.

Response: We disagree with the commenters' assertions that these provisions would reduce spending and access to care. As we note, we expect that these provisions will increase spending, not decrease spending. To date, CMS is not aware of any SDP that results in effective payment rates in excess of ACR. We also believe it would be impossible to project how changes in the rule would lead to changes by provider given the large amount of discretion States continue to have regarding SDP.

After reviewing the public comments, we are finalizing this section of the regulatory impact analysis with changes described above.

2. Medical Loss Ratio (MLR) and Program Integrity Standards (§§ 438.3, 438.8, 438.74, 457.1201, 457.1203, 457.1285)

We proposed 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 will result in transfers from such managed care plans to States in the form of higher remittances or lower capitation rates. Although we did 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,²³⁹ we estimated 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 will increase remittances paid by managed care plans to States by approximately \$12 million per year (total computable).

We proposed 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 will 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 did not know how many managed care plans include indirect expenses in QIA, using information from a previous CCIIO RIA analysis,²⁴⁰ we estimated 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

²³⁹ 87 FR 703.

²⁴⁰ 87 FR 703.

clarification will increase remittances paid by managed care plans to States by approximately \$49.8 million per year.

We proposed 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 were 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.

At the low end of the range, we projected that there will be no impact on Medicaid expenditures. In these cases, we will assume (1) most States

currently base provider incentive payments on performance metrics; and (2) most States currently monitor QIA for unallowable administrative expenditures. At the high end of the range, we projected that there will be some increase in Medicaid remittances, that is, savings to States and the Federal government. In total these changes would increase remittances by \$61.8 million in 2024. We project that remittances would increase by \$373 million between 2024 and 2028. The estimates are provided in Table 10.

TABLE 11: Projected Changes in Medicaid MLR remittances Under Final Rule by Payer, FY 2024-2028 (\$ Billions)

| | 2024 | 2025 | 2026 | 2027 | 2028 | 2024-2028 |
|--------------------|----------|----------|----------|----------|----------|-----------|
| Total impact | (\$0.06) | (\$0.07) | (\$0.07) | (\$0.08) | (\$0.09) | (\$0.37) |
| Federal government | (\$0.04) | (\$0.04) | (\$0.05) | (\$0.05) | (\$0.06) | (\$0.23) |
| States | (\$0.02) | (\$0.02) | (\$0.03) | (\$0.03) | (\$0.03) | (\$0.14) |

We proposed to amend § 438.8(e) and (f) to require managed care plans to report SDPs to States 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 will allow for modeling the effect of the line-item reporting on remittances, we were unable to quantify the benefits and costs of this proposed change. We expected that this proposed change may result in transfers from States and the Federal government to managed care plans in the form of lower remittances or higher capitation rates.

We did not receive any comments in response to our regulatory impact analysis on our proposed Medical Loss Ratio (MLR) and program integrity standards (§§ 438.3, 438.8, 438.74, 457.1201, 457.1203, 457.1285). Therefore, we are finalizing these provisions as described in section I.B.3. of this final rule.

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 will 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 will 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)²⁴¹ that described opportunities

²⁴¹ Opportunities in Medicaid and CHIP to Address Social Determinants of Health, <https://www.medicare.gov/federal-policy-guidance/downloads/sho21001.pdf>.

under Medicaid and CHIP to better address SDOH. Additionally, on January 4, 2023, CMS published a State Medicaid Director (SMD) letter (SMD# 23-001)²⁴² 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 will 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

www.medicare.gov/federal-policy-guidance/downloads/sho21001.pdf.

²⁴² Additional Guide on Use of In Lieu of Services and Settings in Medicaid Managed Care, <https://www.medicare.gov/federal-policy-guidance/downloads/smd23001.pdf>.

information on the additional ILOSs that States may use. Therefore, we provided a range of potential impacts for this section as well.

At the low end of the range, we projected that there will be no impact on Medicaid expenditures. In these cases, we will 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 projected that there will be some increase in Medicaid spending. We made the following assumptions for the high scenario: (1) half of States will use

new ILOSs; (2) States will increase use of ILOSs to 2 percent of total Medicaid managed care spending; and (3) additional ILOSs will offset 50 percent of new spending. Table 12 shows the impacts in the high scenario.

TABLE 12: Projected Medicaid ILOS spending under final rule by payer, high scenario, FY 2024-2028 (\$ Billions)

| | 2024 | 2025 | 2026 | 2027 | 2028 | 2024-2028 |
|--------------------|-------|-------|-------|-------|-------|-----------|
| Total impact | \$0.0 | \$0.8 | \$1.8 | \$2.8 | \$3.0 | \$8.4 |
| Federal government | \$0.0 | \$0.5 | \$1.1 | \$1.8 | \$1.9 | \$5.3 |
| States | \$0.0 | \$0.3 | \$0.6 | \$1.0 | \$1.1 | \$3.0 |

We also believed 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.

We did not receive any public comments on in Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120) in response to our proposals. Therefore, we are finalizing these provisions as proposed.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 final rule. We received 415 unique comments on the proposed 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 proposed 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 commenters was 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 final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimated that the cost of reviewing this rule is \$100.80 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimated that it will take approximately 20 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is \$4,032. Therefore, we estimated that the total cost of reviewing this regulation is \$2 million.

We did not receive any comments in response to our proposals on regulatory review cost estimation. Therefore, we are finalizing this estimate as proposed.

D. Alternatives Considered

1. State Directed Payments (SDPs)

As discussed in section I.B.2.f. of this final rule on provider payment limits, we considered 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 considered include the Medicare rate, some level between Medicare and the ACR, or a Medicare equivalent of the ACR. We also considered an alternative that will 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 also considered and sought 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 (c)(1)(iii)(C) through (E) at the Medicare rate. For each of these alternatives, we acknowledged 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.

Public comments received on the alternatives described above are responded to in detail in section I.B.2.f. of this final rule. We are finalizing these provisions as described in section I.B.2.f. of this final rule.

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 will impose significant burden on States as it will 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 proposed 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.

Public comments received on the alternatives to MLR-related changes, except those relating to SDP reporting, are responded to in detail in section I.B.3. of this final rule. We are finalizing those provisions as described in section I.B.3. of this final rule. Public comments received on the alternatives to MLR-related changes for SDP reporting are responded to in section I.B.2.o. of this final rule. We are finalizing those provisions as described in section I.B.2.o. of this final rule.

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 did not believe the current regulation ensures appropriate enrollee and fiscal protections. As a result, we proposed 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.

We did not receive any public comments in response in lieu of services and settings (ILOSs) (§§ 438.2, 438.3, 438.16, 457.1201, 457.120) below. Therefore, we are finalizing these provisions as proposed.

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 13 showing the classification of the impact associated with the provisions of this final 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 plans 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 believed that *this* is a reasonable estimate of the potential impacts under this final 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 13.

TABLE 13: Accounting Statement [\$ Millions of 2024 dollars]

| Benefits | | | | | | |
|---|--|--------------|---------------|--------------|---------------|-------------------------------|
| Non-Quantified | This final rule will 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 (Fiscal years) |
| From Federal Government to Providers | \$9,626 | \$3,358 | \$15,912 | 2024 | 7% | 2024-2028 |
| | \$9,917 | \$3,450 | \$16,404 | 2024 | 3% | 2024-2028 |
| From States to Providers | \$5,230 | \$1,792 | \$8,649 | 2024 | 7% | 2024-2028 |
| | \$5,391 | \$1,842 | \$8,922 | 2024 | 3% | 2024-2028 |
| From Federal Government to Beneficiaries | \$495 | \$0 | \$991 | 2024 | 7% | 2024-2028 |
| | \$515 | \$0 | \$1,030 | 2024 | 3% | 2024-2028 |
| From States to Beneficiaries | \$280 | \$0 | \$561 | 2024 | 7% | 2024-2028 |
| | \$291 | \$0 | \$583 | 2024 | 3% | 2024-2028 |
| From Managed Care Plans to Federal Government | \$24 | \$0 | \$47 | 2024 | 7% | 2024-2028 |
| | \$24 | \$0 | \$48 | 2024 | 3% | 2024-2028 |
| From Managed Care Plans to States | \$13 | \$0 | \$26 | 2024 | 7% | 2024-2028 |
| | \$13 | \$0 | \$26 | 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 final 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.²⁴³ 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.²⁴⁴ These data also

showed that 32 States use managed care entities for CHIP enrollment contracting with 199 managed care entities.²⁴⁵

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

²⁴³ 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.

²⁴⁵ Results of managed care survey of States completed by Centers for Medicare & Medicaid Services, Center for Medicaid and CHIP Services, Children and Adults Health Programs Group, Division of State Coverage Programs, 2017.

²⁴³ Medicaid Managed Care Enrollment and Program Characteristics (2020).

²⁴⁴ Centers for Medicare and Medicaid Services, Statistical Enrollment Data System (2017), Quarterly Enrollment Data Form 21E: Number of Children Served in Separate CHIP Program/

may be small entities as that term is used in the RFA. We believed that only a few managed care plans may qualify as small entities. Specifically, we believed that approximately 14–25 managed care plans may be small entities. We believed 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 did not believe that this final 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 plans on a per entity basis is approximately \$54,500. This final 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 final rule will 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 will 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 did not believe that this threshold will be reached by the requirements in this final rule. Therefore, the Secretary has certified that this final 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 604 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 final 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 invited comment on our proposed analysis of the impact on small rural hospitals regarding the provisions of this final 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 final 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.

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 2024, that is approximately \$183 million. This final 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 final rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of \$183 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We believed this proposed regulation gives States appropriate flexibility regarding managed care standards (for example, setting network adequacy standards, setting credentialing standards, EQR activities), while also

better aligning Medicaid and CHIP managed care standards with those for QHPs in the Marketplaces 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 final rule will not significantly affect States' rights, roles, and responsibilities.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

I. Waiver Fiscal Responsibility Act Requirements

The Director of OMB has waived the requirements of section 263 of the Fiscal Responsibility Act of 2023 (Pub. L. 118–5) pursuant to section 265(a)(2) of that Act.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on February 28, 2024.

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 amends 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 adding paragraph (e) to read as follows:

§ 430.3 Appeals under Medicaid.

* * * * *

(e) Disputes that pertain to disapproval of written 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;

■ b. Revising paragraph (9) in the definition of “Primary care case management entity (PCCM entity)”; and

■ c. Adding the definition of “State directed payment (SDP)” in alphabetical order.

The additions 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.

* * * * *

State directed payment (SDP) means a contract arrangement that directs an MCO’s, PIHP’s, or PAHP’s expenditures under § 438.6(c).

* * * * *

■ 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 clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that the provider must meet to receive the incentive payment.

(iv) Specify a dollar amount or a percentage of a verifiable 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) of this section, 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) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following July 9, 2024, and paragraphs (i)(3) and (4) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 1 year following July 9, 2024.

■ 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,” “Nursing facility services,” “Outpatient hospital services,” “Performance measure,” “Population-based payment,” “Qualified practitioner services at an academic medical center,” “Total payment rate,” “Total published Medicare payment rate,” and “Uniform increase” in alphabetical order; and

■ b. By revising paragraphs (c) and (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 under the contract.

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).

Nursing facility services means the same as specified in § 440.40(a).

Outpatient hospital services means the same as specified in § 440.20(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 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.

* * * * *

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, to be 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) General rule.* Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation

implementing a Title XIX provision related to payments to providers, that is applicable to managed care programs, the State may not in any way direct the MCO’s, PIHP’s or PAHP’s expenditures under the contract.

(i) The State may require the MCO, PIHP or PAHP to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require MCOs, PIHPs, or PAHPs to participate in a multi-payer or Medicaid-specific delivery system reform or performance improvement initiative.

(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 and, upon request from CMS, the State must provide an evaluation report documenting achievement of these stated goals and objectives;

(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)(1) Ensure that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement for 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 taxpayer harmless for all or any portion of the tax amount, and

(2) Ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations;

(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 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 of the State directed payment 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 maintenance or 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 based 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 treatment during the rating period;

(2) If basing payment on the attribution of enrollees to a provider, have an attribution methodology that uses 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 complete and submit all required documentation for each State directed payment for which written prior approval is required under (c)(2)(i) and for each amendment to an approved State directed payment, respectively, before the start date of the State directed payment or the start date of the amendment.

(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 1 year after each rating period, data to the Transformed Medicaid Statistical Information System, or 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 first rating period that begins after the release of reporting instructions by CMS.

Minimum data fields to be collected include the following, as applicable:

(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, 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:

(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:

(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) All State directed payments must be specifically described and

documented in the MCO's, PIHP's, and PAHP's contracts that must be submitted to CMS no later than 120 days after the start date of the State directed payment.

(6) *Payment to MCOs, PIHPs, and PAHPs for State Directed Payments.* The final capitation rate for each MCO, PIHP, or PAHP as described in § 438.3(c) must account for all State directed payments. Each State directed payment must be accounted for in the base data, as an adjustment to trend, or as an adjustment as specified in § 438.5 and § 438.7(b). The State cannot withhold a portion of the capitation rate to pay the MCO, PIHP, or PAHP separately for a State directed payment nor require an MCO, PIHP, or PAHP to retain a portion of the capitation rate separately to comply with a State directed payment.

(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 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).

(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), (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) of this section beginning on July 9, 2024.

(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 July 9, 2024.

(iii) Paragraphs (c)(2)(vi)(C)(3) and (4), (c)(2)(viii) and (c)(5)(i) through (iv) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after July 9, 2024.

(iv) Paragraphs (c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v), (c)(2)(vii), (c)(6) 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 July 9, 2024.

(v) Paragraph (c)(5)(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 July 9, 2024.

(vi) Paragraph (c)(4) of this section no later than the date specified in the T-MSIS reporting instructions released by CMS.

(vii) Paragraph (c)(2)(ii)(H) of this section no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028.

* * * * *

(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).

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) of this section, 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 must be submitted no later than 120 days after the start date of the State directed payment.

* * * * *

(f) 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 July 9, 2024. 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) Paragraph (c)(6) 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 July 9, 2024.

■ 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); and
■ e. Revising paragraphs (h)(4) introductory text and (k)(1)(vii).

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 to providers under State directed payments described in § 438.6(c).

* * * * *

(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 under State directed payments described in § 438.6(c).

* * * * *

(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).

* * * * *

- 9. Amend § 438.10 by—
- a. Revising paragraphs (c)(3), (d)(2), (g)(2)(ix), and (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 web pages, specified at § 438.602(g) and elsewhere in this part. States must:

- (i) Include clear and easy to understand labels on documents and links;
- (ii) Include all content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, on one web page;
- (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, 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 paragraphs (h)(3)(i) and (ii) of this section.

* * * * *

(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 July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(c)(3) (effective as of October 1, 2023). 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 July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(d)(2) (effective as of October 1, 2023). 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 42 CFR 438.10(h)(1) (effective as of October 1, 2023). 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 July 9, 2024.

* * * * *

■ 10. Section 438.16 is added 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, all State directed payments in effect under § 438.6(c), and pass-through payments in effect under § 438.6(d).

(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, all State directed payments in effect under § 438.6(c), and pass-through payments in effect under § 438.6(d).

(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 substitute by the State;

(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 is required to submit at least one retrospective evaluation of all ILOSs to CMS when the final ILOS cost percentage exceeds 1.5 percent in any of the first 5 rating periods that each ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) following the applicability date in paragraph (f) of this section, or as required in paragraph (v) of this section. The retrospective evaluation must:

(i) Be completed separately for each managed care program that includes an ILOS and include all ILOSs in that managed care program.

(ii) Be completed using 5 years of accurate and validated data for the ILOS with the basis of the data being the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii). 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 later of either the completion of the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under § 438.3(e)(2)(iii) or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent.

(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 part.

(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.* Within 30 calendar days of receipt of a notice described in paragraph (e)(2)(iii)(A), (B), or (C) of this section, the State must submit an ILOS transition plan to CMS for review and approval.

(A) The notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS;

(B) The notice an MCO, PIHP, or PAHP provides to the State of its decision to cease offering an ILOS to its enrollees.

(C) The notice CMS provides to the State of its decision to require the State to terminate an ILOS.

(iv) *Requirements for an ILOS Transition Plan.* 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 July 9, 2024.

■ 11. Amend § 438.66 by revising paragraphs (b)(4), (c)(5), (e)(2)(vi) and (vii), (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 (or as otherwise conducted when all enrollees are also in affiliated Medicare Advantage dual eligible special needs plans subject to the condition in § 422.107(e)(1)(ii) 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 website required under § 438.10(c)(3) within 30 calendar days of submitting it to CMS.

* * * * *

(f) *Applicability.* States will not be held out of compliance with the requirements of paragraphs (b)(4), (c)(5), and (e)(2)(vii) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) 42 CFR 438.66 (effective as of October 1, 2023).

■ 12. Amend § 438.68 by—

■ a. Revising paragraphs (b)(1) introductory text, (b)(1)(iii), (d)(1) and (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 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 or for the service 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 or service 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 for the following services 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 timeframes 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 timeframes 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 timeframes 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 and covered in the MCO's, PIHP's, or PAHP's contract, chosen in an evidence-based manner within State-established timeframes.

(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 this section of at least 90 percent.

(3) *Selection of additional types of services.* After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of services 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)(2) 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 that provides the service type chosen by the State in paragraph (e)(1)(iv) of this section.

(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 for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.68 (b) (effective as of October 1, 2023).

Paragraph (d)(1)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July

9, 2024. States will not be held out of compliance with the requirements of paragraph (d)(2) and of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.68 (d)(2) (effective as of October 1, 2023). Paragraph (e) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024. 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 July 9, 2024. 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 July 9, 2024, so long as they comply with the corresponding standard(s) codified in paragraph 42 CFR 438.68 (g) (effective as of October 1, 2023).

■ 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.

* * * * *

■ 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 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.206(c)(1)(i) (effective as of October 1, 2023).

■ 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) through (f); and

■ e. By 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 an annual payment analysis using paid claims data from the immediate 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 immediate prior rating period for primary care, obstetrical and gynecological, mental health, and substance use disorder services, as well as the percentage that results from dividing the total amount paid by the 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, personal care services, and habilitation 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, personal care services, and habilitation 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) and (ii) 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) Sufficiently in advance to enable CMS to make a determination that the contract entered into as specified at § 438.207(c)(1) is approved under § 438.3(a).

(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's 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 MCO's, PIHP's, or PAHP's 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 July 9, 2024. Paragraph (d)(3) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (e) of this section prior to the

rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 year after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.207 (e) (effective as of October 1, 2023) 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 July 9, 2024.

■ 16. Amend § 438.214 by revising paragraph (b)(1) and adding paragraph (d)(2) to 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 July 9, 2024:

(1) States must comply with updates to § 438.340(c) no later than 1 year from July 9, 2024.

(2) States must comply with updates to §§ 438.358(a)(3), 438.358(b)(1) and

438.364(c)(2)(iii) no later than December 31, 2025.

(3) 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 website 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.

* * * * *

■ 21. 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.

* * * * *

■ 22. 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;

* * * * *

■ 23. Amend § 438.358 by—

■ a. Revising paragraph (a)(1);

■ b. Adding paragraph (a)(3);

■ c. Revising and republishing paragraph (b)(1);

■ d. Revising paragraphs (b)(2); and

■ e. Revising and republishing paragraph (c).

The revisions and addition 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 paragraph (b)(1) of this section (except paragraph (b)(1)(iii) of this section), 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.

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.

(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) For each PCCM entity (described in § 438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section may be performed.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed:

(1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in § 438.310(c)(2)).

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO, PIHP, or PAHP and validated by an EQRO in accordance with paragraph (b)(1)(ii) of this section.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP or PAHP and/or validated by an EQRO in accordance with paragraph (b)(1)(i) of this section.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(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.

* * * * *

■ 24. 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;

* * * * *

■ 25. Amend § 438.362 by revising and republishing paragraph (b)(2) 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.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

* * * * *

■ 26. Amend § 438.364 by—

■ a. Revising paragraphs (a)(1), (a)(2)(iii), (a)(3) through (6), and (c)(2)(i) and (ii); and

■ b. Adding paragraph (c)(2)(iii).

The revisions and addition 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) * * *

(2) * * *

(i) Post the most recent copy of the annual EQR technical report on the website required under § 438.10(c)(3) by April 30th 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 website required under § 438.10(c)(3).

* * * * *

■ 27. Add subpart G to part 438 to read as follows:

Subpart G—Medicaid Managed Care Quality Rating System

- Sec.
- 438.500 Definitions.
- 438.505 General rule and applicability.
- 438.510 Mandatory QRS measure set for Medicaid managed care quality rating system.

- 438.515 Medicaid managed care quality rating system methodology.
 438.520 website display.
 438.525 [Reserved]
 438.530 Annual technical resource manual.
 438.535 Annual reporting.

§ 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 and 423 of this chapter.

Qualified health plan quality 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—

(1)(i) Must adopt the QRS framework developed by CMS, which must implement either the MAC QRS methodology developed by CMS or an alternative MAC QRS rating methodology approved by CMS in accordance with § 438.515(c) of this subpart.

(ii) May, in addition to the MAC QRS framework adopted under paragraph (a)(1)(i) of this section, implement website features in addition to those identified in § 438.520(a), as described in § 438.520(c).

(2) Must implement such managed care quality rating system by the end of the fourth calendar year following July 9, 2024, unless otherwise specified in this subpart.

(3) Must 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 Medicare Advantage Dual Eligible Special Needs Plans that contract with States 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—

(1) Must include the measures that are:

(i) In the mandatory QRS measure set identified and described by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual, and

(ii) Applicable to the State because the measures assess a service or action covered by a managed care program established by the State.

(2) May include other measures identified by the State as provided in § 438.520(c)(1).

(b) *Subregulatory process to update mandatory measure set.* Subject to paragraph (d) of this section, CMS will—

(1) At least every other year, engage 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 CMS to add, remove or update existing measures based on the criteria and standards in paragraph (c) of this section; and

(2) Provide 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 standards described in (c)(1) through (3) of this section 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, to the extent appropriate, 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, managed care plans, and providers such that it is feasible to report by many States, managed care plans, and providers;

(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) of this section.

(4) When making the determinations required under paragraphs (c)(2) and (3) of this section, to add, remove, or update a measure, CMS may consider the measure set as a whole, each

specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas.

(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 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 paragraphs (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) *Quality ratings.* For each measurement year, the State must ensure that—

(1) The data necessary to calculate quality ratings for each quality measure described in § 438.510(a)(1) of this subpart are collected from:

(i) The State's contracted managed care plans that have 500 or more enrollees from the State's Medicaid program, to be calculated as described by CMS in the technical resource manual; 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 to the extent feasible without undue burden.

(2) Validation of data collected under paragraph (a)(1) of this section is performed, including all Medicaid managed care data and, to the extent feasible without undue burden, all data from sources described in paragraph (a)(1)(ii) of this section. Validation of data must not be performed by any entity with a conflict of interest, including managed care plans.

(3) A measure performance rate for each managed care plan whose contract covers a service or action assessed by the measure, as determined by the State, is calculated, for each quality measure identified under § 438.510(a)(1) of this subpart, using the methodology described in paragraph (b) of this section and the validated data described in paragraph (a)(2) of this section, including all Medicaid managed care data and, to the extent feasible without undue burden, all data from sources described in paragraph (a)(1)(ii) of this section.

(4) Quality ratings are issued by the State for each managed care plan for each measure that assesses a service or action covered by the plan's contract

with the State, as determined by the State under paragraph (a)(3) of this section.

(b) *Methodology.* 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 Medicaid FFS and Medicare data for enrollees who receive Medicaid benefits for the State through FFS and managed care, are dually eligible for both Medicare and Medicaid and receive full benefits from Medicaid, or both).

(2) Are issued to each managed care plan at the plan level and 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) *Alternative QRS methodology.* (1) A State may apply an alternative QRS methodology (that is, other than that described in paragraph (b) of this section) to the mandatory measures described in § 438.510(a)(1) of this subpart provided that—

(i) The ratings generated by the alternative QRS methodology 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(b) of this subpart, 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.

(ii) The State receives CMS approval prior to implementing an alternative QRS methodology or modifications to an approved alternative QRS methodology.

(2) To receive CMS approval for an alternative QRS methodology, a State must:

(i) Submit a request for, or modification of, an alternative QRS methodology to CMS in a form and manner and by a date determined by CMS; and

(ii) Include the following in the State's request for, or modification of, an alternative QRS methodology:

(A) The alternative QRS methodology to be used in generating plan ratings;

(B) Other information or documentation specified by CMS to

demonstrate compliance with paragraph (c)(1) of this section; and

(C) Other supporting documents and evidence that the State believes demonstrates compliance with the requirements of (c)(1)(i) of this section.

(3) Subject to requirements established in paragraphs (c)(1)(i) and (ii) and (c)(2) of this section, the flexibility described in paragraph (c)(1) of this section permits the State to request and receive CMS approval to apply an alternative methodology from that described in paragraph (b)(1) and (2) of this section when calculating quality ratings issued to health plans as required under paragraph (a)(4) of this section. CMS will not review or approve an alternative methodology request submitted by the State that requests to implement a MAC QRS that—

(i) Does not comply with—

(A) The requirement to include mandatory measures established in § 438.510(a)(1).

(B) The general requirements for calculating quality ratings established in paragraphs (a)(1) through (4) of this section.

(C) The requirement to include the website features identified in § 438.520(a)(1) through (6) established in § 438.520(a).

(ii) Requests to include plans that do not meet the threshold established in paragraph (a)(1)(i) of this section, which is permitted without CMS review or approval.

(iii) Requests to implement additional measures or website features, which are permitted, without CMS review or approval, as described § 438.520(c).

(d) *Request for implementation extension.* In a form and manner determined by CMS, the State may request a one-year extension to the implementation date specified in this subpart for one or more MAC QRS requirements established in paragraph (b) of this section.

(1) A request for extension of the implementation deadline for the methodology requirements in this section must meet the following requirements:

(i) Identify the specific requirement(s) for which an extension is requested and;

(ii) Include a timeline of the steps the State has taken to meet the requirement as well as an anticipated timeline of the steps that remain;

(iii) Explain why the State will be unable to fully comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement; and

(iv) Include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, the operational steps the State will take to address identified implementation barriers.

(2) The State must submit an extension request by September 1 of the fourth calendar year following July 9, 2024.

(3) CMS will approve an extension for 1 year if it determines that the request:

(i) Includes the information described in paragraph (d)(1) of this section;

(ii) Demonstrates that the State has made a good-faith effort to identify and begin executing an implementation strategy but is unable to comply with the specified requirement by the implementation date identified in this subpart; and

(iii) Demonstrates that the State has an actionable plan to implement the requirements by the end of the 1-year extension.

(e) *Domain ratings.* After engaging with States, beneficiaries, and other interested parties, CMS implements domain-level quality ratings, including care domains for which States are 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) *website display requirements.* 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 and make accessible to the public 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 are requested to input user-specific information, including the information described in paragraph (a)(2)(i) of this section, an explanation of why the information is requested, how it will be used, and whether it is

optional or required to access a QRS feature or type of information.

(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 and other similar information specified by CMS, such as whether access to the benefit requires prior authorization from the plan;

(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) The quality ratings described in paragraph (a)(2)(iv) of this section 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.

(ii) An interactive tool that enables users to view the quality ratings described at paragraph (a)(2)(iv) of this section, stratified by the factors described in paragraph (a)(6)(i) of this section.

(iii) For managed care programs with two or more participating plans—

(A) A search tool that enables users to identify available managed care plans within the managed care program that provide coverage for a drug identified by the user; and

(B) A search tool that enables users to identify available managed care plans within the managed care program that include a provider identified by the user in the plan's network of providers.

(b) *Request for implementation extension.* In a form and manner determined by CMS, the State may request a 1-year extension to the implementation date specified in this subpart for one or more of the

requirements established under paragraphs (a)(2)(v) and (6) of this section.

(1) A request for extension of the implementation deadline for the website display requirements in this section must meet the requirements described in § 438.515(d)(1);

(2) For extensions of the website requirements specified in paragraph (a)(6) of this section, the extension request must be submitted no later than 4 months prior to the implementation date specified pursuant to paragraph (a)(6) of this section for those requirements; for extensions of the requirements specified in paragraphs (a)(2)(v) of this section, the extension request must be submitted no later than September 1, 2027.

(3) CMS will approve the State's request for a 1-year extension if CMS determines that the request meets the conditions described in § 438.515(d)(3).

(c) *Additional website features.* The State may choose to display additional website features not described in § 438.520(a) in their MAC QRS, or may choose to implement the features described in § 438.520(a)(6)(i) through (iv) before the date specified by CMS as described in paragraph (a)(6) of this section.

(1) Additional website features may include additional measures not included in the mandatory measure set described in § 438.510(a)(1), supplementary data on displayed quality measures, and extra interactive functions, and may be implemented without CMS review.

(2) If the State chooses to display quality ratings for additional measures as described in paragraph (c)(1) of this section, the State must:

(i) 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

(ii) Document the input received from prospective users required under paragraph (c)(2)(i) of this section, including modifications made to the additional measure(s) in response to the input and rationale for input not accepted.

(d) *Continued consultation.* 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 [Reserved]

§ 438.530 Annual technical resource manual.

(a) Beginning in calendar year 2027, CMS will publish a Medicaid managed care quality rating system technical resource manual annually, which may be released in increments throughout the year. Subject to the limitation described in paragraph (a)(4) of this section, the technical resource manual must include all the following:

(1) Identification of all Medicaid managed care quality rating system measures, including:

(i) A list of the mandatory measures

(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)(v) and (a)(6)(i).

(2) Guidance on the application of the methodology used to calculate and issue quality ratings as described in § 438.515(b).

(3) Measure steward technical specifications for mandatory measures.

(4) If the public notice and comment process described in § 438.510(b) of this subpart occurs in the calendar year in which the manual is published, a summary of interested party engagement and public comments received during the notice and comment process 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.

(c) No later than August 1, 2025, CMS will publish the information described at paragraph (a)(1) of this section for the initial mandatory measure set.

§ 438.535 Annual 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) The following measure information:

(i) A list of all mandatory measures identified in the most recent technical resource manual that indicates for each measure:

(A) Whether the State has identified the measure as applicable or not applicable to the State's managed care program under § 438.510(a)(1) of this subpart;

(B) For any measures identified as inapplicable to the State's managed care program, a brief explanation of why the State determined that the measure is inapplicable; and,

(C) For any measure identified as applicable to the State's managed care program, the managed care programs to which the measure is applicable.

(ii) A list of any additional measures the State chooses to include in the Medicaid managed care quality rating system as permitted under § 438.510(a)(2).

(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(c), if including additional measures in the State's Medicaid managed care quality rating system.

(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 methodology approved by CMS, including the effective dates for each approved alternative QRS.

(8) If all data necessary to calculate a measure described in § 438.510(a)(1) of this subpart cannot be provided by the managed care plans described in § 438.515(a)(1) of this subpart:

(i) A description of any Medicare data, Medicaid FFS data, or both that cannot, without undue burden, be collected, validated, or used to calculate a quality rating for the measure per § 438.515(a) and (b), including an estimate of the proportion of Medicare data or Medicaid FFS data that such missing data represent.

(ii) A description of the undue burden(s) that prevents the State from ensuring that such data are collected, validated, or used to calculate the measure, the resources necessary to overcome the burden, and the State's plan to address the burden.

(iii) An assessment of the impact of the missing data on the State's ability to fully comply with § 438.515(b)(1).

(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.

■ 28. 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) through (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) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after July 9, 2024.

■ 29. Amend § 438.608 by revising paragraphs (a)(2) and (d)(3) and adding paragraph (e) and (f) to read as follows:

§ 438.608 Program integrity requirements under the contract.

(a) * * *

(2) Provision for reporting within 30 calendar 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).

(f) *Applicability date.* Paragraphs (a)(2), (d)(3) and (e) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year from July 9, 2024.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 30. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 31. 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.

* * * * *

■ 32. Amend § 457.1200 by adding paragraph (d) to read as follows:

§ 457.1200 Basis, scope, and applicability.

* * * * *

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates established at §§ 438.3(v), 438.10(j), 438.16(f), 438.68(h), 438.206(d), 438.207(g), 438.310(d), 438.505(a)(2), 438.602(j), and 438.608(f) of this chapter, so long as they comply with the corresponding standard(s) of this subpart, edition revised as of July 9, 2024. States will not be held out of compliance with the requirement at § 457.1207 to post comparative summary results of enrollee experience surveys by managed care plan annually on State websites, nor the requirement for States to evaluate annual enrollee experience survey results as part of the State's annual analysis of network adequacy as described at § 457.1230(b), so long as

they comply with the corresponding standard(s) of this subpart, 2 years after July 9, 2024.

■ 33. 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).

* * * * *

■ 34. 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.

■ 35. 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.

■ 36. Revise § 457.1230(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.

* * * * *

■ 37. 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 in subpart G of part 438 of this chapter, except that references to dually eligible beneficiaries, a beneficiary support system, and the terms 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.

■ 38. Revise § 457.1250(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 for nonduplication of EQR activities with private accreditation) and 438.364 of this chapter.

* * * * *

■ 39. 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.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024-08085 Filed 4-22-24; 4:15 pm]

BILLING CODE 4120-01-P