Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality
[CMS-2439-F]

Final Rule Summary

On April 22, 2024, the Centers for Medicare & Medicaid Services (CMS) placed on public display the final rule entitled "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality." The rule finalizes policies that CMS believes would advance efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and CHIP managed care enrollees. Specifically, the rule addresses standards for timely access to care and states' monitoring and enforcement efforts, reduces burden for some state directed payments 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 specify the scope and nature of ILOS, specifies medical loss ratio (MLR) requirements, and establishes a quality rating system for Medicaid and CHIP managed care plans.

This final rule is scheduled for publication in the Federal Register on May 10, 2024. These regulations are effective July 9, 2024, with applicability dates that vary by policy.

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I. Background

CMS notes that as of September 2023, more than 88 million individuals were enrolled in Medicaid. The agency states that the use of managed care in Medicaid has grown from 81 percent in 2016 to 85 percent in 2021. In 2021, 74.6 percent of Medicaid beneficiaries were enrolled in comprehensive managed care plans while the remainder received all of their care, or some services carved out of managed care, through fee-for-service (FFS) Medicaid.

CMS describes its approach to promoting consistent access to health care for all Medicaid beneficiaries across all types of health care delivery systems. Specifically, it views the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. On

March 27, 2024, CMS finalized the Streamlining Eligibility & Enrollment rule[1] to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP). Another final rule entitled "Medicaid Program; Ensuring Access to Medicaid Services" (CMS-2442-F)[2] and this final rule are both designed to improve access to services and supports by Medicaid beneficiaries.

States may implement a Medicaid managed care delivery system under certain federal authorities—sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Social Security Act (the Act)—each of which is described in the preamble to the rule. While section 1915(a) permits state implementation of a voluntary managed care program, the other authorities permit states to mandate enrollment in managed care programs for beneficiaries to receive Medicaid services. These authorities for managed care programs waive compliance with requirements for statewideness, comparability of services, and freedom of choice.[3] A state may opt to operate a separate CHIP within a managed care delivery system, which does not require specific statutory authority; however, certain provisions of sections 1903 and 1932 of the Act apply to separate CHIPs. States that elect a Medicaid expansion CHIP that operates within a managed care delivery system are subject to all requirements under section 1932 of the Act.

Throughout the preamble to the final rule and in this summary, certain terms are ascribed specific meanings:

- "PAHP" means a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services.
- "Non-Emergency Medical Transportation (NEMT) PAHP" means a PAHP that exclusively provides non-emergency medical transportation services.
- "Managed care plan" includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and PAHPs; it is used only when the policy applies to all three arrangements.
- "CHIP" refers collectively to separate child health programs and Medicaid expansion programs.
- "Separate CHIP" refers to separate child health programs and also to any changes in subpart L of part 457, which are only applicable to separate child health programs operating in a managed care delivery system.

CMS notes that all changes to the Medicaid managed care regulations are equally applicable to Medicaid expansion CHIP managed care programs.

CMS provides an extensive description of recent rulemaking for the Medicaid and CHIP programs that were designed to reflect changes in the use of managed care delivery systems,[4]

[1] https://www.federalregister.gov/public-inspection/2024-06566/medicaid-program-streamlining-the-medicaid-childrens-health-insurance-program-and-basic-health.
[2] https://www.federalregister.gov/public-inspection/2024-08363/medicaid-program-ensuring-access-to-medicaid-services.
[3] See sections 1902(a)(1), 1902(a)(10)(B), and 1902(a)(23)(A), respectively, for these requirements.
[4] "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 (the "2016 final rule") (81 FR 27498).

address pass-through payments in managed care delivery,[5] and streamline the managed care regulatory framework.[6] The goal of this final rule is to build stronger managed care programs for the Medicaid and CHIP populations by improving access to, and the quality of, care. Policies are finalized to improve and monitor access to care under these managed care programs, including the following:

- Requiring new standards for appointment wait times, use of secret shopper surveys, and use of enrollee experience surveys, and requiring states to submit a managed care plan analysis of payments made by plans to providers for specific services to more closely monitor plan network adequacy.
- Applying standards for states' use of "in lieu of services and settings" to promote effective utilization and that specify the scope and nature of these services and settings.
- Reducing burden for states that choose to direct managed care plans in certain ways to use their capitation payments to pay certain providers specified amounts (known as state directed payments (SDPs)), enhancing fiscal and program integrity of SDPs, addressing impermissible redistribution arrangements related to SDPs.
- Adding clarity to the requirements related to medical loss ratio calculations.
- Enhancing existing state website requirements for content and ease of use to improve transparency and provide valuable information to enrollees, providers, and CMS.
- Making quality reporting more transparent and meaningful to drive quality improvement, to reduce burden for certain quality reporting requirements, and to 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.
- Working 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. States may report the same measurement and stratification methodologies and classifications as those finalized in the Mandatory Medicaid and CHIP Core Set Reporting final rule[7] and the Ensuring Access to Medicaid Services final rule with respect to the home and community-based services (HCBS) Quality Measure Set.

States must comply with requirements finalized in this rule by July 9, 2024 or as otherwise specified in regulation text. However, states will not be held out of compliance with the changes adopted in the final rule until the applicability date indicated in regulation text for each provision if they comply with the corresponding standard(s) in 42 CFR parts 438 and 457 effective as of

[5] "Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems" final rule (the "2017 final rule") (82 FR 5415).
[6] "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care" final rule (the "2020 final rule") (85 FR 72754).
[7] "Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting (88 FR 60278); https://www.federalregister.gov/documents/2023/08/31/2023-18669/medicaid-program-and-chip-mandatory-medicaid-and-childrens-health-insurance-program-chip-core-set.

October 1, 2023. Table 1 in the final rule (reproduced below) provides a summary of the applicability dates.

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)(*1*) 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.
§§438.505(a)(1); 457.1240(d)	Applicable by the end of the fourth calendar year following July 9, 2024.

Regulation Text	Applicability Date
§§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).

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

CMS reports having received 415 public 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.

In preparing for possible legal challenges to provisions of the rule, the agency notes that each policy and regulation in the final rule is intended to be distinct and severable from the others to the extent it does not rely on another final policy or regulation. Thus, if any provision of the final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further state action, it shall be severable from this final rule, and from rules and regulations currently in effect, and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

A. Access

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

Addition to State Monitoring Systems. Under §438.66, states must have monitoring systems for all managed care programs, which must include performance of each managed care plan and primary care case manager (PCCM) entity (if applicable) in a number of areas, including enrollee materials and customer services. CMS finalizes its proposal to explicitly include performance in enrollee experience to the regulatory text at §438.66(b)(4).

Similarly, the monitoring system under §438.66(c)(5) requires states to use data collected from its monitoring activities to improve the performance of its managed care program, including results from any enrollee or provider satisfaction survey conducted by the state or managed care plan. CMS also finalizes its proposal to require states—not the managed care plan—to conduct

an annual enrollee experience survey. In the final rule, an exemption is provided for Medicaid managed care plans in which all enrollees are enrolled in a Medicare Advantage (MA) dual eligible special needs plan (D-SNP). CMS did not propose to mandate provider surveys but notes that either the state or the managed care plan could conduct those surveys.

CMS believes these survey results will provide direct and candid enrollee input, which could be used by states and managed care plans to evaluate whether their networks offer an appropriate range of services and access as well as whether they provide a sufficient number, mix, and geographic distribution of providers to meet enrollee needs. The agency notes that authority for enhanced federal match of up to 75 percent is available for the administration or validation of consumer or provider surveys of quality of care.

Selected Comments/Responses. Some commenters believe the annual enrollee experience survey would be duplicative of other state surveys. CMS is aware of the possibility of survey fatigue and, as noted above, provided an exemption for Medicaid managed care plans where all enrollees are in D-SNPs. Some commenters recommended that CMS mandate a specific survey instrument or measure set, but CMS agrees with comments that supported giving states the flexibility to develop questions tailored to their programs and populations.

Reporting. A conforming change is made to §438.66(e)(2)(vii) to require that the results of the enrollee experience be included in the annual assessment of the operation of the managed care program report (i.e., the Managed Care Program Annual Report (MCPAR)). States must post the report on their website within 30 calendar days.

Translation. The final rule also applies the translation and tagline standards to the enrollee satisfaction surveys to ensure that notice of availability of oral interpretation and written translation is available for the surveys for individuals with limited English proficiency.

Effective Date. The deadline by which states must implement the enrollee satisfaction survey requirements is 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.

CAHPS Surveys under CHIP. States currently collect enrollee experience data for CHIP through annual CAHPS surveys, but 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. CMS proposed requiring states to evaluate the annual CAHPS survey results as part of the annual analysis of network adequacy, and it proposed an effective date of 60 days after the effective date of the final rule. CMS finalizes its proposal with one modification to the implementation timeframe. Commenters recommended a range of implementation timelines, from 1 to 2 years following the effective date of the final rule. CMS finalizes an implementation date of 2 years after the effective date of the final rule for the proposals at §§457.1230(b) and 457.1207.

States must annually post comparative summary results of CAHPS surveys by managed care plans on state websites.

Burden Estimates. CMS estimates an aggregate, one-time state burden for 49 states of 5,390 hours at a cost of $475,840, and subsequent annual state burden of 3,185 hours at a cost of $281,608. An additional estimate of 3,920 hours at a cost of $311,640 is attributable to the state annual program assessment reports.

2. Appointment Wait Time Standards (§§438.68(e), 457.1218)

Stakeholder feedback convinced the agency of the need for greater oversight of network adequacy and access to services under managed care plans, which it proposed to add. The proposed changes would also apply to separate CHIP managed care plans. CMS finalizes the proposals with minor modifications described below.

Appointment Wait Times for Certain Provider Types. New appointment wait time standards are added to §438.68 in a new paragraph (e), which requires states to establish and enforce wait time standards for routine appointments with providers furnishing the following four types of services:

i. Outpatient mental health and substance use disorder (SUD)—adult and pediatric, but no longer than 10 business days from the date of the request.
ii. Primary care—adult and pediatric, but no longer than 15 business days from the date of the request.
iii. Obstetrics and gynecology (OB/GYN), but no longer than 15 business days from the date of the request.
iv. An additional type of service determined by the state. Managed care plans will have to comply with wait time standards for the first three types of services only if those services are covered under their contracts.

For the fourth type of service, states select a service type in an evidence-based manner within state established timelines and use the wait time standard to address access challenges in local markets. States will choose the evidence source (e.g., encounter data, grievance and appeals information, etc.) and consult with managed care plans in choosing the service type.

Selected Comments/Responses. Commenters suggested a variety of alternative wait time standards, including the use of calendar days instead of business days, using 30 or 45 business days, and one request for 90 days. Acknowledging that the deadlines under these standards are shorter than those that apply under the Medicare Advantage program and other federal programs, CMS nonetheless believes that the standards for these three types of services are both achievable and appropriate. It agrees with commenters who recommended collecting data to assess whether the 10- and 15-business day standards need revision. Some commenters objected to any appointment wait time standards noting the difficulty contracting with providers in certain areas or certain specialties and that appointment wait time standards cannot address provider supply. Others suggested that the standards increase pressure on providers, which could lead to burn-out, expand patient panels to unmanageable levels, and potentially drive providers out of Medicaid. The agency acknowledges the standards will not solve all access issues, but it believes they can be effective for the majority of the routine appointments for services finalized in the rule.

Another commenter suggested an exception process for rural areas and health professional shortage areas (HPSAs). CMS declines to create such a process, but it notes that states may do so under existing regulations at §438.68(d) for any of the provider-specific network standards required in §438.68.

CMS had referred to "provider type" in its proposed wait time standards but, in response to comment, changes the reference to "service type" in the regulation text to avoid confusion.

CMS reserves the right to add additional types of services for which appointment wait time standards would apply. New service types will only be selected after consultation with states and other stakeholders and after public notice and opportunity for comment.

States may vary the wait time standards for the same provider type by adult versus pediatric, telehealth versus in-person, geography, etc. Contracts with managed care plans are revised to include the appointment wait time standards. CMS clarifies that the appointment wait time standards may not be the quantitative network adequacy standard at §438.68(b)(1).

Selected Comments/Responses. CMS did not propose to define "routine appointment" even though some commenters encouraged the agency to do so for consistency in implementation and results. States are encouraged to work with plans to develop a definition of routine, but the agency expects that such a definition must include appointments for certain services, such as well-child visits, annual gynecological exams, and medication management. Even though some commenters also urged the agency to codify definitions of "urgent" and "emergent," CMS declines to do so because it did not propose wait time standard for these types of appointments. Stakeholders are reminded of the prudent layperson standard for patients with an emergency medical condition.

A commenter sought clarification on which appointment wait time standards applied to D-SNPs. For Medicaid managed care plans that are also D-SNPs in Medicare Advantage, the wait time standards under §438.68(e)(1)(i) through (iii) only apply if the managed care plan is the primary payer. Requirements for D-SNPs for services under the D-SNP contract with CMS are addressed in Medicare Advantage regulations.

Transparency. States must publish the appointment wait time standards and the network adequacy standards on their websites and, upon request, make the network adequacy standards available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

Exceptions. CMS notes that circumstances may arise where an exception to the network adequacy standards, including appointment wait time standards, may be necessary. It finalizes its proposal to add a new standard for state review of exception requests; specifically, the state must consider payment rates that the managed care plan pays providers included in the provider group subject to the exception. CMS believes managed care plans often have difficulty building provider networks due to low reimbursement rates, and states should consider whether this contributes to the plan's inability to meet the network adequacy standards.

Compliance. A minimum compliance standard with the new appointment wait times is finalized as proposed. Specifically, managed care plans will be deemed as having complied with the appointment wait time standards if secret shopper results (described below) achieve an appointment availability rate of 90 percent or better.

Effective Dates. There are different applicability dates for the various policies finalized for appointment wait time standards:

- The development and publication of the wait time standards and network adequacy requirements are required 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.
- The requirement for secret shopper surveys (described below) applies 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.
- The new standard for state review of exception requests is required 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.
- The requirement for managed care contracts to be revised to include appointment wait time standards applies 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.

Burden Estimates. For Medicaid, CMS estimates an aggregate, one-time state burden for 44 states of 880 hours at a cost of $69,960 and subsequent annual state burden of 440 hours at a cost of $34,980. For CHIP, CMS estimates an aggregate, one-time state burden for 32 states of 640 hours at a cost of $50,880 and subsequent annual state burden of 320 hours at a cost of $25,440.

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

CMS cites evidence suggesting that in some areas and for some services, it takes Medicaid beneficiaries longer to access medical appointments compared to individuals with other types of health coverage, which the agency believes may in part be attributable to out-of-date plan network provider directories as well as to the fact that only a small percentage of those network providers furnish the vast majority of services to Medicaid beneficiaries. CMS proposed requiring states to contract with independent entities to conduct secret shopper surveys of the electronic provider directory and the appointment wait times of each managed care plan to determine compliance with regulatory requirements. The proposed requirements would also apply to separate CHIP plans. CMS finalizes the requirements as proposed.

Selected Comments/Responses. In response to questions about the applicability of the requirements for enrollees of D-SNPs, CMS clarifies secret shopper surveys only apply for services for which the Medicaid managed care plan is the primary payer; they do not apply for services for which Traditional Medicare, a D-SNP, or another MA plan has primary responsibility for dually eligible Medicaid managed care plan enrollees. In response to another

comment, CMS clarifies that secret shopper surveys may not be used to collect any other information or make public information beyond information on the performance of managed care plans in meeting wait time standards. CMS also explains that its intent is not that the appointment wait time standard has to be met by a 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. Thus, an enrollee who is offered an appointment by any provider in a practice is sufficient for determining compliance with appointment wait time standards.

Provider Directories. Secret shopper surveys will be used to determine the accuracy of the plan's most recent electronic provider directory for the types of providers for which the appointment wait time standards apply. These are primary care providers, OB/GYN providers, outpatient mental health and SUD providers, and a provider type selected by the state. At a minimum, these surveys must assess the provider's active network status, street address, telephone number, and whether the provider is accepting new patients.

The entities conducting secret shopper surveys must provide states information on all provider directory errors within 3 business days of identification; states must then pass on that information to the plan involved within 3 business days. CMS notes that states could require the entity to provide that information directly to the plan involved. The error information from surveys must be sufficiently specific to facilitate correction, and plans have a duty to correct and update their directories within the timeframes that apply under §438.10(h)(3)(i) and (ii) for paper and electronic directories, respectively.[8] Some commenters objected to the 3-business-day timeframe, arguing that it was unreasonable. The agency acknowledges 3 business days is a quick turnaround time, but it notes the 4-year period before compliance is required and the fact that information will be electronically transmitted.

The agency also clarifies that when verifying the accuracy of provider directory data, secret shopper surveys must verify the published information for each provider. Thus, a directory reflecting accurate information for some but not all providers in the same practice is not sufficient for the data to be considered "accurate" for compliance with §438.68(f)(1)(ii).

Relatedly, CMS requires managed care plan electronic provider directories to be searchable, and that all provider directories indicate whether providers furnish services via telehealth. The compliance date for these proposals is July 1, 2025.

Appointment Wait Times. Secret shopper surveys must be used to determine compliance with the wait time standards finalized in the rule. States may, in consultation with stakeholders and after public notice and comment, select additional types of appointments for its secret shopper surveys. In determining compliance with the wait time standards, telehealth visits will only be counted if the provider being surveyed also offers in-person appointments to the plan's enrollees; additionally, telehealth appointments must be identified separately from in-person appointments

[8] The timeframes are 30 days for electronic directories, and either monthly or quarterly for paper directories depending on whether the plan has a mobile-enabled, electronic provider directory.

in the survey results. CMS believes reliance on telehealth visits alone to determine compliance with wait time standards is inappropriate and does not provide states adequate information to assess access. It considered applying the Medicare Advantage policy of providing a 10-percentage point credit for telehealth services towards demonstration of plan network adequacy, but the agency prefers this policy approach because it should provide states with better information.

Some commenters objected to the 90 percent threshold for compliance with appointment wait time standards as being unrealistic. The agency acknowledges that achieving a 90 percent compliance rate is a high standard but notes that it is only being applied initially to four types of services, three of which are the most commonly used on a frequent and repetitive basis.

Independence of Entity. To ensure that an entity conducting secret shopper surveys is independent of both the state and the plans subject to the surveys, the final rule prohibits the use of an entity if it is part of the state Medicaid agency or if it is a managed care plan, is owned or controlled by a managed care plan, or owns or controls a managed care plan. These independence criteria are similar to, though not as restrictive as, those that apply to enrollment brokers. CMS notes that enhanced FMAP may be available for these contracts to conduct secret shopper surveys. Some commenters supported a more robust definition of independence, such as the one used at §438.810(b)(2) to ensure enrollment brokers are independent of plans, but CMS feels the higher standard required for enrollment brokers is appropriate because enrollees are often limited to changing their managed care plans annually. It feels the level of risk for secret shopper surveys is lower.

Methodological Standards and Reporting Results. While deferring to states on the design of their secret shopper surveys, the final rule mandates certain minimum methodological standards for the surveys. Specifically, the surveys must (i) use a random sample, (ii) include all areas of the state covered by the plan, and (iii) complete surveys of appointment wait time standards for a statistically valid sample of providers. States must report the results of the secret shopper surveys to CMS and, within 30 days of that submission, post the results on the websites.

Effective Date. The requirements for secret shopper surveys apply 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.

Burden Estimates. For Medicaid, CMS estimates an aggregate, one-time state burden for 44 states of 4,840 hours at a cost of $427,284 and subsequent annual state burden of 2,860 hours at a cost of $252,872. For CHIP, CMS estimates an aggregate, one-time state burden for 32 states of 3,520 hours at a cost of $310,752 and subsequent annual state burden of 2,080 hours at a cost of $183,907.

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

CMS seeks greater transparency in provider payment rates from plans and states, which it believes are lower than other payer rates and thus contribute to reduced access to services. The

agency also believes greater oversight of plan payments is warranted as the share of these payments has grown compared to FFS payments. Plans may negotiate payments with providers, and there is no federal regulatory or statutory limit, maximum or minimum, on those negotiated rates. Information available to states on these negotiated payment rates varies, in both quantity and quality. Thus, CMS proposed a process through which managed care plans must report, and each state must review and analyze, managed care payment rates to providers for certain types of services as part of the state's duty to ensure network adequacy and enrollee access consistent with state and federal standards. States must submit the payment analyses to CMS. The proposal also applied to separate CHIP plans. CMS finalizes the proposals with a couple minor technical changes described below.

Selected Comments/Responses. Some comments supported the proposals, arguing that increased transparency of provider payments rates will help in the analysis of barriers in access to care. Those opposed objected to the high cost of compliance and cautioned that this type of analysis will be misleading and statistically invalid, present an incomplete narrative on provider payment, and will dissuade participation by providers in the Medicaid program; they also believe this is a matter for states to determine. CMS believes that these analyses will not be useful unless there is consistency, and allowing each state to conduct a unique analysis would not achieve that. The agency believes providers can 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.

Plan Payment Analyses. Each managed care plan must submit to the state a payment analysis that shows their level of payment for the following services if covered under the contract: primary care services, OB/GYN services, mental health services, SUD services, homemaker services, home health aide services, and personal care services. CMS clarifies that the payment analysis is to be conducted by each managed care plan—not the state. The states' only requirement is 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.

Several comments supported including habilitation services in the payment analysis because these services are critical for enrollees, particularly those in the intellectual and developmental disabilities population, who commonly receive personal care services as part of their habilitation services. CMS agrees; the final rule adds habilitation services, irrespective of population or setting, to the payment analysis because it will provide states with valuable information for monitoring access to vital services for certain enrollees.

Claims Data. For primary care services, OB/GYN services, mental health services, and SUD services, plans will use paid claims data from the immediate prior rating period to reflect appropriate weighting to each payment based on utilization. The payment analysis must provide the total amount paid for evaluation and management (E/M) current procedural terminology codes in such paid claims data for such services from the prior rating period. The plan payment rates must also be compared to published Medicare payment rates, expressed as a percentage. Separate totals and percentages must be reported for primary care services, OB/GYN services,

mental health services, and SUD services; additionally, if the percentage differs between adult and pediatric services, both those percentages must be reported. Some commenters opposed using Medicare FFS payment rates, suggesting instead the use of Medicaid FFS rates as the more appropriate benchmark. CMS believes using separate state FFS benchmarks would not provide any level of consistency or comparability among the analyses. The agency also believes 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 that Medicare does not pay for a large volume of OB/GYN, neonatal, and pediatric services.

For homemaker services, home health aide services, and personal care services, similar policies apply, except that the plan payment rates are compared to the FFS payment rate for those same services under the state Medicaid or CHIP program. Clarification was sought 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. CMS responds that the payment analysis includes all codes for homemaker services, home health aide services, personal care services, and, as finalized, habilitation services. There are no limitations on where the services are provided, and only services covered in a managed care delivery system can be included in the analysis.

Some commenters voiced concern about the release of proprietary and confidential data and urged the agency to protect against unauthorized disclosure of the information. CMS responds that the analyses will only produce aggregate results without revealing specific payments or specific providers. Others noted the reporting requirements do not adequately account for value-based purchasing (VBP) arrangements, bundled payments, or other unique payment arrangements that reward and support quality over quantity. CMS intends to use the analysis reports submitted by plans to determine a consistent way to include these arrangements in these analyses going forward.

Exclusions. The final rule excludes from the payment analysis payments by plans where they are not the primary payer and payment rates for services when furnished by FQHCs and rural health clinics (RHCs).

Effective Date. States must comply with the payment analysis provision no later than the first rating period that begins on or after 2 years after the effective date of the final rule.

Burden Estimates. For Medicaid, CMS estimates an aggregate, one-time private sector burden of 94,350 hours at a cost of $10,031,921 and subsequent annual private sector burden of 28,305 hours at a cost of $2,883,021. For CHIP, CMS estimates an aggregate, one-time private sector burden of 29,850 hours at a cost of $3,173,851 and subsequent annual private sector burden of 8,955 hours at a cost of $912,117. For Medicaid, CMS estimates an annual aggregate state burden for 44 states of 1,760 hours at a cost of $139,920 and for CHIP an annual aggregate state burden for 32 states of 1,408 hours at a cost of $111,936.

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

Currently, states must first review the documentation submitted by managed care plans to verify plan compliance with regulatory requirements for network adequacy and availability of services and then submit assurances to CMS that each plan does in fact comply with those requirements. CMS proposed adding a requirement that states include (i) the results from the secret shopper surveys and (ii) the payment analyses described immediately above. The payment analysis reported to the agency will contain data provided by each plan as well as a state level payment percentage for each service type in the payment analysis, weighted by each plan's reported percentages. CMS finalizes its proposals with a modification to the time for submission of assurances described below.

The agency published a reporting template[9] for purposes of submitting state assurances and finalizes its proposal to require its use. CMS also establishes in regulations report submission timelines. Specifically, states must submit to CMS the assurance of compliance as follows:

- For new managed care plans, sufficiently in advance of contract approval;
- Annually and no later than 180 calendar days after each rating period; and
- Any time there has been a significant change (as specified in §438.207(c)(3)) and with the submission of the associated contract (as required at §438.3(a)).

Additionally, a state must post the report on the state Medicaid website within 30 calendar days of its submission to CMS. A stakeholder pointed out that having a new plan submit an assurances report at the same time as the readiness review information would be duplicative. CMS agrees and revises the submission deadline for new plans; the assurances report must be submitted sufficiently in advance to allow CMS to determine that the contract is approved.

Under §438.207(e), CMS has a right to inspect documentation collected by states from managed care plans; that section is amended to include a specific reference to secret shopper survey evaluations.

CMS notes that it did not adopt the Managed Care Program Annual Report (MCPAR) for separate CHIP plans. In the final rule, it requires separate CHIPs to align with Medicaid for the network adequacy analysis submission timeframes.

The inclusion of the payment analysis in the assurances report must begin 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. For the secret shopper survey evaluations, CMS says that states will not be held out of compliance with the requirement before the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule if they comply with the corresponding standard(s) codified in section 438.207(e) contained in the 42 CFR, parts 430 to 481, most recently published before the final rule.

[9] Network Adequacy and Access Assurances Report; https://www.medicaid.gov/medicaid/managed-care/downloads/network-assurances-template.xlsx

Burden Estimates. The aggregate annual state burden for 44 states is estimated to be 1,760 hours at a cost of $139,920 for Medicaid and 1,408 hours (for 32 states) at a cost of $111,936 for CHIP.

6. Remedy Plans to Improve Access (§438.207(f))

CMS proposed a process under which states must submit to CMS a plan to remedy access issues identified in managed care plans within certain timeframes. The access issue could be identified by CMS, the plan, or the state, and the issue would relate to the plan's performance on any state standard for access to care under part 438 of the regulations. CMS finalizes its proposal without modification.

Once a state becomes aware of a plan's access issue, the state has 90 days to develop and submit to CMS a remedy plan. That remedy plan must address the access issue within 12 months and identify specific steps, with timelines for implementation and completion, for the responsible parties. Some examples of remedial action are included in the regulatory text, including (i) increasing payment rates to providers, (ii) improving outreach and problem resolution to providers, (iii) reducing barriers to provider credentialing and contracting, (iv) providing for improved or expanded use of telehealth, and (v) improving the timeliness and accuracy of processes such as claim payment and prior authorization.

CMS expects 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. Some commenters complained that 90 days was insufficient to develop a remedy plan and urged CMS to extend the deadline. The agency disagrees, noting that states have a duty to monitor and oversee plans. Other commenters objected to the requirement because in the past CMS typically relied on technical assistance and periodic meetings to monitor states' progress to strengthen program performance. The agency responds that these past practices have not always yielded the desired results or produced traceable progress. The agency states that it does not intend to use remedy plans to usurp authority from states or intervene inappropriately in their contractual relationships with plans.

Any remedy plan must be designed so that improvements are sustainable and can be measured. States must submit quarterly updates to CMS describing the progress of the implementation of the remedy plan. If the remedy plan fails to address the managed care plan's access issue within 12 months, CMS may extend the plan for another 12-month period and could require that the plan be revised. Some comments argued that 12 months was not long enough to remedy certain issues, but the agency reminds readers that it can extend the first 12-month period and that there are a number of suggested actions that may be adopted to resolve the access issue.

States must comply with the remedy plan requirement 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.

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

CMS sees a state Medicaid's website as the single most important source of information about the state's Medicaid program. However, stakeholders have complained that some of these websites are less "user friendly" than others and that it can be very challenging to locate information that is required under regulations to be made available to the public on these websites. The agency believes it is necessary to revise current website requirements to ensure a consistent and easy user experience. CMS finalizes its proposals without modification.

General Transparency Requirements for State Medicaid Websites. Several specific requirements are added to the current requirement (at §438.10(c)(3)) for states to operate a website that provides the required content, either directly or by linking to individual managed care plan web pages. First, states must include all content, either directly or by linking to individual plan websites, on one web page. The website must include clear and easy to understand labels on documents and links; this should be done using the terminology and reading grade level that is used in other enrollee materials, such as handbooks. Every calendar quarter, states must verify that the website functions accurately and that the information presented is current. Finally, states must explain that assistance in accessing the required information on the website is available at no cost. The website must also include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. These requirements also apply to separate CHIP.

CMS clarifies, in response to a comment, that the link to the plan's website must be to the required content—not just to a random location on the plan's website. One commenter suggested CMS also require posting of plan MLR reports on each state's managed care webpage, which CMS may consider for future rulemaking, but it is concerned about the amount of information posted on the websites.

Transparency Requirements for State Medicaid Websites on Monitoring Contractor Compliance. Section 438.602(g) currently includes a short list of items that states must post on their website for each managed care plan with which it contracts. The final rule significantly expands the list of mandatory matters to be disclosed and posted for each plan on that website. These include (i) enrollee handbooks, provider directories, and formularies; (ii) information on rate ranges, if applicable; (iii) annual state reports on managed care programs and state assurance reports on compliance with access to care; (iv) network adequacy standards; (v) results of secret shopper surveys; (vi) state directed payment evaluation reports; (vii) information on all required APIs; (viii) quality related information; and (ix) documentation of compliance with mental health and SUD parity (as required in subpart K of part 438).

Effective Dates. There are different effective dates for the revised website requirements:

- Compliance with the revised general transparency requirements for state Medicaid websites under §438.10(c)(3) is required 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.

- Compliance with the requirement to make oral interpretation available in all languages and written translation available in each prevalent non-English language under §438.10(d)(2) applies 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.
- Compliance with the expanded list of transparency requirements for state Medicaid websites for monitoring contractor compliance under §438.602(g) is required 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.

Separate CHIP. CMS adopts for separate CHIP most of the requirements under the expanded list of transparency requirements for state Medicaid websites for monitoring contractor compliance under §438.602(g). The items that are not required for separate CHIP are (i) information on rate ranges, (ii) annual state reports on managed care programs, and (iii) state directed payment evaluation reports.

Burden Estimates. In aggregate, CMS estimates a one-time state burden of 900 hours at a cost of $108,126 for Medicaid for 45 states and a one-time state burden of 640 hours at a cost of $76,890 for CHIP for 32 states. Annual aggregate estimates for the new requirements are 1,800 hours at a cost of $216,252 for Medicaid and 1,312 hours at a cost of $157,624 for CHIP.

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

The term "behavioral health" is used throughout part 438 to mean mental health and SUD; CMS believes this is an imprecise term. CMS finalizes its proposal to substitute use of the term "mental health" for the term "behavioral health" throughout part 438.

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

1. Background

Federal Medicaid statute (section 1903(m)(2)(A)) requires risk-based contracts between states and MCOs to provide actuarially sound payments for services and associated administrative costs.[10] Not only is it the responsibility of managed care plans to negotiate payment rates with providers, but states are generally prohibited by regulation from directing plans' expenditures to providers. In the 2016 final rule, CMS established specific exceptions, thus allowing states to direct expenditures of managed care plans, referred to as state directed payments (SDPs).[11] Such funding may be used, for example, to ensure certain minimum payments to safety net providers, to enhance payments to behavioral health care providers as mandated by state legislative directives, or to ensure providers are rewarded for meeting certain program goals.

[10] Under its authority in section 1902(a)(4), CMS extends the same requirements to state contracts with PIHPs and PAHPs. MCOs, PIHPs and PAHPs are collectively referred to here as managed care plans or plans.
[11] The specific term state directed payments (SDPs) does not occur in current regulations at §438.6 but does appear in subsequent subregulatory guidance and is added at §438.6 under this final rule.

CMS describes the permissible SDPs at §438.6(c) established in the 2016 final rule, such as the following directives:

- Certain providers of the managed care plan must participate in value-based payment (VBP) models.
- Certain providers must participate in multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives.
- The managed care plan must adhere to certain fee schedule requirements, such as minimum fee schedules, maximum fee schedules, and uniform dollar or percentage increases.

Current regulatory requirements also include the following:

- All SDPs must be included in all applicable managed care contract(s) and described in all applicable rate certification(s) (§438.7(b)(6)).
- Most SDPs must be approved in writing prior to implementation (§438.6(c)(2)(ii)), with states submitting a completed Section 438.6(c) SDP Preprint documenting how the SDP complies with the regulatory requirements.

Every SDP preprint submitted to CMS is reviewed by a broad federal review team, which has recently expanded to include subject matter experts on financing of the non-federal share and demonstration authorities. Most preprints are reviewed on an annual basis, although some are eligible for multi-year approval (SDPs for VBP arrangements, delivery system reform, or performance improvement initiatives that meet additional criteria in the federal regulations). For calendar year 2022, CMS received 298 preprints for review, bringing the total as of October 2023 to 1,400 reviewed SDP proposals and 1,244 approved proposals since the 2016 final rule was issued. MACPAC, GAO and CMS present various estimates of federal and state spending under SDPs, with the most recent indicating approximately $52 billion for the year. At least half of this is for provider payments that states require plans to pay in addition to their negotiated rates.

Due to the increased number of SDP preprint submissions and dollars flowing through SDPs, CMS offered this proposal, with the intent to ensure the following policy goals:

1. Medicaid[12] managed care enrollees receive access to high-quality care under SDP arrangements.
2. SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the SDP arrangements.
3. CMS and states have the appropriate fiscal and program integrity guardrails to strengthen the accountability and transparency of SDP arrangements.

For the first time, CMS proposed to define SDP in regulation as a contract that directs a managed care plan's expenditures, as further described in this section. This definition reflects current use

[12] In the 2016 rule, the SDP requirements were not applied to separate CHIPs because there was no statutory requirement to do so. Even if it had the statutory authority, CMS indicates it also wishes to limit the scope of new regulations and administration burden on separate CHIP managed care plans. Similarly, these SDP provisions do not apply to separate CHIPs.

by states and CMS in standard interactions as well as in published guidance describing these contract requirements. In fact, the agency finalizes its proposal to rename the header for §438.6(c) to "State directed payments under MCO, PIHP, or PAHP contracts."

CMS highlights its regulatory changes regarding SDPs as follows:

- Exempting SDPs from requiring written prior approval if they establish payment rate minimums at 100 percent of Medicare's rate;
- 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;
- Addressing how SDPs are incorporated into capitation rates or separate payment terms;
- Creating a new appeal process for states dissatisfied with CMS' determination related to a specific SDP preprint; and
- Establishing new oversight and monitoring standards.

Given the scope of changes, a series of applicability dates apply over a roughly 5-year period, described below in section II.B.16 of this summary.

Final Action Overview. CMS finalizes 20-plus definitions as proposed, with a few modifications, including:

- The definition of "State directed payment" is finalized as proposed but moved from proposed §438.6(a) to finalized §438.2.
- The term "separate payment term" and the provisions regarding separate payment terms are *not* finalized (see section II.B.12 of this summary for discussion).

The table below summarizes some of the key SDP provisions as finalized, based on the type of SDP to which they apply.

Selected SDP Provisions in §438.6(c) and Their Applicability to Various SDPs

SDP provision	All SDPs	All SDPs except those (1) adopting a minimum fee schedule from Medicaid state plan rates or (2) 100% of Medicare rates[1]	SDPs in the prior column pertaining to (a) professional services at an AMC, (b) inpatient hospital, (c) outpatient hospital, and (d) NF services[2]
General *standards* for SDPs (§438.6(c)(2)(ii))[3]	✓		
CMS' *written prior approval* required that those standards and requirements are met (§438.6(c)(2)(i)), along with a written *evaluation plan* (§438.6(c)(2)(iv))		✓	
If any SDP has a final SDP cost percentage greater than 1.5%, the state must submit an *evaluation report* based on the *evaluation plan* (§438.6(c)(2)(v))		✓	
If any SDP has a final SDP cost percentage below 1.5%, the state must provide to CMS a *final SDP cost percentage report* (§438.6(c)(7))		✓	
SDP's total payment rate cannot exceed the average commercial rate (ACR), based on state's submission of *ACR commercial rate demonstration* and a *total rate comparison* (§438.6(c)(2)(iii))			✓
Reporting requirements of SDPs in *MLR reports* (§438.8(e)(2)(iii)(C)) and *T-MSIS* (§438.6(c)(4))	✓		
SDPs must be specifically described and documented in the *plan's contracts* (§438.6(c)(5))[4]	✓		
States' *final capitation rates* to plans must account for all SDPs, be accounted for in the base data, and related requirements (§438.6(c)(6))[5]	✓		

Source: HPA analysis, with references to finalized provisions.

[1] §438.6(c)(1)(iii)(A) and (B).

[2] CMS notes, between 2017 and March 2022, these four types of SDPs accounted for more than two-thirds of approved SDPs. AMC is an academic medical center. NF is nursing facility.

[3] In addition to the requirements in this table, other specified SDPs have additional requirements. Under §438.6(c)(2)(vi), SDPs have additional requirements if they are value-based purchasing models for provider reimbursement (§438.6(c)(1)(i)) or part of a multi-payer or Medicaid-specific delivery system reform or performance improvement initiative (§438.6(c)(1)(ii)); for all other SDPs (§438.6(c)(1)(iii), except for those exempted from written prior approval), SDPs must (A) condition payment from the plan to the provider on the

utilization/delivery of services under the contract for the rating period, and (B) not condition payment from the plan to the provider on utilization/delivery of services outside of the rating period for which the state is seeking written prior approval and then require payments be reconciled to utilization during the rating period (§438.6(c)(2)(vii)).

[4] For all SDPs, the contract must include the following: (1) the SDP's start date and, if applicable, the end date within the applicable rating period; and (2) a description of the provider class eligible for the SDP and all eligibility requirements. In addition, specific contract requirements are listed that vary by type of SDP. For example, SDPs that are based on a fee schedule must therefore describe the required fee schedule, the procedure and diagnosis codes to which the fee schedule applies, etc. (§438.6(c)(5)(A)).

[5] This provision prohibits and phases out separate payment terms by the first rating period that begins on or after July 9, 2027, as described in section II.B.12.b of this summary.

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

CMS describes a couple scenarios where, based on guidance from 2016-2017, the agency believed the contract arrangements were not subject to the requirements for SDPs under §438.6(c) or for pass-through payments under §438.6(d). Since then, subsequent guidance has reflected CMS' evolving thinking on these scenarios (SMDL #21-001). While CMS proposed no regulatory changes for these "grey area payments," because it believes none are necessary, it uses the discussion in the preamble of these two scenarios, summarized below, to elaborate on its current interpretation.

a. Required Percentage Toward VBP

CMS' November 2017 CMCS Informational Bulletin (CIB) entitled "Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts" provided a specific example of contract language generally requiring managed care plans to make 20 percent of their provider payments as VBP or alternative payment arrangements (APMs). Both then and now, CMS believes this scenario does not meet the criteria requiring approval as an SDP or a pass-through payment if the plan retains the discretion to negotiate with network providers regarding the specific terms for the amount, timing and mechanism of the VBP or APM. However, CMS does consider the approach to be the state imposing a quality metric on the managed care plans rather than on the providers. CMS clarifies that this specific type of contractual condition and measure of plan accountability is permissible, as long as it meets the requirements for an incentive arrangement (§438.6(b)(2)) or a withhold arrangement (§438.6(b)(3)).

b. General Requirement to Increase Provider Payment Rates

The second scenario is where the state contractually implements a general requirement on plans to increase provider payments but without mandating a specific methodology or amount. Under this scenario, managed care plans retain the discretion for the amount, timing and mechanism for making such provider payments. While CMS once believed this flexibility was adequate to exclude the state's contract requirement from §438.6, the agency has become increasingly concerned about vague contractual requirements for increased provider payment. For example, some of these general state requirements necessitate that the state add money to plans' capitation rates but without any further accountability to ensure the additional funding is paid to those

providers. Thus, these payments do not completely comply with §438.6(c) or §438.6(d)—hence the term "grey area payments."

Since publication of the 2017 CIB, CMS has concluded that general contractual requirements to increase provider payment rates circumvent the intent of the relevant prior rules. CMS sought to close this unintentional loophole in SMDL #21-001, which provides that if a state includes such a general contract requirement 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. CMS maintains this interpretation.

CMS further states 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. 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). CMS does not believe any changes are needed to the regulation text to reflect this reinterpretation.

Final Action. CMS is making its intent clearer through a minor modification to §438.6(c)(1), adding the phrase "in any way" after "…The State may not…." This makes the regulation more explicit that any state direction of a managed care plan's expenditures is impermissible unless it meets the requirements in §438.6(c).

Selected Comments/Responses. Some commenters supported CMS' restatement of its 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.

Other commenters opposed, encouraging 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 initiatives to ensure access to medically necessary services while still operating within the financial realities of state budgets.

In response, CMS continues to believe that its current policy is reasonable and appropriate, and declines 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. The agency rejects the recommendation to continue to permit "grey area payments" that are about general direction to increase payments, given existing authorities available to states, including SDPs and incentive arrangements.

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

Under current §438.6(c), states may direct managed care plans' expenditures under the contract subject to written prior approval based on complying with certain requirements. Many of these submissions required managed care plans to adopt minimum fee schedules specified under a methodology in the Medicaid state plan, which prompted CMS to adopt several revisions to §438.6(c) in the 2020 final rule (85 FR 72754) in order to eliminate unnecessary and duplicative review processes.

Some of those particular changes in the 2020 rule included the following:

- 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.
- In §438.6(c)(1)(iii)(A), explicitly listed SDPs that are a minimum fee schedule for network providers that provide a particular service under the contract using state plan approved rates and exempted these specific SDPs from the written prior approval requirement, although they still must comply with other requirements and be appropriately documented in the managed care contract(s) and rate certification(s).

CMS continues 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. T-MSIS reporting requirements apply to SDPs that do not require prior approval. The agency continues to review associated managed care contracts and rate certifications, combined with its state plan review process that ensures Medicaid state plan approved rates are consistent with 1902(a)(30)(A).

CMS believes the same rationale applies to SDPs adopting a minimum fee schedule using *Medicare* approved rates. Therefore, the agency finalizes exempting from written prior approval those SDPs that adopt a minimum fee schedule of *100 percent* of the total published Medicare payment rates, as it would be unnecessary and duplicative. In the regulatory text, this is accomplished by:

- Adding a definition for "total published Medicare payment rate" in §438.6(a),
- Explicitly recognizing SDPs that are a minimum fee schedule using a total published Medicare payment rate in effect no more than 3 years before the start of the rating period as a permissible type of SDP (finalized §438.6(c)(1)(iii)(B)), and
- Making related conforming changes—for example, in the new paragraph §438.6(c)(5) for audit and oversight purposes as summarized below at section II.B.11, adding that the contract must also include information about the Medicare fee schedule(s) necessary to implement the SDP, 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 (finalized §438.6(c)(5)(iii)(A)(5)).

This policy to exempt certain SDPs from written prior approval from CMS is specific to

SDPs that require the Medicaid managed care plan to use a minimum fee schedule that *is equal to* 100 percent of the total published Medicare payment rate. SDP arrangements that use a different percentage—whether lower or higher than 100 percent—of a total published Medicare payment rate as the minimum payment amount (or are simply based off of an incomplete total published Medicare payment rate) would remain subject to written prior approval by CMS.

Final Action. CMS finalizes its proposal without modification to exempt minimum fee schedule SDPs at 100 percent of the total published Medicare payment rates from written prior approval and 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.

CMS notes the exemption is limited to written prior approval of a preprint. *All* SDPs, including those described in §438.6(c)(1)(iii)(A) and (B), must comply with the standards finalized in §438.6(c)(2)(ii), reporting requirements in paragraph (c)(4), certain contract term requirements in paragraph (c)(5), and appropriate documentation in the managed care contract and rate certification submission in §438.7 (see section II.B.11 of this summary).

Selected Comments/Responses. Many commenters supported the proposal. Several suggested a range that would be exempted from written prior approval, such as 95 to 105 percent of Medicare payment rates, or a threshold as high as 125 percent of Medicare payment rates. CMS has concerns about expanding this exemption to SDPs that use other percentages of total published Medicare payment rates, since 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. Thus, minimum fee schedule SDPs that use Medicare payment rates 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.

One commenter suggested that any minimum fee schedule using Medicare as a benchmark should be exempt from all SDP requirements. CMS disagrees, citing 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.

Another commenter requested that CMS revise its definition of state plan approved rates to include payments 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. CMS points out that 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. CMS does not intend to revisit the definition for state plan approved rates or the associated exemption from written prior approval.

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

SDP regulations permitting adoption of a fee schedule amount or uniform increase are currently limited to only plans' network providers.[13] CMS finalizes its proposal, without modification, to remove this limitation. In its experience working with states, CMS has found that the limitation is too narrow and has created an unintended barrier to states' and CMS' policy goals to ensure access to quality care for beneficiaries. As justification, CMS describes several scenarios, such as that it is impractical for every plan to obtain individual network agreements with all facilities and providers.

CMS notes it is maintaining the phrase "network provider" for pass-through payments (PTPs, §438.6(d)), which are distinct from SDPs. Such PTPs are being phased out. Hospital PTPs must be fully eliminated by the rating period beginning July 1, 2027; NF and physician services PTPs were required to have been eliminated by no later than the rating period beginning July 1, 2022, with exceptions up to 3 years for transitioning services and populations in accordance with §438.6(d)(6). Therefore, CMS does not believe it is appropriate or necessary to eliminate the word "network" from §438.6(d).

Final Action. CMS finalizes its proposal, without modification, to remove "network" from §438.6(c)(1)(iii).

Selected Comments/Responses. Many commenters supported CMS' proposal to 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. In response to a question, CMS said this provision does not require including non-network providers in SDPs but gives states the option. 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 includes network and/or non-network providers.

In addition to expressing support for the provision, several commenters requested that CMS permit SDPs that require network providers to be paid higher payment amounts than out-of-network providers. CMS says that states are permitted to direct payment in many ways, subject to all the requirements in §438.6(c) and applicable law. For example, 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).

Several commenters opposed the proposal, recommending that CMS continue to limit certain types of SDPs to network providers. Some of these noted that this change might disincentivize

[13] This current limitation that SDP arrangements can only be used for network providers does not apply to SDPs that are VBP, delivery system reform or performance improvement initiatives.

providers from contracting with managed care plans and undermine network adequacy or access to network providers, counter to CMS's goals to improve access to managed care network providers. CMS disagrees 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, reiterating prior arguments. To the extent that a state decides that concerns about disincentivizing network participation should limit SDPs to non-network providers, this regulation permits that policy choice.

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

While current SDP regulations have no submission timeframes, CMS has encouraged states to submit their requests for written prior approval 90 days in advance of the start of the rating period whenever possible. This provides CMS and states time to work through the written prior approval process before the state includes the SDP in their managed care plan contracts and associated rate certifications. Since CMS 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 routinely submit SDP preprints at the very end of the rating period, with implementation dates retroactive to the start of the rating period. CMS says it has provided repeated technical assistance to these states and published additional guidance in 2021 to reiterate its 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, the agency has not been able to correct the situation with some states.

CMS proposed a new §438.6(c)(2)(viii)(A) through (C), which it is *not* finalizing, to set a deadline for submission of SDP preprints when written prior approval from CMS is required—no later than 90 days in advance of the *end* of the rating period to which the SDP applies (proposed 438.6(c)(2)(viii)(A)).[14] Thus, when a state fails to submit all required documentation for any SDP arrangement that requires written prior approval 90 days prior to the end of the rating period to which the SDP applies, the SDP would not be eligible for written prior approval, and the state would not be able to include the SDP in its Medicaid managed care contracts and rate certifications for that rating period. In proposed §438.6(c)(2)(viii)(B), CMS would have given itself flexibility to address the use of shorter-term SDPs in response to infrequent events, such as PHEs and natural disasters. In proposed §438.6(c)(2)(viii)(C), CMS specified the policies for the multi-year SDPs that are permitted for certain SDPs, such as for VBP—that the same timeframes apply (up to three rating periods) to the *first* rating period of those SDPs.

CMS provided an example scenario. Under current regulations, CMS would strongly recommend that a state seeking approval of an SDP for the calendar year (CY) 2025 rating period would ideally submit the preprint by October 3, *2024*. Under this proposal, if the start of the SDP was

[14] Similarly, for amendments to approved SDPs requiring written prior approval, CMS proposed but did not finalize §438.6(c)(2)(ix) that those amendments to SDPs also be submitted for written prior approval, before the end of the rating period to which the SDP would apply.

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 would not grant written prior approval for the CY 2025 rating period. Instead, the state could instead seek written prior approval for the CY *2026* rating period.

Final Action. CMS is not finalizing its proposed §438.6(c)(2)(viii)(A) through (C) and (ix). Instead, the agency finalizes a shorter §438.6(c)(2)(viii) that says, "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."

Selected Comments/Responses. CMS received a wide range of comments on the submission timeframes that were proposed for SDP preprints and amendments, as well as alternatives described in the proposed rule. One commenter said 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. A few commenters also did not support having submission dates that varied from the initial year to subsequent years, since those dates could be hard to track as SDPs changed over time. On the other hand, some suggested that SDP preprints be required to be submitted before the start of the rating period to ensure prospective implementation of SDPs.

While CMS received comments in support of and in opposition to the proposal, the comments persuaded the agency that its proposal could inadvertently make submission timeframes overly complicated, potentially exacerbating rather than alleviating submission compliance and hindering states' efforts to respond to unexpected issues. CMS recognizes 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.

After reviewing the comments that emphasized the need for state flexibility, CMS has 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, least burdensome, and strikes the right balance between the extremes of the start and end of the rating period. As such, it is 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, the agency believes a more relevant date upon which to base preprint submission than the start or end of the rating period. Nevertheless, CMS encourages states to submit their preprints as far in advance of an SDP's start date as possible to facilitate approval before the start date.

6. Standard for Total Payment Rates for Each SDP, Establishment of Payment Rate Limitations for Certain SDPs, and Expenditure Limit for All SDPs (§§438.6(a) and (c)(2)(ii)(I) and (c)(2)(iii))

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

Actuarially sound capitation rates must be projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for costs associated with the operation of the managed care plan for the time period and the population covered under the contract terms. Managed care plans have the responsibility to manage the financial risk of the contract, with negotiating payment rates with providers as one of the primary tools. As long as plans are meeting access and network adequacy requirements, states typically provide plans with latitude to develop a provider network for appropriate access and to fulfill all of their contractual obligations while managing the financial risk. However, given both the increasing volume of SDP preprints submitted by states and the total dollars flowing through SDPs, CMS believes it is appropriate to apply additional regulatory requirements regarding the totality of provider payment rates under SDPs.

CMS proposed several related regulatory changes to payment rate and expenditure limits. First, the agency proposed to codify the requirement in SMDL #21-001 for states, as part of the preprint review process, to demonstrate that SDPs result in total payment rates for each service and provider class that are reasonable, appropriate, and attainable. It thus proposed, and finalizes without modification, to define "total payment rate" in §438.6(a) as the following for each managed care program:

1. The average payment rate paid by all managed care plans to all providers included in the specified provider class for each service identified in the SDP;
2. The SDP's effect on the average rate paid to providers included in the specified provider class for the 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 service for which the state is seeking written prior approval; and
4. The effect of any and all allowable pass-through payments 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.

With this broad definition, CMS can then assess if the total payment level across all SDPs, pass-through payments, etc., in a managed care program is reasonable, appropriate, and attainable.

Final Action. CMS finalizes the definition as proposed of "Total payment rate" at §438.6(a). It also finalizes a standard for the provider payment rate applicable to all SDPs at §438.6(c)(2)(ii)(I), with minor modifications from the proposal to read as follows: Each SDP must "[e]nsure 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."

Selected Comments/Responses. Some commenters supported the proposal at §438.6(c)(2)(ii)(I) 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.

CMS responds that this finalized language codifies an existing standard in the 2021 SMDL. In reviewing all SDPs, CMS may request that states provide additional information to assess whether payments *to providers* are reasonable, appropriate, and attainable. 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 services as a comparative benchmark for provider payment analysis, or provide another methodologically sound analysis deemed acceptable by CMS.

The agency further clarifies that although it is only finalizing the total payment rate limit at the average commercial rate (ACR) for the four provider types and services at §438.6(c)(2)(iii),[15] described in the next section, in practice it intends to use ACR as the fiscal benchmark by which it will evaluate whether *all* SDP total payment rates are reasonable, appropriate, and attainable.

Some commenters requested further clarification on the state documentation requirement demonstrating the total payment rate by service and provider class. For example, one commenter requested that CMS allow a comparison by service category rather than per specific CPT code to avoid administrative burden. CMS clarifies that (1) it 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, and (2) it does not believe or anticipate that it would request a state to conduct and provide a total payment rate analysis at the CPT code level when exercising its authority under §438.6(c)(2)(ii)(I) to request documentation demonstrating the total payment rate for each service and provider class. States frequently complete total payment rate analyses at the service category level as part of CMS' current SDP review process, and the agency does not intend for §438.6(c)(2)(ii)(I) to prohibit this practice—although states could choose to conduct this analysis at the CPT code level.

b. Establishment of Payment Rate Limitations for Certain SDPs (§438.6(c)(2)(iii))

CMS proposed, and now finalizes, additional standards and documentation requirements for certain types of SDPs—that is, all *except* those adopting a minimum fee schedule based on Medicaid state plan approved rates or 100 percent of Medicare rates—where the SDP is for any of the following types of services:

- Inpatient hospital services,
- Outpatient hospital services,

[15] That is, inpatient hospital services, outpatient hospital services, nursing facility (NF) services, and qualified practitioner services at an academic medical center (AMC).

- Nursing facility (NF) services, and
- Qualified practitioner services at an academic medical center (AMC).

As finalized, the total payment rate for each SDP for the services above cannot exceed the average commercial rate (ACR).[16] To demonstrate this, the state must submit the following:

- The ACR demonstration, and
- A total payment rate comparison between the SDP and the ACR.

As summarized below, CMS describes the history and rationale for using the ACR benchmark for SDPs; the finalized payment rate limits using the ACR for inpatient hospital services, outpatient hospital services, NF services, and qualified practitioner services at an AMC; and specific requirements for the ACR demonstration and total rate comparison.

Historical Use of the Average Commercial Rate Benchmark for SDPs. In 2017, CMS faced a dilemma when it received an SDP preprint to increase inpatient hospital rates above Medicare levels but below the ACR for the specified service and provider class in that state. This would not be permissible in FFS Medicaid due to Medicaid's upper payment limits (UPLs) for specific classes of institutional providers.[17] The UPLs are based on Medicare's payment levels; however, CMS had concerns about applying the same standards for the total payment rate under managed care SDPs, especially if higher payments would still be "reasonable, appropriate, and attainable."

Current SDP regulations provide states with broader flexibility that has proven important for states to achieve their policy goals tied to their managed care quality strategy. CMS points to examples of approved SDPs for provider classes defined by such criteria as participation in state health information systems or by participation in learning collaboratives focused on health equity or social determinants of health (SDOH). Thus, SDP provider classes have not always aligned with those used in Medicaid FFS UPL demonstrations, which are only based on the facility's ownership/operation status and include all payments made to all facilities that fit in those ownership-defined classes. Under SDPs, while states are required to direct expenditures equally for a *class* of providers furnishing services under the contract, they are not required to direct expenditures for *all providers* providing services under the contract.

CMS has decided not to attempt to align SDPs requirements under managed care with UPL requirements under FFS Medicaid. Nevertheless, CMS needed to establish a benchmark that could be applied uniformly across all SDPs to evaluate preprints for approval and to ensure that payment rates projected to be paid under the SDP(s) remained reasonable, appropriate, and attainable. States have been approved to make Medicaid FFS supplemental payments up to the

[16] Related, CMS also finalizes its proposal, without modification, adding a definition for "average commercial rate" at §438.6(a), that it "means the average rate paid for services by the highest claiming third-party payers for specific services as measured by claims volume."

[17] Such institutional providers include hospitals, nursing facilities, and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID). The UPL regulations for FFS Medicaid are at §§447.272 (inpatient hospital services), 447.321 (outpatient hospital services) and 447.325 (other inpatient and outpatient facility services). 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.

ACR for qualified practitioners affiliated with and furnishing services—for example, physicians under the physician services benefit—in AMCs, physician practices, and safety net hospitals. CMS has approved SDPs with total payment rates up to the ACR for the same providers for which the state had approved state plan authority to make supplemental payments up to the ACR in Medicaid FFS.

In 2018, CMS ultimately interpreted regulations to permit total payments in an SDP up to the ACR. CMS adopted the ACR as the standard benchmark for all SDPs, with a broader application—that is, across more services and provider types—than under FFS Medicaid UPLs.[18] The agency presents additional reasons for this decision.

As a result of 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. In 2021, this was formalized in the revised preprint form and accompanying SMDL. When a state has not demonstrated that the total payment rate in the SDP is at or below either the Medicare or, when Medicare does not cover the service, the Medicaid FFS rate, then CMS has requested documentation for the state to demonstrate that those total payment rates do not exceed the ACR. CMS has not "knowingly approved" an SDP where the total payment rate was projected to exceed the ACR.

Payment Rate Limit for Inpatient Hospital Services, Outpatient Hospital Services, Qualified Practitioner Services at AMCs, and NF Services. Increasingly, states are submitting preprints that would push total payment rates up to the ACR. Thus, CMS proposed moving away from using an internal benchmark to a regulatory limit on the projected total payment rate—using the ACR for inpatient hospital services, outpatient hospital services, qualified practitioner services at an AMC, and NF services. The agency presents additional analyses and its own experience as to why it believes the ACR is appropriate, particularly for inpatient hospital services, outpatient hospital services, and qualified practitioner services at an AMC. Of note, 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.

Between 2017 and March 2022, CMS has approved 145 preprint actions that were expected to yield SDPs equal to the ACR, more than two-thirds of which intended to raise total payment rates up to the ACR for the four provider types, as follows:

- 33 percent are for professional services at AMCs;
- 18 percent are for inpatient hospital services;
- 17 percent are for outpatient hospital services; and
- 2 percent are for nursing facilities.

[18] Because statutory and regulatory UPL requirements in Medicaid FFS do not apply to risk-based managed care plans, CMS may permit states to direct managed care plans to make payments higher than the UPL without violating any Medicaid managed care statutory or regulatory requirements.

Very few states are pursuing SDPs to increase total payment rates up to the ACR for other categories or types of services. Although there have not been many SDP submissions to bring nursing facilities up to a total payment rate near the ACR, concerns have been raised about the size of the payment increases as well as the results of a public audit regarding a NF SDP.[19]

Thus, as proposed and finalized, states directing expenditures by managed care plans in a manner that results in a total payment rate above the ACR for any of these four types of services would not be approvable because they would violate the standard—that total payment rates be reasonable, appropriate, and attainable—as well as the standard in §438.6(c)(2)(iii) setting specific payment level limits for certain types of SDPs. This applies across all SDPs in a managed care program so that states could not, for example, create multiple SDPs in an attempt to exceed the ACR. In addition to the changes at §438.6(c)(2)(iii), CMS finalized a number of related definitional additions to §438.6(a).

CMS acknowledges that where Medicaid is the most common or only payer for some services—such as HCBS, mental health services, substance use disorder services, and obstetrics and gynecology services—instituting a limit on SDP payment amounts based on the ACR, particularly when access concerns have been raised in the commercial markets, may have a deleterious effect on access to care for Medicaid managed care enrollees. Thus, CMS did not propose payment rate ceilings for any other services. Although the SDPs for all other services will still need to meet the standard that the total payment rate for each SDP is "reasonable, appropriate, and attainable," it believes further research is needed before codifying a specific limit.

CMS also acknowledges that codifying this payment limit could incent states and interested parties to implement additional arrangements that raise total payment rates up to the ACR for reasons other than advancing access and enhancing quality. Most SDPs that increase total payment rates up to the ACR are primarily funded by either provider taxes, IGTs, or a combination of these two sources of the non-federal share—and they represent some of the largest SDPs in terms of total dollars beyond base managed care rates. CMS is 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.[20] To mitigate this concern, CMS proposed additional regulatory changes related to financing the non-federal share (section II.B.7 of this summary, below).

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[19] 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.

[20] From the June 2022 MACPAC chapter "Oversight of Managed Care Directed Payments" (pp. 38, 40): "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, stakeholders 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."

CMS described several alternatives to the ACR—including the Medicare rate—as the total payment limit for the 4 service types and other services. The Medicare rate is also not based on proprietary data, is often the standard for Medicaid FFS under UPL demonstrations (42 CFR part 447), and could be verified and audited more easily than the ACR. Using the Medicare rate could limit the growth in payment rates more than using the ACR. On the other hand, CMS expresses concerns with relying on Medicare rates for the purpose of Medicaid managed care SDP total payment limits. In addition to limitations described in the previous subsection, CMS expressed concerns about differences in populations covered by each program. Having said that, the agency noted that 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. Moreover, beneficiaries enrolled in Medicaid managed care are often more aligned with individuals in commercial health insurance (such as, non-disabled adults under age 65 and children), whereas the Medicaid FFS population is generally more aligned with the Medicare population (older adults and individuals with complex health care needs).

ACR Demonstration Requirements. CMS finalizes its proposal that if a state seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an AMC, or NF services, it must submit for those services an *ACR demonstration* and a *total rate comparison to the ACR*.

The *ACR demonstration* must satisfy all of the following 6 requirements (§438.6(c)(2)(iii)(A)), each of which CMS elaborates on in the preamble:

(1) Is specific to the state (rather than a regional or national analysis);
(2) Is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request;[21]
(3) Is specific to the service(s) addressed by the SDP (but not *required* by provider class, as is current practice—a nuance described below in greater depth);
(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 Medicaid managed care plan does not cover.

CMS notes that payment data from qualified health plans (QHPs) operating in the ACA Marketplace should be included when available.

CMS also finalizes its proposed requirements for the *total payment rate comparison to the ACR* when a state seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an AMC, or NF services. The

[21] As an example, for an applicable SDP for the CY 2025 rating period, the data for the ACR demonstration must be from calendar year 2021 and later.

comparison would be required to satisfy all of the following 5 requirements (§438.6(c)(2)(iii)(B)):

(1) Be specific to each managed care program to which the SDP applies;
(2) Be specific to each provider class to which the SDP applies;
(3) Be projected for the rating period for which written prior approval is sought;
(4) Use payment data that is specific to each service included in the SDP; and
(5) Include a description of each of the components of the total payment rate as a percentage of the average commercial rate, for each of the four categories of services included in the SDP submitted to CMS for review and approval.

CMS codifies that the total payment rate comparison would be specific to each Medicaid managed care program to which the SDP under review would apply, specific to both the service *and* the provider class. While this is current practice, it differs from the requirement for the ACR demonstration, which is service specific only, not by provider class. CMS describes in detail how doing away with the ACR demonstration requirement at the level of each provider class gives states greater flexibility in directing payments across provider classes for a service—for example, permitting SDPs so that the total payment rates could exceed the ACR for rural hospitals but be below the ACR for non-rural hospitals.

The agency notes it is establishing a set of standards and practices for states' ACR analysis, without requiring states use a specific source of data, template, or format.

ACR Demonstration and Total Payment Rate Comparison Compliance. The finalized proposal requires states to submit the ACR demonstration and the total payment rate comparison 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 final rule's effective date. The total payment rate comparison would need to be updated with each subsequent preprint amendment and renewal. The ACR demonstration would only need to be updated every 3 years, as long as the state continues to include the SDP in the plan's contract.

Final Action. CMS finalizes its proposed §438.6(c)(2)(iii), with one minor modification, to establish a total payment rate limit at the ACR when states choose to implement SDPs for one of the four service types—inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center—along with requirements that states submit for those services an ACR demonstration and a total rate comparison to the ACR.

Selected Comments/Responses. Many commenters supported the proposal, saying that the ACR is a reasonable threshold that allows managed care plans to compete with commercial plans for providers to participate in their networks and is consistent with the goal of equity in payment across delivery systems. A number of concerns were raised if CMS used a total payment limit below the ACR. CMS agrees but reiterates that although it is only finalizing the total payment rate limit at the ACR for the four service types, it will continue to use ACR as the fiscal benchmark for evaluating whether total payment rates for all SDPs are reasonable, appropriate, and attainable.

Some commenters recommended a total payment rate limit at the Medicare rate rather than ACR for the four service types, noting that Medicare rates are published yearly and available to the public, which would increase transparency and in alignment with the UPL. A few commenters also supported using the Medicare rate as the total payment rate limit for SDPs for these four services for fiscal integrity reasons, noting 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.

In response, while CMS recognizes using the Medicare rate would provide a strong fiscal guardrail for SDPs, it could impact states' efforts to further their overall Medicaid program goals and objectives. Medicaid managed care plans have the responsibility to negotiate payment rates with providers at levels that will ensure network adequacy. SDPs allow states to direct how managed care plans pay providers to further the state's overall Medicaid program goals and objectives. CMS' 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. Again, although it is only finalizing the total payment rate limit at ACR for the four service types at §438.6(c)(2)(iii), CMS will continue to use ACR as the fiscal benchmark to evaluate whether total payment rates are reasonable, appropriate, and attainable.

CMS agrees 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. The agency encourages states to take such factors into account when considering the implementation and design of an SDP, since they have significant flexibility in designing the SDP, including the provider class(es) and the type of payment arrangement.

Some commenters supported applying the ACR limit to all service types, not just those four service types proposed. In response, CMS says there is currently enough evidence to support that the ACR is an appropriate limit for the total payment rate for SDPs for the four service types. Further research is needed before codifying a specific total payment rate limit for other services, but CMS will continue to review and monitor all payment rate information submitted by states for all SDPs as part of its oversight activities, including ensuring compliance with the requirement (finalized 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.

Some commenters requested clarification on how CMS intends to enforce the SDP total payment rate limit for the four service types if actual payments made by the plans to eligible providers exceed the total payment rate limit. CMS points to the requirement (below in section II.B.15 of this summary) for states to submit to CMS, no later than 1 year after each rating period, T-MSIS data specifying the total dollars expended by each managed care plan 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. CMS will use the data collected from states on the actual final payment rate through T-MSIS as part of its monitoring

and oversight; if the actual final payment rates differ from what was projected, at minimum, CMS says it will use this information to inform future reviews of SDPs.

CMS received a wide range of comments on establishing a total payment rate limit at the ACR for nursing facilities. Many broadly supported establishing a total payment rate limit at the ACR for all four service types, but some 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, and that Medicare is not a reasonable benchmark either.

In response, and as previously noted, CMS has received SDP proposals that increase total payment rates up to the ACR for nursing facilities, along with a growing number 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.[22]

Many comments supported establishing a total payment rate limit at the ACR for qualified practitioner services provided at an academic medical center, 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. Academic medical centers are often the only source for certain specialty and sub-specialty care. CMS appreciates the support and notes this will align with long-standing Medicaid FFS payment policy.

Several commenters requested clarification on the data sources that should be utilized for ACR demonstrations and total payment rate comparisons. Some noted that commercial rate data are difficult for states to provide absent an all-payer claims database. CMS acknowledged that commercial data are often proprietary and, to its 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. Some states have purchased access to private commercial databases to inform these analyses. Other states have required providers to provide commercial payment data as a condition of eligibility for the SDP. The agency expects 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).

Many commenters supported the 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 they are not required to be specific to both each service type and each provider class. Commenters noted 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 the proposal and recommended that the ACR must also be specific to the provider

[22] 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.

class(es) addressed by the SDP, to align with current practice. CMS restates its prior explanation in this rule and its "lengthy discussion" in the proposed rule (88 FR 28125) in finalizing its proposal without modification.

c. Potential Addition of Expenditure Limit for SDPs

States' increased use of SDPs has been raised as an area of increased oversight risk for CMS by several oversight bodies and interested parties. As use of SDPs grows, the risk-based nature of capitation rates has arguably diminished. CMS cites an example in one state where an SDP accounts for 9 percent of the total projected capitation rates, and as much as 43 percent of the capitation rates by rate cell for SFY 2023. In another state, SDPs accounted for more than 50 percent of the projected Medicaid managed care hospital component of capitation rates in 2022. Some stakeholders have raised concerns that such percentages are not reasonable and that states are using SDP arrangements to circumvent Medicaid FFS UPLs by shifting costs from Medicaid FFS to managed care.

In the proposed rule, CMS presented a number of potential options for imposing a limit on the amount of SDP expenditures and sought comment.

Final Action. CMS is not finalizing an overall SDP expenditure limit in this final rule.

Selected Comments/Responses. For a number of reasons, many commenters did not support the alternative options outlined in the proposed rule for an expenditure limit on SDPs. A few recommended that CMS complete additional studies, including using future SDP evaluations, to better understand the impact of an SDP expenditure limit and whether such a limit is truly needed. CMS recognizes 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. It agrees with commenters that the total payment limit at the ACR for the four specific categories is the reasonable and appropriate policy to ensure the fiscal integrity of SDP arrangements.

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

a. Background on Medicaid Non-Federal Share Financing

Federal statute requires states to share in the cost of medical assistance and in the cost of administering the Medicaid program. Federal financial participation (FFP)—that is, federal Medicaid matching funds—is not available for expenditures for services and activities that are not medical assistance authorized under a Medicaid authority or allowable state administrative activities. In addition, FFP is not available for expenditures that do not conform to approved state plans, waiver, demonstration projects, or contracts.

Examples of options for financing the non-federal share of Medicaid expenditures include the following:

- State general funds, typically derived from tax revenue appropriated directly to the Medicaid agency;
- Revenue derived from health care-related taxes (also known as provider taxes);
- Provider-related donations that are "bona fide"—that is, truly voluntary and not part of a hold harmless arrangement under §433.54(c); and
- Intergovernmental transfers (IGTs) from units of state or local government that contribute to the non-federal share of Medicaid expenditures by transferring their own funds to and for the unrestricted use of the Medicaid agency.

Regardless, the state must fund at least 40 percent of the non-federal share of total Medicaid expenditures with *state* funds.

Health care-related taxes made up approximately 17 percent ($37 billion) and IGTs approximately 10 percent of all states' non-federal share in 2018 (the latest year for which data are available). Medicaid statute clearly permits certain health care-related taxes and IGTs for the non-federal share, which CMS supports (where consistent with applicable federal requirements) and approves hundreds of such payment proposals annually.

CMS reviews the history of health care-related taxes and provider-related donations. Their creation in the mid-1980s led to arrangements where providers would agree to make a donation or would support (or not oppose) a tax on their activities or revenues, which 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 enacted limits in section 1903(w) to require, among other things, that health care-related taxes be broad-based and applied uniformly, with a prohibition on hold harmless arrangements (1903(w)(4)). CMS recounts numerous regulatory and administrative activities and guidance over the years regarding hold harmless arrangements. For example, citing the preamble of a February 2008 final rule, the agency points out that 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 the non-federal share.

b. Non-Federal Share Financing and State Directed Payments

CMS employs various mechanisms for reviewing state methods for financing the non-federal share of Medicaid expenditures, including reviews of fee-for-service state plan amendments (SPAs), reviews of managed care SDPs, quarterly financial reviews of state expenditures reported on the Form CMS-64, and reviews of state health care-related tax and provider-related donation proposals. In its reviews of SDP proposals, the agency is increasingly encountering issues with state financing of the non-federal share of SDPs—for example, health care-related taxes and IGT arrangements that may not be in compliance with the federal requirements. In

January 2021, CMS released a revised SDP 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 CMS' increased awareness of non-federal share financing issues associated with SDPs. Concerns regarding funding of the non-federal share of SDPs have been raised by MACPAC, GAO, and HHS' Office of the Inspector General (OIG).

CMS recites its own recent experience with states that appear to use impermissible hold harmless arrangements. These include redistribution arrangements not described on states' SDP applications—and if they were described, those applications would be denied because they are impermissible. The agency says 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; the effect is to ensure that taxpaying providers are held harmless for all or a portion of their cost of the health care-related tax.

CMS provides examples of how some of these arrangements have been structured. The agency believes providers with higher Medicaid volume agree to redistribute some of their Medicaid payments to ensure broad support for the tax. Doing so ultimately works to the advantage of those providers since the tax supports increased Medicaid payments to them—even net of Medicaid payments that they redistribute to other providers—compared to Medicaid payments without the tax program. These redistribution arrangements help state and local governments enact or continue provider tax programs.

CMS restates that the Medicaid statute in section 1903(w) prohibits FFP 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. Such payment redistribution arrangements often occur without notice to CMS (and possibly states) and are not described as part of a state payment proposal submitted to CMS. The agency says it would be inconsistent with the proper and efficient operation of the Medicaid state plan to approve an SDP when it knows the payments would be funded under such an arrangement. For example, CMS 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 it approve an SDP requiring 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. Such redistribution arrangements undermine Medicaid's fiscal integrity and are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements.

The February 2008 final rule on health care-related taxes specified that hold harmless arrangements prohibited by §433.68(f)(3) exist "[w]hen a State payment is made available to a taxpayer or a party related to the taxpayer (for example, as a nursing home resident is related to a nursing home), in the reasonable expectation that the payment would result in the taxpayer being held harmless for any part of the tax" (73 FR 9694). CMS says that references to "indirectly" in the regulation indicate 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 arrangement. Hold harmless arrangements also 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.

CMS elaborates that regardless of whether the taxpayers participate voluntarily, whether the taxpayers receive the Medicaid payments from the state or 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 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.

CMS says it will disapprove an SDP when it is aware that the state share in the SDP would be based on an arrangement that violates section 1903(w) of the Act. SDPs 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; it would not be permissible for CMS to provide federal Medicaid matching funds for expenditures not used for medical assistance but diverted for another purpose.

The agency cites a 2007 example where written agreements among certain hospitals redirected Medicaid payments to other entities to fund non-Medicaid costs and therefore were not authorized. This payment of FFP for non-qualifying activities also has the effect of inflating the federal matching rate that the state receives for qualifying Medicaid expenditures.

CMS notes states' challenges with identifying and providing details on redistribution arrangements as requested by CMS during the review of SDPs. The lack of transparency prevents both CMS and states from having information necessary to ensure they meet federal requirements—for reviewing both the proposed non-federal share financing source and the proposed payment methodology. While some states have also expressed concerns with ongoing oversight CMS activities to obtain information involving arrangements to which only private entities are a party, CMS says it is only interested in any business arrangements that could result in a violation of federal statutory and regulatory requirements.

With that background, CMS then suggests current regulations need to be enhanced regarding SDPs and the financing of the non-federal share. Specifically, the agency finalizes its proposal to explicitly require that an SDP comply with all federal legal requirements for the financing of the non-federal share, including 42 CFR part 433, subpart B, as part of the CMS review process (§438.6(c)(2)(ii)(G)). States would also be required to ensure that each participating provider in an SDP arrangement attests that it does not participate in any hold harmless arrangement for any health care-related tax for any direct or indirect payment, offset, or waiver that directly or indirectly guarantees, or produces a reasonable expectation, to hold the provider harmless for all or any portion of the tax amount (§438.6(c)(2)(ii)(H)). States will be required to note in the preprint their compliance with this requirement prior to CMS' written prior approval of any contractual payment arrangement directing how Medicaid managed care plans pay providers.

States would obtain each provider's attestation or require the Medicaid managed care plan to obtain each provider's attestation, which would be available to CMS upon request.

As proposed, CMS may deny written prior approval of an SDP if it does not comply with any of the standards in §438.6(c)(2), including the financing of the non-federal share is not fully compliant with all federal legal requirements for the financing of the non-federal share and/or the state does not require an attestation from each provider receiving a payment based on the SDP that it does not participate in any hold harmless arrangement. These provisions would apply to all SDPs, regardless of whether written prior approval is required.

After reviewing comments, CMS modified its proposal so 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.

Although the applicability dates for the policies in this rule are detailed in section II.B.16 of this summary, CMS notes it is updating the effective date for the providers' attestation (§438.6(c)(2)(ii)(H)) to no later than the first rating period for contracts with managed care plans beginning on or after January 1, 2028.

Final Action. CMS finalizes its proposal in §438.6(c)(2)(ii)(G), without modification, that all SDPs must comply with all federal legal requirements for the financing of the non-federal share.

It also finalizes in §438.6(c)(2)(ii)(H) that states must ensure providers receiving SDPs attest they do not participate in any impermissible hold harmless arrangement for a provider tax and that such attestations are available to CMS upon request (or that the state provides a satisfactory explanation to the agency as to why specific providers are unable or unwilling to make such attestations). This was modified from the proposal by allowing flexibility if states were unable to obtain attestations from uncooperative or unresponsive providers, along with slight wording modifications.

To help ease the transition to the collection of required provider attestations, an applicability date is established (§438.6(c)(8)(vii)) of no later than the first rating period for contracts beginning on or after January 1, 2028, to allow states sufficient time to establish the attestation collection process that works best for their individual circumstances.

Selected Comments/Responses. Some commenters stated that the proposal will restrict states' ability to raise funds to finance the non-federal share in the same manner as in the past and would reduce payment rates to providers, which may harm access to care for Medicaid beneficiaries. CMS disagrees that the regulation would restrict non-federal share financing sources, stating that 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, as it has done over the years.

Some commenters were concerned that the proposal allowing states to delegate to managed care plans the responsibility for gathering the attestations 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. CMS acknowledges 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 networks. The agency recommends states that delegate the collection of provider attestations to Medicaid managed care plans furnish standardized attestation language or forms that reflect the tax at issue and what time period it covers. Ultimately, states will be responsible for implementing the attestation requirement under this final rule, and CMS encourages them to consider the complexities that may arise from delegating the responsibility to plans.

One commenter sought clarification on how the proposal 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 requested clarity about how CMS would treat states when a provider fails to comply with the signed attestation. States would be required to note in the preprint their compliance with this requirement prior to CMS' 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.

Having said that, CMS does not believe that it makes policy sense 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. Nor would it make policy sense for CMS 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. CMS will still be performing a comprehensive review of the permissibility of the SDP and the source(s) of the non-federal share that support the SDP.

CMS provides several possible scenarios where a state might be unable to collect one or more attestations, yet would determine that their absence does not indicate the existence of an impermissible hold harmless arrangement. 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 the agency's overall review of approvability. For a state's explanation to be satisfactory, it must demonstrate why the absence of the attestation(s) is not indicative of a hold harmless arrangement, how the state 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. As one of many examples, CMS says a state might describe its efforts to obtain all attestations and indicate that of 150 participating providers, only two with an extremely small amount of all-payer revenue (who may be less motivated to assist with SDP approval) did not file an attestation.

If a provider submits an inaccurate attestation or refuses to submit a signed attestation, CMS says that 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. The state could make signing an attestation a condition of eligibility for the SDP, according to the terms of the contract, which some states have already done. CMS will disapprove an SDP when it knows 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.

Private Party Pooling. Several commenters stated that CMS' interpretation of hold harmless arrangements overstepped or misinterpreted the "plain language" of the statute—that the statute specifies that *states* must be responsible for arranging the hold harmless agreement. If private actors create an arrangement without state involvement, it should not be considered a violation of the statute. They noted that the proposal would further codify what they consider to be CMS' erroneous interpretation and illegally interferes with private providers engaging in private arrangements to mitigate the impact of a provider tax. Several commenters referenced a lawsuit brought by Texas against CMS that has resulted in the court preliminarily enjoining CMS from disapproving or acting against certain financing arrangements within Texas.

CMS disagrees with commenters' characterization that the requirements of this 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, with similar regulations at §433.68(f)(3). CMS says that by providing a payment that is redistributed through private arrangements to offset the amount paid by a taxpayer, a state has indirectly provided for a payment that guarantees to hold the taxpayer harmless. Thus, CMS does not agree with commenters' assertion that the proposal 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." Regardless of whether the taxpayers 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, 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 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."

CMS acknowledges 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 1903(w)(4)(C)(i) found therein.[23] That injunction remains in effect, and CMS says it 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.

One state commenter said they currently have a pooling arrangement that is compliant with federal law and working well. Providers have had various private agreements to redistribute funds among themselves for decades, with the full knowledge and approval of CMS. CMS does 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, stating that the foundation of federal-state shared responsibility for Medicaid is that the state must participate in the financial burdens and risks of the program. Section 1902(a)(2) 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. Medicaid payment redistribution arrangements undermine the fiscal integrity of Medicaid 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. According to CMS, they are also inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements and artificially inflate federal Medicaid expenditures.

Safe Harbor. As way of background, there are different regulatory hold harmless provisions for bona fide donations (§433.54(c)) and for health-care related taxes (§433.68(f)). In the proposed rule, CMS made no mention of a safe harbor. For health-care related taxes, direct and indirect hold harmless guarantees are prohibited. An *indirect hold harmless guarantee* is determined under a two-prong test. First, if the health care-related tax does not exceed the safe harbor threshold of 6 percent of net patient revenue, it is permissible. However, if it does exceed 6

[23] In its preliminary injunction, the court said: "But the statute still requires that the state, not a private party, provide the 'payment' that 'guarantees' to hold taxpayers harmless. … In fact, in its 2008 rule, CMS provided an example demonstrating it shared this interpretation. … The Court thus concludes that the Bulletin conflicts with the statutory definition of 'hold harmless provision' found in § 1396b(w)(4)(C)(i). Because courts must 'hold unlawful and set aside agency action' that is 'not in accordance with law' or 'in excess of statutory . . . authority,' 5 U.S.C. §706(2)(A), (C), the Bulletin will likely be set aside. Texas has thus shown a 'substantial likelihood of success on the merits.' "

percent but at least 75 percent of taxpayers in a class receive 75 percent or more of their total tax costs back from Medicaid, that is also permissible (§433.68(f)(3)(i) and section 1903(w)(4)(C)(ii)).

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. In response, CMS agrees that enforcing the existing requirements concerning health care-related taxes would be beneficial and believes that the attestation requirement is necessary to ensure that SDPs are financed appropriately. In addition, CMS notes that the "safe harbor" threshold located at §433.68(f)(3)(i)(A) says that taxes under 6 percent of net patient revenue attributable to an assessed permissible class pass the *indirect* hold harmless test, a test not addressed in this rulemaking. The agency points out that the 6 percent indirect hold harmless limit does not mean 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.[24]

8. 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 managed care contract. This differentiates SDPs from pass-through payments.[25] Current regulations require states to 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 contract. Specifically, as implemented, SDPs must be conditioned on the utilization or delivery of services during the rating period identified in the preprint for which the state is seeking written prior approval.

CMS believes further clarification is necessary due to the variety of payment mechanisms that states use in their SDP arrangements. This section addresses the required tie to utilization and delivery of services for the more straightforward SDPs that are generally linked to a fee schedule,[26] while the following section addresses SDPs that are VBP initiatives.[27]

[24] Similarly, in the February 2008 final rule on Medicaid health care-related taxes, CMS clarified that "a State can provide a direct guarantee through a direct or indirect payment" (73 FR 9686). For additional background information, see MACPAC's Issue Brief "Health Care-Related Taxes in Medicaid."

[25] In fact, pass-through payments are not consistent with the regulatory standards for actuarially sound rates because they do not tie provider payments to the provision of services, which led CMS to phase them out (§438.6(d)).

[26] Specifically, minimum fee schedules, maximum fee schedules, and uniform increases, per §438.6(c)(1)(iii) and with definitions for inclusion in §438.6(a).

[27] Specifically, those found in current §438.6(c)(1)(i) and (ii), which are not altered by this rule. CMS notes that ensuring that payments in VBP initiatives are based on the delivery of services in ways that do not hinder states' ability to pursue VBP efforts is more difficult because, by their nature, VBP initiatives seek to move away from paying for volume in favor of paying for value and performance, as described in the next section of this summary.

a. Utilization Based on Current Rating Period (§438.6(c)(2)(vii)(A))

Similar to the current requirements in the preprint, for the fee-schedule SDPs, the proposal (finalized without modification) would require that SDPs condition payment from the managed care plan to the provider on the utilization and delivery of services under the contract only for the rating period for which the state is seeking written prior approval. Thus, payment cannot be based solely on historical utilization or any other basis not tied to the delivery of services in the rating period itself.

b. Prohibition on Post-Payment Reconciliation (§438.6(c)(2)(vii)(B))

This proposal has implications for states using SDPs that rely on reconciliation for their payments to managed care plans—for example, where states require managed care plans to make interim payments based on historical utilization and then reconcile the payments to actual utilization after the close of the rating period. CMS has seen instances where states have their actuaries submit an amendment to adjust the amount paid to plans (whether through a separate payment term or an adjustment to base rates) to account for this reconciliation, which essentially removes risk from those managed care plans participating in the SDP. CMS finds that making managed care plans "whole" through such reconciliation adjustments and removing risk from the plans participating in the SDP is not consistent with the nature of risk-based managed care. In sum, if states 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.

To address this, CMS proposed (and finalizes without modification) to 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. In the same way that CMS phased out pass-through payments because they were not consistent with actuarially sound rates and do not tie provider payments with the provision of services, the agency reaches a similar conclusion regarding SDP proposals that use reconciliation of historical to actual utilization. If states want to ensure payment rates for specific services are at or above a certain level, CMS suggests they instead require plans to use minimum fee schedules or uniform increases, which would also allow states' actuaries to include the SDPs in the standard capitation rate development process using the same utilization projections used to develop the underlying capitation rates.

Final Action. CMS finalizes its proposals for §438.6(c)(2)(vii)(A) and (B), without modification.

Selected Comments/Responses. While some commenters supported the proposal, many were opposed, stating concerns that it would preclude states and managed care plans from making SDP payments to providers based on historical data altogether and create cash flow problems for providers. CMS acknowledges the concerns while restating its goal is to ensure the integrity of risk-based managed care and that payments to providers under SDPs be based on utilization and delivery of services during the rating period. The agency clarifies that this provision does not prohibit all administrative reconciliation processes. For example, those standard provider

payment processes associated with claims processing (such as runout, adjudication, and appeal) that may not be completed within the rating period are processes that could continue.

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

CMS proposed several changes to §438.6(c) to address how VBP initiatives 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. CMS proposed the following changes to the requirements for SDPs involving VBP initiatives:

- Remove requirements that prohibit states from setting the amount or frequency of the plan's expenditures;
- Remove requirements that prohibit states from recouping unspent funds allocated for these SDPs;
- Revise and clarify how performance in these types of arrangements is measured for participating providers (§438.6(c)(2)(vi)(B)); and
- Adopt a new §438.6(c)(2)(vi)(C) to establish requirements for use of population-based and condition-based payments in these SDP arrangements.

The current regulatory prohibition on states setting the amount or frequency of the plan's expenditures in SDPs that are VBP initiatives was established in 2015 by CMS under the belief that plans should retain such control. The agency gives examples of how this limitation interfered with state VBP efforts. One was that, as states began to implement VBP initiatives—sometimes across delivery systems or focused on broad population health goals—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 state's goals.

In addition, states often direct plans to distribute earned performance improvement payments on a quarterly basis. Because these payment arrangements affect provider revenue differently than the usual per claim payment methodology, establishing strong parameters and operational details defining when and how providers receive their payments is critical for robust provider participation.

Current regulations also prohibit states from recouping any unspent funds allocated for SDP arrangements from plans when the SDP arrangement is for VBP, delivery system reform, or performance improvement initiatives. Originally, CMS reasoned that because funds associated with these initiatives are part of the capitation payment, any unspent funds would remain with the plans. However, allowing plans to retain unspent funds when providers fail to achieve performance targets can create perverse incentives for states and plans; for example, states are often not incentivized to establish VBP arrangements with ambitious targets if those arrangements result in plans profiting from weak provider performance. CMS believes that removing this prohibition could enable states to reinvest these unspent funds to further promote VBP and delivery system innovation. If a state intends to recoup unspent funds from plans for any SDP, this would need to be described in the state's preprint.

To expand the types of VBP initiatives that would be allowed under current §438.6(c)(1)(i) and (ii) and to ensure a focus on value over volume within the managed care environment, CMS also proposed regulatory revisions to differentiate performance-based payments from population-based or condition-based payments to providers, which do not lend themselves to being conditioned upon provider performance during the rating period. Instead, they can be conditioned on other factors, such as the volume and characteristics of a provider's attributed population of patients or meeting a total cost of care (TCOC) benchmark through the provision of intense case management resulting in a reduction of chronic disease, for example. Thus, CMS specifies different requirements for VBP initiatives that condition payment on performance from ones that are population or condition-based, as described separately below.

a. Performance-Based Payments (§438.6(c)(2)(vi)(B))

For SDPs where payment is conditioned on performance, that performance must be tied to the delivery of covered services. As a result, pay-for-reporting initiatives have not been allowed as the basis for SDP because merely the act of reporting is not a covered service but is an administrative activity.[28] CMS finalizes its proposal to codify its interpretation by explicitly requiring payments to providers under SDPs that are based on performance to not be conditioned on administrative activities, such as the reporting of data, participation in learning collaboratives or similar administrative activities (§438.6(c)(2)(vi)(B)(*1*)).[29]

Current policy is that the performance measurement period for these SDPs must overlap with the rating period in which the payment for the SDP is made. However, states frequently experience delays in obtaining performance-based data due to claims run-out time and the time needed for data analyses and validation, making it difficult, if not impossible, to comply with this requirement. Thus, CMS proposed (and finalizes) permitting 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. Along with this new flexibility, though, CMS also finalizes that the SDP's performance period cannot exceed the length of the rating period and that all payments must be documented in the rate certification for the rating period in which the payment is delivered (§438.6(c)(2)(vi)(B)(*3*)).

The OIG found that a quality improvement incentive SDP implemented in Texas resulted in incentive payments paid to providers whose performance declined. MACPAC and others have noted concerns with performance improvement SDPs that continue even when quality or access has declined. To address this, CMS proposed (and finalizes without modification) to require that:

[28] CMS says that if states seek to design SDPs that pay providers for administrative activities, they can use provider reporting as a condition of eligibility for the SDP. However, those activities cannot be the basis for receiving payment from the plan under an SDP described in §438.6(c)(1)(i) or (ii) that is based on performance.
[29] Finalized §438.6(c)(2)(vi)(B)(*2*) maintains the current requirement that the SDP must use a common set of performance measures across all of the payers and providers specified.

- Baseline statistics be identified on all metrics that will be used to measure provider performance as the basis for the SDP's performance-based payment (§438.6(c)(2)(vi)(B)(*4*)); and
- In §438.6(c)(2)(vi)(B)(*5*), measurable performance targets be used that:
    - Are attributable to providers' performance in delivering services to enrollees in each of the state's managed care program(s) where the SDP applies, and
    - Demonstrate improvement over baseline data on all metrics selected to measure the performance that is the basis for the SDP's performance-based payments.

CMS also finalizes its proposed definition in §438.6(a) "performance measure" for SDPs as a quantitative measure with a numerator and denominator that is used to monitor performance at a point in time or track performance over time of provider service delivery, quality of care, or outcomes (as defined in current §438.320) for enrollees.

b. Population-Based Payments and Condition-Based Payments (§438.6(c)(2)(vi)(C))

This provision establishes new regulatory pathways for approval of VBP initiatives *not* conditioned on specific measures of performance. CMS supports these efforts and encourages the use of methodologies or approaches to provider reimbursement that prioritize achieving improved health outcomes over volume of services. To do so, CMS finalizes two proposed definitions in §438.6(a):

- Population-based payment: 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.[30]
- Condition-based payment: 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.

For population-based and condition-based payments to be exempt from the SDP requirement of being conditions on specific measures of performance, CMS finalizes its proposal that the arrangement must satisfy all 4 of the following criteria (§438.6(c)(2)(vi)(C)):

- The payments are conditioned on either the delivery by the provider of a specified Medicaid service(s) or an enrollee's attribution to the provider during the rating period.[31]
- If the payment is conditioned on the attribution of an enrollee to a provider, the attribution methodology must:
    - Use data 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

[30] An example of a population-based payment would be an SDP for a primary care medical home (PCMH) with prospective per member per month (PMPM) payments for care management to primary care providers. In this case, care management is the service being delivered under the contract and covered by the PMPM. An attributed population could also be selected based on their condition(s).

[31] This satisfies the broader SDP standard 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.

    - Describe when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers.
- The payments replace the negotiated rate between a plan and providers for the Medicaid covered service(s) being delivered as a part of the SDP; no other payment may be made by a plan to the same provider for the same enrollee for the same services included in the population or condition-based payment.[32]
- At least one metric is included in the evaluation plan[33] that measures performance at the provider class level, with a target set to demonstrate improvement over baseline or, as finalized, maintenance of baseline.

c. Approval Period (§438.6(c)(3)(i))

Current regulations permit SDPs that are VBP initiatives and meet additional criteria to obtain multi-year approval, if requested. Although current regulatory language does not limit the number of years for that multi-year approval, CMS has limited it to 3 years to align with the managed care quality strategy in current §438.340(c)(2).

CMS finalizes its proposal, with minor revisions, to codify this policy—that a multi-year written prior approval for these SDPs can be for up to 3 rating periods.[34]

Final Action. CMS finalizes its proposals, with minor modifications, affecting SDPs for value-based payments and delivery system reform initiatives (§438.6(c)(2)(vi)). The sole substantive change was in §438.6(c)(2)(vi)(B)(*5*), to allow performance targets that demonstrate *either maintenance of or* improvement over baseline.

Selected Comments/Responses. Many commenters were broadly supportive of the proposed changes to the VBP initiative SDP provisions, including to remove existing requirements that prevent states from setting the amount and frequency of payments or from recouping unspent funds from VBP initiative SDPs. Commenters stated support for removing barriers to allow for flexible collaboration and innovation.

Some commenters requested that CMS provide further direction and requirements for how recouped funds can be spent. In response, CMS says it did not propose and is not finalizing spending requirements for such recouped funds, but notes 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. Under the managed care contract requirements in this final rule (§438.6(c)(5)(iii)(D)(*6*)), states must document how any unearned payments will be handled, and any other significant relevant information, as described below in section II.B.11 of this summary. These contract requirements

[32] This is to prevent any duplicate payments for the same service and because CMS has seen proposals for VBP initiatives with prospective population-based payments lacking a direct tie to value or quality for the payments above the negotiated rate.
[33] Required at §438.6(c)(2)(iv), as described below in section II.B.10 of this summary.
[34] CMS did not propose any substantive changes to the criteria in subparagraphs (A) through (C) of §438.6(c)(3)(i). For all other SDPs, a written prior approval period of one rating period continues as the policy (§438.6(c)(3)(ii)), with an explicit statement that SDPs are not automatically renewable (redesignated as §438.6(c)(3)(iii)).

will help ensure that states and plans have explicit documentation of the goals of each VBP initiative SDP and the disposition of unspent funds.

A few commenters opposed 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. CMS' intent was to ensure that performance-based VBP initiative SDPs do not pay providers for performance that is declining. Therefore, the finalized provision is modified so that performance targets must demonstrate *either maintenance of 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; CMS will not preclude states from setting performance targets that represent maintenance of baseline performance if the state believes those targets help further its goals.

Some commenters supported the proposed provisions at §438.6(c)(2)(vi)(C) that establish a pathway specifically for approval of population-based and condition-based VBP initiative SDPs. CMS expresses appreciation for the support, noting that these provisions will create a pathway for approval of such SDPs that are based on prospective PMPM payments, to allow for the implementation of innovative models, such as hospital global budgets, that emphasize value and that rely on robust quality improvement frameworks but that to date have not been allowable under §438.6(c).

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

For an SDP to obtain approval under current regulations, states must demonstrate in writing that the SDP is expected to advance at least one of the goals and objectives in its managed care quality strategy and have an evaluation plan to measure the degree to which the SDP advances those goals and objectives. CMS provides results showing that most evaluation plans submitted were incomplete and most renewal preprints included no evaluation results. GAO and MACPAC have also expressed concerns about the detail and quality of SDP evaluations, even when the arrangements had been renewed multiple times.

CMS says its policy goals here are frustrated by the lack of regulation requiring submission of evaluation results and finalizes requirements for submission of evaluation plans and reports that should improve compliance and oversight. CMS finalizes several proposed changes to the SDP regulations to support quality improvement and evaluation, including adopting requirements for submission of evaluation plans and reports.

a. Evaluation Plan (§438.6(c)(2)(iv))

For each SDP requiring written prior approval, the state must submit an *evaluation plan*. The evaluation plan must include 4 specific elements (that is, minimum content requirements):

- On an annual basis, at least 2 metrics 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.[35]
    - The metrics must be specific to the SDP and attributable to the performance by the providers for enrollees where the SDP applies, when practicable and relevant.
    - At least one of the selected metrics must be a performance measure as previously described per finalized §438.6(a)—not, for example, an access measure.
- Baseline performance statistics for all metrics to be used in the evaluation.
- Performance targets for all metrics to be used in the evaluation 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 must demonstrate improvement.
- An assurance by the state committing to provide an *evaluation report* based on the evaluation plan's foregoing elements and satisfying additional requirements (summarized below) if the final SDP cost percentage exceeds 1.5 percent.

b. Final SDP Cost Percentage (§438.6(c)(7))

Requiring an evaluation report only when the final state directed payment cost percentage exceeds 1.5 percent is a risk-based approach, intended to allow states and CMS to focus resources on the payment arrangements with the highest risk. CMS selected 1.5 percent since it aligns both with existing Medicaid managed care policy for when rate amendments are necessary (often referred to as a *de minimis* threshold) and with proposed policies for in lieu of services (below, in section II.D of this summary).

The *final state directed payment cost percentage* is calculated by the state (unless the state voluntarily submits the evaluation report) for each SDP and each managed care plan (§438.6(c)(7)). As finalized, if the final state directed payment cost percentage is below 1.5 percent, it must provide CMS with a *final state directed payment cost percentage report* with the following:

- SDP Cost Percentage Calculation. The final state directed payment cost percentage must be calculated on an annual basis and recalculated annually.
- SDP 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.
- Calculation of Final SDP Cost Percentage. The final state directed payment cost percentage is the result of dividing the following two numbers for each managed care program:
    - Numerator: The portion of the actual total capitation payments attributable to the SDP for which the state obtained written prior approval.
    - Denominator: The actual total capitation payments, including all SDPs and pass-through payments.

[35] For SDPs that are population- or condition-based payments, CMS also finalizes elsewhere (§438.6(c)(2)(vi)(C)(*4*)) that at least one of those metrics must measure performance at the provider class level.

CMS proposed but did not finalize including the term *separate payment term*[36] as part of the numerator and denominator, as described in greater detail in the comments/responses below.

The agency details why it believes the final SDP cost percentage should be measured distinctly for each managed care program and SDP, and why it should be calculated and recalculated annually.

The submission of the final SDP cost percentage data must be submitted concurrent with the rate certification submission (§438.7(a)) no later than 2 years after the completion of each 12-month rating period that included an SDP (finalized §438.6(c)(7)(iv)). 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.

CMS says it is appropriate for states' actuaries to develop a separate report to document that the final SDP cost percentage does not exceed 1.5 percent, rather than including it in a rate certification, because the final SDP 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 (§438.5(c)(2)). CMS notes this approach is similar to the concurrent submission for this rule's MLR reporting at §438.74 and ILOS projected and final cost percentage reporting at §438.16(c), described below in sections II.C and II.D of this summary, respectively.

c. Evaluation Report (§438.6(c)(2)(v))

Based on its statutory authority to require that states provide reports as the Secretary may require (section 1902(a)(6)), CMS finalizes its proposal to require the submission of an evaluation report for specified types of SDPs with a final state directed payment cost percentage that exceeds 1.5 percent. The report must:

- Include the elements approved in the evaluation plan,
- Include the three most recent and complete years of annual results for each metric as required in paragraph §438.6 (c)(2)(iv)(A), and
- Be published on the public facing website required under §438.10(c)(3).

In addition, CMS finalizes requiring that states submit the initial evaluation report no later than 2 years after the conclusion of the 3-year evaluation period, with subsequent evaluation reports submitted to CMS every 3 years. The agency describes why it chose the timeframes it did and the alternatives it explored.

[36] While this term is summarized in greater depth below in section II.B.12 of this summary, one might say this is a supplemental payment to plans, rather than an adjustment to capitation rates. The proposed definition for "separate payment term" (proposed but not finalized for addition in §438.6(a)) was that it is a pre-determined and finite funding pool that the state establishes and documents in the Medicaid managed care contract for an SDP for which the state has received written prior approval; payments made from this pool are made by the state to managed care plans 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.

Final Action. CMS finalizes its proposal with only a couple modifications—to align with the finalized prohibition on separate payment terms (as discussed in greater depth below in section II.B.12 of this summary) and to clarify that, at CMS' 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.

Selected Comments/Responses. Several commenters were broadly supportive of the proposed SDP evaluation plan policies at §438.6(c)(2)(iv).

Among the broader SDP standards in §438.6(c)(2)(ii) was a proposed standard for all SDPs to result in the achievement of the stated goals and objectives identified in the state's evaluation plan(s) for the SDPs (§438.6(c)(2)(ii)(F)). Some commenters opposed this particular provision, noting concern that it would result in states setting overly modest targets to avoid putting initiatives at risk if performance does not meet the established targets.

In response, CMS revises paragraph (c)(2)(ii)(F) to make abundantly clear that, at CMS' 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. The agency notes 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 that 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). In response to commenters' concerns about underachievement and unnecessarily low-quality targets putting SDP initiatives at risk, the agency encourages states to request technical assistance from CMS for choosing targets that are commensurate with the size and scope of their SDP and that are compliant with §438.6(c)(2)(iv).

Some commenters were concerned 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.

CMS reiterates that 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 SDP cost percentage greater than 1.5 percent, states will be required (§438.6(c)(2)(v)) to submit evaluation reports every 3 years that contain the 3 most recent and complete years of available data, which gives states adequate opportunity to show trends and explain anomalies or other issues. If an evaluation report fails to show attainment of any of the identified quality strategy goals, CMS will work with the state to help ensure that the subsequent evaluation report, 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, CMS would not approve a renewal of the SDP.

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, CMS says it is 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.

Many commenters supported the proposed requirement that evaluation reports be made publicly available on states' websites, with a few also encouraging CMS to also consider making SDP evaluations publicly available on Medicaid.gov, as done with section 1115 demonstration evaluations. CMS says it intends to make states' evaluation results available on Medicaid.gov.

11. 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. Every SDP must be documented in the managed care contract and actuarial rate certification (§§438.3(c)(1)(i) and 438.7(b)(6)). According to previous CMS guidance, including 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), with the State Guide providing examples. Nevertheless, CMS reports that states' contracts often 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 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 plan to make. Such vague contractual provisions represent significant oversight risk for states and CMS.

CMS proposed to codify minimum requirements for the content of a Medicaid managed care contract that includes an SDP. As proposed, SDPs must be specifically described and documented in the managed care plan's contract and must include the following for each SDP:

- The SDP start date and, if applicable, the end date within the rating period (§438.6(c)(5)(i));
- A description of the provider class eligible for the SDP and all eligibility requirements (§438.6(c)(5)(ii));
- A description of the SDP, with a host of specific requirements (not restated here) that vary by the type of SDP (§438.6(c)(5)(iii));
- Any encounter reporting and separate reporting requirements necessary for auditing the SDP and provider-level payment amounts to CMS (§438.6(c)(5)(iv)); and
- Not finalized was whether the state will be using a separate payment term to implement the SDP (proposed §438.6(c)(5)(v)).

The proposal would also require that states submit to CMS their SDP-related contract requirements and rate certification documentation no later than 120 days after the later of the following:

- The start of the SDP, or
- The date CMS granted written prior approval of the SDP.

Final Action. CMS finalizes the minimum contract documentation requirements, mostly without modification except for minor grammatical edits and:

- Not finalizing the provision related to separate payment terms (described in greater detail in the next section);
- Finalizing in §438.6(c)(5)(v) a requirement for submission of SDP-related contract requirements and rate certifications to CMS no later than 120 days after the SDP start date, rather than the proposal for submission "within 120 days of CMS's written prior approval if that is later than the start date of the SDP."[37] Conforming amendments are made to rate certification requirements in §438.7(c)(6).

Selected Comments/Responses. Some commenters stated that the proposal 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. 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.

In response, CMS points to its statement in the proposed rule that contracts or amendments can be submitted in draft form as long as they include all required (and applicable) elements in §438.6(c)(5)(i) through (iv) to meet the requirement finalized here to document SDP terms in contract documents no later than 120 days after the SDP start date. 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, CMS finalizes §438.6(c)(5)(v) with a revision to replace "contracts that are submitted to CMS" with "contracts 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 the reasoning for revising the SDP submission timeframe in §438.6(c)(2)(viii) (section II.B.5 of this summary), CMS is persuaded by comments that its proposal was overly complex with the "later of" submission timelines. Thus, from its proposal, it is finalizing that all SDPs to be specifically described and documented in the managed care contracts that must be

[37] CMS' description of the proposal here does not appear to align with the proposed regulatory text for §§438.6(c)(5)(vi) and 438.7(c)(6)), which indicated that the extra 120 days apply to both the start date of the SDP and the date that CMS granted written prior approval of the SDP (88 FR 28238 and 28239).

submitted to CMS no later than 120 days after the start date of the SDP (§438.6(c)(5)(v)). This provision does not require a final signed copy of the contract amendment within 120 days of the start of the SDP; it may be met using a draft complete contract or draft excerpt of the contract that provides the required information about 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.

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

a. Including SDPs in Rate Certifications (§438.6(c)(2)(ii)(J))

Current regulations—in a single sentence in §438.7(b)(6)—require all SDPs be included in all applicable managed care contract(s) and described in all applicable rate certification(s). As part of its changes in §438.6(c), CMS proposed to redesignate another existing regulatory requirement—that each SDP must be developed in accordance with §438.4 and the standards specified in §§438.5, 438.7, and 438.8—to §438.6(c)(2)(ii)(J).

CMS also proposed to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices, because it is duplicative of language in §438.4 and because the agency is concerned the duplicative language could suggest that SDPs require an actuary to be involved in the development of the SDP arrangement. While an actuary must develop the capitation rates to ensure they are actuarially sound and account for all SDPs, CMS believes states should have the flexibility to determine if they wish to involve actuaries in the development of each specific SDP arrangement.

CMS received no comments on this proposal, which it finalizes without modification.

b. Separate Payment Terms (§438.6(c)(6))

CMS proposed but ultimately did not finalize provisions for separate payment terms in SDPs.

Background. Historically, states have been permitted to make payments to managed care plans for SDPs in one of two ways: through adjustments to the base capitation rates or through a separate payment term. Separate payment terms are unique to Medicaid managed care SDPs. CMS has not previously formally defined separate payment terms in regulation but has included it in the annual "Medicaid Managed Care Rate Development Guide" since March 2019.[38]

Separate payment terms are most commonly sourced from a state-established pool of funding paid by the state to the plan(s) separately and in addition to the capitation payments for a specific SDP. These payments may occur quarterly, for example, based on the services provided in that quarter (or applicable rating period) to increase total provider payments or reach a specific

[38] For the most recent example as of this summary's publication, see "2024-2025 Medicaid Managed Care Rate Development Guide."

payment rate target. Typically, states divide the dedicated funding pool into equal allotments for each rating period, review the encounter data for the service(s) and provider class identified in the approved preprint for the quarter that has just ended, and divide the allotment by the total service utilization across all providers in the defined class—for example, inpatient discharges for all rural hospitals—to determine a uniform dollar amount to be paid in addition to the initial payment by the managed care plan for rendered services. The state pays the quarterly allotment to the plans, separate from the capitation rate payment, and directs them to use that allotment for additional retroactive payments to providers for the utilization that occurred in the quarter that just ended.

The development of the separate payment term is frequently done by the state rather than the state's actuaries. CMS has never required actuaries to certify the reasonableness of the amount of the separate payment term, but only that the separate payment term is consistent with what was approved in the SDP preprint. However, CMS has always requested actuaries to document the separate payment terms in the state's rate certification because the separate payment terms are required payments for services under the risk-based contract.

Separate payment terms can have a significant impact on the assessment of the actuarial soundness of the rates. In some cases, capitation rates may not be sufficient without taking separate payment terms into account. In one state, CMS found that the separate payment term for an SDP for inpatient hospital services represented 40 percent of the total amount paid in certain rate cells.

Of SDPs that began in 2021, 55 percent used separate payment terms. While acknowledging several reasons for states to want to use separate payment terms, CMS expressed concerns with their increased use in its January 2021 SMDL:

> *"…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."*

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, but also recognizes states' belief in the utility of separate payment terms for specific programmatic or policy goals.

The agency considers separate payment terms part of the contract with managed care plans, 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. Thus, it proposed to define and regulate separate payment terms under this authority.

Proposed Regulatory Changes for Separate Payment Terms—Contract Requirements. In the list of definitions at §438.6(a), the proposal would add "separate payment term" as a predetermined 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 managed care plans 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.

Additionally, the proposal would require all of the following:

- All separate payment terms must be reviewed and approved as part of the SDP review, consistent with current practice.
- Separate payment terms would not be permitted for SDPs that do not require written prior approval (that is, minimum fee schedules using state plan approved rates and minimum fee schedules using approved Medicare fee schedules, which must have their payment adjustment through the capitation rates).
- Each separate payment term must be specific to both an individual approved SDP and to each Medicaid managed care program.
- The separate payment term cannot exceed the total amount documented in the written prior approval for each SDP, to end the practice where states exceed their approved amounts and submit amendments afterward.
- States must document the separate payment term in their 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.

This last requirement is designed to curtail practices—with an example provided in the preamble—that CMS finds concerning and that are driven by a focus on financing the non-federal share associated with SDPs rather than on furthering the goals and objectives in the state's managed care quality strategy. The contract action could be submitted to CMS in draft form as long as it includes all of the required elements; a final signed copy of the amendment would not be required within this proposed 120-day timeframe, but states would still be required to submit a final signed contract action prior to CMS' approval of the managed care contract.

CMS also proposed 4 specific pieces of information to be documented in the state's Medicaid managed care plan contracts for SDP separate payment terms:

- The total dollars the state would pay to plans for the individual approved SDP;
- The timing and frequency of payments under the separate payment term from the state to the plans;
- A description (or reference to the contract requirement) for the specific SDP for which the separate payment term would be used; and
- Any reporting that the state requires to ensure appropriate reporting of the separate payment term for purposes of MLR reporting.

Proposed Regulatory Changes for Separate Payment Terms—Rate Certification (§438.7(f)). For managed care rate submissions, the proposal would codify the following existing practices:

- Require the state, through its actuary, to certify the total dollar amount for each separate payment term as detailed in the state's Medicaid managed care contract;

- Permit the state to pay each managed care plan a different amount under the separate payment term so long as the aggregate total dollars paid does not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract; and
- Require the state, through its actuary, 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.

As proposed, no later than 12 months following the end of the rating period, the state would also be required to submit documentation to CMS that includes the total amount of the separate payment term in the rate certification consistent with the distribution methodology described in the approved SDP. To align with the contract requirement described above, states would have 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.

Although CMS offered these proposals, and described alternatives, it also said it was considering—

> "*requiring all SDPs to be included only through risk-based adjustments to capitation rates and eliminate the State's ability to use separate payment terms altogether in the final rule based on comments received. Prohibiting the use of separate payment terms would align with CMS' stated preference and would be most consistent with the nature of risk-based managed care*" (88 FR 28149).

Final Action. CMS is not finalizing §438.6(c)(6) as proposed. At paragraph (c)(6) as finalized, all SDPs must be incorporated into Medicaid managed care capitation rates as adjustments to base capitation rates, thus prohibiting separate payment terms. The text also prohibits the state from either withholding a portion of the capitation rate to pay the plan separately for an SDP, or requiring a plan to retain a portion of the capitation rate separately to fulfill the contractual requirement of an SDP.[39]

In finalized §438.6(c)(8)(iv), this new prohibition is applicable beginning with the first rating period for contracts with managed care plans beginning on or after 3 years after July 9, 2024, providing states with three rating periods to transition from use of separate payment terms.

Selected Comments/Responses. Many commenters supported the proposal to codify state use of separate payment terms to formally recognize what has been an operational flexibility to date. However, most of these commenters did not support the specific proposals in §438.6(c)(6) to require that the total amount of each separate payment term 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. They said states should not be hampered from using separate payment terms as they provide greater transparency, ensure that payments flow to

[39] To conform with this final policy, CMS did 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).

providers as intended, minimize administrative burden for states, and make it easier for states to track SDPs.

On the other hand, other commenters agreed with CMS that SDPs are best implemented through adjustments to base capitation rates, 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 should consider giving states and their actuaries time to phase out separate payment terms.

CMS says when it proposed seven new regulatory requirements for separate payment terms, it was still concerned about their appropriateness in risk-based managed care. The comments in support of the continued use of separate payment terms with none of the guardrails proposed added to CMS' concern that some states are increasingly relying on this payment mechanism to circumvent risk-based payment to managed care plans. 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, according to CMS. As noted in the proposed rule and reaffirmed by commentors, CMS says that 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 sum, CMS is 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.

Several commenters who supported separate payment terms stated that CMS' concerns about removing risk from managed care plans for SDP expenditures are inconsistent with the original purpose for SDPs, which is specifically to provide an exception and permit states to direct payment. These commenters point to §438.6(c)(1)—"Except as specified in this paragraph (c)…"—as explicitly condoning exceptions to risk-based Medicaid managed care.

CMS disagrees with this interpretation and says that this misinterpretation further highlights the need to eliminate the use of separate payment terms. SDPs are an exception to the prohibition on states paying for or specifying payment rates for providers in a risk-based managed care system; they were never intended to be an exception to the risk-based payment requirements. CMS restates requirements on SDPs and managed care plans generally, along with previously stated concerns with separate payment terms.

Other commenters noted that safety-net providers would be at particular risk if CMS prohibited states from using separate payment terms, with one commenting 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. CMS disagrees with commenters that using separate payment terms is necessary for states to accomplish Medicaid goals. States have significant flexibility in designing SDPs under this final rule, including determining the provider class. SDPs can define 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.

Many commenters said that eliminating separate payment terms would be a notable departure from current practice, since CMS has been approving SDPs with separate payment terms for 6 years. Eliminating separate payment terms could cause significant disruption for existing SDPs, threaten the viability of existing SDPs, and jeopardize CMS' compliance with the statutory mandate to safeguard equal access to care. CMS recognizes that nearly half of approved SDPs use separate payment terms. However, it is confident states can transition those SDPs into adjustments to base rates. Recognizing this transition will take time, as noted earlier, it is 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, giving states until the first rating period that begins on or after July 9, 2027.

CMS further disagrees 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 managed care plans; states are not required to use SDPs. Separate regulations require states that contract with plans to address network adequacy and access to care—regardless of the use of SDPs. Further, the managed care capitation rates must be adequate to meet these requirements, as required under §438.4(b)(3).

13. SDPs included through Adjustments to Base Capitation Rates (§438.7(c)(4) and (5))

CMS proposed changes in §438.7(c) regarding adjustments to managed care capitation rates for SDPs. Specifically, retroactive adjustments to capitation rates resulting from an SDP may only be the result of one of the following:

- An approved SDP being added to the contract,
- An amendment to an already approved SDP,
- An SDP not requiring prior written approval (that is, one that adopts a minimum fee schedule based on Medicaid's or Medicare's rates), or
- A material error in the data, assumptions, or methodologies used to develop the initial rate adjustment.

Again, CMS made this proposal citing its experience with states taking action that appears related to the financing of the non-federal share and inconsistent with the prospective and risk-based nature of Medicaid managed care—in this case, through submission of amendments to base rates for SDPs that do not appear related to changes in payment methodology, changes in benefit design, or general actuarial practices.

In addition, states would be required to submit a revised rate certification for *any* changes in the capitation rate per rate cell for any SDPs (as well as any other special contract provisions in

§438.6) if such changes are not already described in the rate certification. This requirement would apply regardless of the size of the change in the capitation rate per rate cell. Although current regulations permit flexibility to increase or decrease the capitation rate per rate cell up to 1.5 percent during the rating period without submitting a revised rate certification for rate changes unrelated to special contract provisions, CMS believes it would be "incongruent" with requirements at §438.7(b)(6) and elsewhere to provide that same flexibility to special contract provisions like SDPs.

Comments were mostly supportive, and CMS finalizes its proposal for §438.7(c)(4) and (5) without modification.

14. Appeals (§430.3(e))

The number and complexity of SDP submissions have increased, as well as the burden on CMS to provide states with associated technical assistance and review. As examples of more complex payment arrangements, the agency cites Total Cost of Care (TCOC) programs and multi-metric and multi-year VBPs. CMS describes its efforts to provide technical assistance to states.

To date, when CMS and states have been unable to reach agreement on an SDP proposal, states have agreed to withdraw the submission. However, as proposed, this informal process would be replaced with CMS formally disapproving proposals that do not comply with Medicare requirements and regulations.

To be consistent with other CMS processes that issue formal disapprovals, the agency proposed a formal process for states to appeal a disapproval of written prior approval for a state's SDP proposal. Rather than leaving states to seek redress in the courts, CMS believes states would benefit from and appreciate an established, consistent, familiar administrative process. Specifically, a new proposed §430.3(d)—finalized as proposed, but moved to §430.3(e)[40]—would explicitly permit disputes that pertain to written disapprovals of SDPs to be heard by the HHS Department Appeals Board (DAB, or "the Board") in accordance with procedures set forth in 45 CFR part 16. The preamble reviews the DAB's appeals processes that would apply to SDP disapprovals.

Final Action. CMS finalizes its proposal regarding appeals for SDP disapprovals (§430.3(e)).

Selected Comments/Responses. A few commenters supported this proposal.

Many commenters expressed 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 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.

[40] A new §430.3(d) was established 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.

CMS responds that the administrative process finalized at §430.3(e) is at the option of the appellant; states may seek redress in the courts at any time. Although CMS believes that an administrative appeals process is a timelier and more cost-effective path to resolution, nothing in this rule precludes any party from seeking redress in the courts. CMS further notes that the Board has sufficient legal authority and expertise to adjudicate appeals regardless of their statutory basis, including those outside of the parameters of §438.6(c).

Some commenters were more supportive of the alternative CMS offered in the proposed rule, to use the CMS Offices of Hearings and Inquiries (OHI) and the CMS Administrator for final agency action, as governed by part 430, subpart D. They said CMS OHI decisions would be faster in practice, despite the Board's faster timelines in regulation, for a number of reasons. In addition, some commenters suggested OHI has greater subject matter expertise. CMS describes why it shares none of these concerns and finalizes its proposal.

15. 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))

GAO and MACPAC have recommended that CMS collect and make available provider-specific information about Medicaid payments to providers, including SDPs, even though its current review process for SDPs is prospective. MACPAC noted that expenditures for SDPs are larger than either DSH payments or UPL supplemental payments,[41] but there is much less data on who is receiving SDPs. CMS acknowledges it does not consistently or systematically review the actual amounts that states pay to managed care plans for these SDPs, nor the actual amounts that plans pay to providers.

The agency proposed two approaches—one near term and one longer term—for collecting both aggregate and provider-level information. First, at 438.8(e)(2)(iii)(C) and (f)(2)(vii), existing MLR reporting would be used as the vehicle to collect actual plan-level SDP expenditure data, by including SDPs and associated revenue as separate lines in plans' MLR reports to states. Managed care plan-level SDP expenditure reporting would also be explicitly reflected in states' annual summary MLR reporting to CMS. These MLR requirements would apply to all SDPs—those that do and do not require prior CMS approval.

In addition, the proposal would establish a new requirement at §438.6(c)(4) for states to annually submit data, no later than 180 days after each rating period,[42] to CMS' Transformed Medicaid Statistical Information System (T-MSIS) (or any successor format/system) specifying the total dollars expended by each managed care plan for SDPs in effect for the rating period, including amounts paid to individual providers. CMS will develop and provide the form through which the

[41] According to MACPAC, in FY 2020, states spent $17.9 billion on DSH payments and $24.4 billion in UPL supplemental payments, compared to $25 billion for SDPs.
[42] CMS proposed a 180-day deadline because it believes this timeframe permits adequate time for claims run-out, submission of the necessary data to the state, and for the state to format the data for submission to CMS.

reporting would occur so that there would be one uniform template, with the following minimum data fields:

- Provider identifiers,
- Enrollee identifiers,
- Managed care plan identifiers,
- Procedure and diagnosis codes, and
- Allowed, billed, and paid amounts, which would include the amount representing the managed care plan's negotiated payment amount, the amount of SDPs, the amount for any pass-through payments, and any other amounts included in the total paid to the provider.

CMS believes states and plans already collect provider-level SDP data, including the negotiated rate between the plan and provider and any additional SDPs. The agency also describes proposed conforming amendments and data-reporting alternatives it considered.

Final Action. CMS finalizes its proposal to require use of existing MLR reporting and T-MSIS for SDP information to be shared by plans and states with the federal government. The only substantive changes from the proposed version were to extend the 180-day timeframe for reporting T-MSIS data to a whole year and to not require SDP line-level reporting in the state summary and plan-specific MLR report. The agency also finalizes clarifications to require states and plans to report SDPs made by plans to providers as incurred claims in the MLR numerator and SDPs to Medicaid managed care plans as premium revenue in the MLR denominator.[43]

Selected Comments/Responses. Some commenters supported including SDPs in MLR reporting as a reasonable step to increase transparency and improve oversight of SDPs.

Many commenters questioned the feasibility of the SDP line item MLR reporting proposals, 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. It would also 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. They noted there was minimal value to CMS or states of this information given other available SDP data, and cautioned against overly rigid regulatory language that could result in distorted MLR reporting that does not accurately reflect SDP arrangements. Another commenter requested additional time for states and plans to comply with the SDP reporting requirements through the MLR process.

While CMS is finalizing the provisions to require that all SDPs be included in plan-level and state summary MLR reports, it agrees that requiring plans and states to report SDPs on a line

[43] SDPs 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.

item basis would require extensive state and plan administrative work, as well as CMS technical assistance, and therefore is not finalizing that line-level reporting of SDPs. As a result, states will likely not be required to make as many modifications to systems and MLR reporting templates. Thus, CMS believes it is reasonable to require states to comply with the requirement that states and plans include all SDPs within MLR reporting no later than 60 days following the effective date of this final rule.

Many commenters supported the proposal for states to report SDP expenditure data in T-MSIS. CMS notes it did not receive comments from state Medicaid agencies opposing the use of T-MSIS for SDP reporting. Although this will require encounter system changes for both states and plans, CMS believes the additional detail provided by T-MSIS is critical given the high levels of spending associated with SDPs. For example, with the procedure codes available from T-MSIS, CMS says it 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. This will also improve program integrity and provide CMS with information to assist in determining if an SDP should be renewed.

CMS says that after careful consideration of its existing processes for the release of T-MSIS specifications and the typical compliance dates, it is modifying the applicability date from the first rating period beginning on or after the release of T-MSIS reporting instructions to the applicability date set forth in the T-MSIS reporting instructions released by CMS. The agency's method of releasing new reporting instructions includes preparation time for states and plans, and CMS is aware that any changes to data systems require substantial programming and testing before implementation.

Some commenters cautioned CMS on any additional administrative reporting burden and 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. CMS says it attempted to strike the right balance between oversight and transparency versus additional administrative burden. 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. The agency intends to further revise T-MSIS reporting in the future to better enable states to report more complex SDP data easily and effectively.

Some commenters stated concern that requiring states to report the total dollars expended by each plan 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. In response, CMS acknowledges that all paid claims data would likely not be complete within 180 days of the end of a rating period and therefore finalizes a modification 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.

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

Regarding the various SDP provisions, CMS proposed and now finalizes several applicability and compliance dates for states and managed care plans, mostly without modification. Only the finalized dates are shown. All regulatory references are to 42 CFR §438.6 unless noted otherwise.

- Upon the effective date of this final rule—that is, July 9, 2024:
  - Definitional changes in (a)
  - General rule for SDPs in (c)(1)
  - Revised and additional types of SDPs in (c)(1)(iii)
  - Types of SDPs requiring written prior approval in (c)(2)(i)
  - Standards for SDPs in (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) through (J)
  - Evaluation report requirements in (c)(2)(vi)(A)
  - Approval and renewal timeframes in (c)(3)
  - Requirements for revised SDP rate certifications or retroactive adjustments in §438.7(c)(4) and (5)
- No later than the first rating period for contracts with managed care plans beginning on or after the effective date of this final rule (July 9, 2024):
  - Average commercial rate requirements in (c)(2)(iii)
  - Performance-based payment requirements in (c)(vi)(B)
  - Population-based and condition-based payment requirements—to be conditioned on delivery of a service or the attribution of an enrollee, along with attribution-based data and other requirements—in (c)(vi)(C)(*1*) and (*2*)
- No later than the rating period for contracts with managed care plans beginning on or after 60 days following July 9, 2024, requirement for rate certifications to include description of any SDPs, in §438.7(b)(6)
- No later than the first rating period for contracts with managed care plans beginning on or after 2 years after the effective date of this final rule:
  - Population-based and condition-based payment requirements—to replace the negotiated rate and to include at least one performance measure and target—in (c)(2)(vi)(C)(*3*) and (*4*)
  - 90-day and other deadlines for states submitting required SDP documentation in (c)(2)(viii)
  - SDP managed care contract term requirements in (c)(5)(i) through (iv)
- No later than the first rating period for contracts with managed care plans beginning on or after 3 years after the effective date of this final rule:
  - Requirements to have an evaluation plan and for SDP to result in achieved for stated goals, in (c)(2)(ii)(D) and (F)
  - Evaluation plan requirements in (c)(2)(iv)
  - Evaluation report requirements in (c)(2)(v)
  - Requirements for SDP in (c)(1)(iii)—that is, those based on minimum or maximum fees or uniform increases for a particular service(s)—in (c)(2)(vii)

    - Prohibition on separate payment terms—that is, that the final capitation rate must account for all SDPs, which must be accounted for in the base data—in (c)(6)
    - Final state directed payment cost percentage in (c)(7)
- No later than the first rating period for contracts with managed care plans beginning on or after 4 years after the effective date of this final rule:
    - 120-day SDP contract requirement in (c)(5)(v)
    - 120-day SDP rate certification requirement in §438.7(c)(6)
- No later than the date specified in the T-MSIS reporting instructions released by CMS, requirements to submit the initial T-MSIS report in (c)(4).
- No later than the first rating period for contracts with managed care plans beginning on or after January 1, 2028, ensure participating providers attest they do not participate in a hold harmless arrangement in (c)(2)(ii)(H).

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

Managed care plans must submit medical loss ratio reports to states annually, and states must provide a summary of those reports to CMS each year. Medical loss ratios are one way states and CMS can assess whether adequate amounts of the capitation payments are spent on services for enrollees. Medicaid and CHIP managed care MLR reporting requirements align, generally, with Marketplace standards for QHPs and Medicare Advantage standards for Medicare Advantage organizations. The agency finalized regulatory changes for QHP MLR effective July 1, 2022, and it proposed several changes to the Medicaid and CHIP managed care regulations to align them with the new Marketplace provisions. Several revisions were proposed to requirements, including 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. Other changes included specifying the timing of updates to credibility adjustment factors, establishing deadlines for the submission of MLR reports to the state, specifying the level of data aggregation required for state MLR summary reports to CMS, and clarifying contract requirements for reporting overpayments.

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

In conducting oversight of plan MLR reporting, CMS examined contract language for provider incentive arrangements between plans and network providers. It identified certain plan practices that were troublesome and that could impact the reliability of the MLR reports. It found (i) inconsistent documentation and contracting practices for these incentive arrangements, (ii) the absence of quantitative or qualitative improvement standards in the criteria for these payments, (iii) arrangements that were not developed prospectively and did not include performance expectations, (iv) performance periods that did not align with the MLR reporting period, and (v) provider incentive contracts signed after the performance period ended.

Contract Requirements for Provider Incentive Arrangements. CMS finalizes requiring the addition of the following new conditions to state contracts with a managed care plan that include incentive payment contracts between the plan and network providers:

- The performance period for the incentive arrangement must be tied to the applicable MLR reporting periods.
- The arrangement must be signed and dated by all appropriate parties before the beginning of the applicable performance period.
- The arrangement must include clearly defined, objectively measurable, and well-documented clinical or quality improvement standards that the provider must meet to receive the incentive payment.
- The arrangement must specify a dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a payment date.

Selected Comments/Responses. Some commenters asked that the performance period not be tied to the MLR reporting period, suggesting instead a calendar year or other periods. CMS believes the incentive payment contract period of performance must be tied to an MLR reporting period to improve program integrity and transparency around these arrangements. The agency notes that plans and network providers may implement effective periods on a calendar year, or other appropriate basis, as long as the incentive payment contract is clearly associated with a specific MLR reporting period. However, the contract must include a defined start and end date for the effective period so provider incentive payments can be tied to a specific MLR reporting period. Some commenters found the requirement for arrangements to be signed and dated before the performance period to be overly prescriptive. CMS disagrees, noting that standard contracting practice requires all parties to sign before performance; it is also concerned that permitting signatures after the performance period would provide an opportunity for a plan to more easily pay network providers solely to expend excess funds to increase their MLR numerator under the guise of paying incentives.

One commenter sought clarification on the difference (if any) between "well-defined quality improvement performance metrics" described in the Contract Requirements for Provider Incentive Payment Arrangements section of the 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 at §438.8(e)(2)(iii)(A) and found in the private market regulations at 45 CFR 158.140(b)(2)(iii). CMS did not intend any difference; in the final rule, it revises §438.3(i)(3)(iii) to include the following language, "clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards," which it notes reflects the language used in the private market regulations at 45 CFR 158.140(b)(2)(iii).

Some commenters sought additional flexibility for the requirement that incentive payment contracts between plans and network providers specify a dollar amount that can be clearly linked to successful completion of the metrics; they suggested also permitting a percentage of a verifiable dollar amount as this is a common practice for these arrangements. CMS agrees to

make both options—a dollar amount and a percentage of a verifiable dollar amount—available under the final rule.

A number of commenters thought plans should be required to use the measure sets developed by the Core Quality Measures Collaborative (CQMC) for provider incentives. While CMS does not require the use of CQMC measure sets, it notes that if a plan's provider bonus and incentive program is based on those measure sets, then any payments made based on the CQMC would qualify as a bonus or incentive includable in the MLR calculation.

The state through its contracts with a managed care plan must do all of the following:

- Define the documentation that must be maintained by the plan to support the provider incentive payments;
- Prohibit the use of attestations as supporting documentation for data that factor into the MLR calculation; and
- Require the plan to make incentive payment contracts, and any documentation, available to the state upon request and at any routine frequency established in the state's contract with the plan.

Conforming amendments to the program integrity contract requirements for these policy changes are made at §438.608(e).

CMS proposed a compliance date of no later than the rating period for contracts with managed care plans beginning on or after 60 days following the effective date of the final rule. However, taking into account reactions from stakeholders, the agency finalizes a compliance 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) and 438.608(e).

The policies also apply to separate CHIP managed care plans.

Alignment with Marketplace Regulations. Unlike Medicaid and CHIP regulations, the Marketplace regulations require issuers to tie provider bonuses and incentive payments to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards for these costs to qualify as expenditures in the MLR numerator. CMS finalizes its proposal to align the Medicaid and CHIP regulations with those Marketplace regulations; thus, to be included in the MLR numerator, a provider bonus or incentive payment arrangement must require providers to meet clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards to receive the bonus or incentive payment. The goals of this policy are to address inappropriate inflation of the MLR numerator, facilitate data comparisons, increase transparency in these incentive arrangements, and improve quality of care.

States and managed care plans must comply with these requirements no later than the first rating period beginning on or after 1 year after the effective date of the final rule. The policies also apply to separate CHIP managed care plans.

Regulatory Impact. In states that require managed care plans to repay remittances for not meeting a minimum MLR, and where remittance calculations are based on the MLR standards in §438.8, the remittance amounts to states may be affected. CMS estimates that its clarification and alignment with the Marketplace regulations would increase remittances paid by managed care plans to states by approximately $12 million per year.

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

CMS found that there are wide discrepancies in the types of expenses insurers include in quality improvement activities (QIA) that are included in MLR calculations in the Marketplace, and it revised those regulations accordingly. Medicaid and separate CHIP regulations include QIA that meet the Marketplace MLR requirements, but they do not explicitly prohibit managed care plans from including indirect or overhead expenses when reporting QIA costs in the MLR because the commercial regulations did not have this exclusion at the time. CMS proposed to apply that prohibition in the Marketplace regulations to the Medicaid and separate CHIP rules through cross-reference; thus, managed care plans would be prohibited from including overhead or indirect expenses that are not directly related to health care quality improvement. In the proposed rule, the change would be effective 60 days after the effective date of the final rule.

CMS finalizes its proposals without modification.

Selected Comments/Responses. CMS was urged to monitor how plans categorize utilization management activities; the agency notes that plans may not 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. States are also required to monitor QIA expenditures reported by plans to see if any of the reported expenditures have the primary goal of cost containment and thus should be excluded from the MLR numerator as QIA. Some commenters sought more clarity about the types of overhead and indirect costs prohibited for QIA, including whether administrative costs for certain QIA should be allowed in the MLR numerator. CMS does not specify whether certain types of administrative costs are prohibited for QIA in the regulation because there are many types of such costs; it is also concerned that providing a list of prohibited costs in the regulation could lead stakeholders to conclude that costs not specified on the list were allowable. The agency says that if a plan indicates that it cannot separate indirect or overhead expenses for QIA, the state should disallow the entirety of QIA expenditures in the MLR. Additionally, plan expenditures that meet the requirements related to Health Information Technology (HIT) in the private market MLR regulations (at 45 CFR 158.151) qualify as QIA expenditures under this rule.

On the topic of including expenditures for activities related to social determinants of health (SDOH) and health-related social needs (HRSN) in the MLR, CMS previously provided guidance for inclusion of expenses for activities to address SDOH in the MLR in a State Health Official Letter dated January 7, 2021.[44] It is also relevant for expenditures for HRSN activities.

[44] https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf.

In response to questions on treatment of salaries and benefits of staff furnishing QIA, CMS affirms those salary and non-salary benefits for those employees are directly tied to QIA and are direct QIA expenses. However, those costs may only be included up to the amount that reflects the percentage of the employees' time actually spent on QIA.

Regulatory Impact. In states that require managed care plans to repay remittances for not meeting a minimum MLR, and where remittance calculations are based on the MLR standards in §438.8, the remittance amounts to states may be affected. CMS estimates that its clarification and alignment with the Marketplace regulations will increase remittances paid by managed care plans to states by approximately $49.8 million per year.

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

The Medicaid MLR regulations 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. CMS has found that several plans operating in multiple markets (e.g., Medicaid and Medicare Advantage) failed to adequately describe how certain costs that may apply across multiple lines of business were allocated to the Medicaid MLR report.

CMS proposed adding a new requirement for plans to include information on the methodology 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 the Marketplace regulations.

CMS finalizes its proposals without modification.

States and managed care plans must comply with the requirements no later than 60 days after the effective date of the final rule. The requirements also apply to separate CHIP managed care plans.

In aggregate CMS estimates an annual private sector burden with respect to Medicaid of 1,887 hours at a cost of $176,775 and with respect to CHIP of 597 hours at a cost of $55,927.

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

Under the NAIC model regulation and under the Medicaid and CHIP regulations, smaller plans may adjust their MLR calculations 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. The regulations refer to annual updates to these factors; however, CMS notes the factors have not been changed since

2017. CMS finalizes its proposal to strike the phrase "On an annual basis" from the regulations, which will take effect 60 days after the effective date of the final rule.

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

Medicaid and CHIP managed care plans may be required to resubmit MLR reports to states under certain circumstances, such as when a state makes retroactive changes to capitation rates that could impact the plan's MLR. However, the regulation text, which was modified in 2016, refers to capitation payments instead of capitation rates, which has caused confusion about the requirement for resubmission of MLRs. States often make payments to plans as part of the retroactive eligibility review process. CMS believes that when a state changes the number of payments, but not the rate of payment to a managed care plan, it is unnecessary for a plan to resubmit the MLR to the state. CMS proposed changes to §438.8(m) to replace the term "payments" with "rates" and to insert "retroactive rate" before the word "change."

Several commenters opposed the changes because retroactive eligibility determinations could have a significant impact on the MLR report calculation. CMS agrees, especially in light of states restarting the eligibility redetermination process, 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.

It does not finalize this proposal.

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

States must submit to CMS summary reports of the detailed MLR reports that are submitted by managed care plans to states. CMS finalizes its proposal to specify that the summary state reports must include both MLR data aggregated over the entire state as well as abbreviated MLR data for each managed care plan. This also applies for separate CHIP managed care plans. The requirements are effective 60 days after the effective date of the final rule.

CMS estimates an aggregate one-time state burden for 5 states of 25 hours at a cost of $1,988 for Medicaid and the same amounts for CHIP.

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

CMS seeks to ensure that Medicaid and CHIP managed care plans report comprehensive overpayment data to states in a timely manner. It believes this would facilitate state efforts to execute program integrity efforts and develop actuarially sound capitation rates.

Currently, states must 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. CMS proposed to revise the regulation to require reporting of all overpayments identified or recovered, specifying

the overpayments due to potential fraud, to the state within 10 business days. The addition of "identified" in the regulation text is designed to address plan practices of reporting only partial overpayments. A partial overpayment may occur due to negotiations between the plan and provider or to the use of an overpayment as an offset to a future payment. These practices negatively impact the accuracy of the MLR report. The requirements also apply to separate CHIP managed care plans.

CMS finalizes the proposals with several modifications in response to comments. First, the deadline to report all overpayments identified or recovered is extended to 30 calendar days. Second, CMS clarifies that overpayment reporting requirements at §§438.608(a)(2) and (d)(3) do not apply to NEMT PAHPs. Finally, CMS changes the effective date for these requirements to the first rating period beginning on or after 1 year from the effective date of this final rule (in lieu of the 60-day effective date in the proposed rule).

CMS also clarifies that plans must separately report overpayments when the payments are both identified and when/if they are eventually recovered. It also emphasizes that all overpayments must be identified and reported; the proposal did not include any threshold below which identifying and reporting overpayments would not apply.

In states that require managed care plans to repay remittances for not meeting a minimum MLR, and where remittance calculations are based on the MLR standards in §438.8, the remittance amounts to states may be affected. However, because states do not currently report this level of payment detail, CMS cannot quantify the impact of the new requirement.

D. In Lieu of Services and Settings (ILOS) (§§438.2, 438.3, 438.7, 438.16, 438.66, 457.1201, 457.1207)

1. Overview of ILOS Requirements (§§438.2, 438.3(e), 438.16, 457.1201(e))

Managed care plans have the flexibility under risk contracts to, at the option of the plan and enrollees under the plan, provide a substitute service or setting in lieu of a service or setting covered under the state plan, when such substitution is medically appropriate and cost effective (81 FR 27538 and 27539). Such a substitute service or setting so provided is known as an "in lieu of service or setting" (ILOS). An ILOS is part of the state contract with its managed care plans, incorporated into the associated capitation rates, and subject to CMS review and approval. CMS views ILOSs as an innovative tool that states may use in their Medicaid and CHIP managed care programs to address SDOHs and HRSNs, improve population health, reduce health inequities, lower overall health care costs in Medicaid, and address many unmet needs of enrollees. CMS, however, believes explicit clarifications on ILOSs policies and requirements, improved assessment and monitoring of utilization of ILOSs and beneficiary protections are necessary. It also believes that appropriate fiscal protections and accountability of expenditures on ILOSs are needed, as they are alternative services and settings not covered under the state plan.

CMS finalizes its proposal 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). The definition explicitly states 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 a state plan-covered service or setting. CMS incorporates this defined term for purposes of application to separate CHIP as well.

Relatedly, CMS finalizes several conforming amendments in the regulations that strike descriptions of services or settings that are in lieu of services or settings covered under the state plan and instead reference the defined term.

For readability, CMS is creating a new §438.16 titled *In lieu of services and settings (ILOS) requirements* for Medicaid that will contain all of the provisions being finalized for ILOS requirements, and applying these requirements to separate CHIP by cross referencing the new section in §457.1201(c) and (e). As an overview, the new section (described further below and in sections I.B.4.b. through I.B.4.h. of the rule) will:

- Include requirements that ILOSs (i) meet general parameters, (ii) be provided in a manner that preserves enrollee rights and protections, (iii) be medically appropriate and cost-effective substitutes for state plan services and settings, (iv) be subject to monitoring and oversight, and (v) undergo a retrospective evaluation, when applicable;
- Specifically include the requirements for ILOSs to be appropriately documented in managed care plan contracts and considered in the development of capitation rates;
- Specifically include a risk-based approach for state documentation and evaluation requirements of any managed care plan contracts that include ILOSs; and
- Explicitly state that CMS has the authority to deny approval of any ILOS that does not meet standards in regulatory requirements as part of its review of the associated Medicaid managed care plan contracts and capitation rates.

One of the most commonly used ILOSs is inpatient mental health or substance use disorder treatment provided during a short stay in an Institution for Mental Disease (IMD). This is because FFP is statutorily not available - other than as an ILOS - for medical assistance for services provided to an individual who is 21 to 64 years of age and who is a patient in an IMD. The changes finalized in this section of the rule will not apply to, and therefore will not affect, the coverage of short term stays in an IMD as ILOS, or payments to MCOs and PIHPs for enrollees who are patients in IMDs. CMS explicitly exempts from the finalized §438.16 short term stays, as specified in §438.6(e), for inpatient mental health or substance use disorder treatment in an IMD. The IMD exception does not apply for separate CHIP since there are no similar payment restrictions for stays in an IMD in separate CHIP. CMS notes that states and managed care plans will still be required to comply with other applicable federal requirements for all ILOS (including short term stays in an IMD), including the requirement that ILOSs which are included in a managed care plan's contract be part of the state's monitoring activities.

Selected Comments/Responses. There was widespread support generally for the ILOS policies. However, some commenters expressed concerns that the additional guardrails and requirements (including by merely having a definition for ILOSs) will increase state and plan burden, and potentially disincentivize the use of ILOSs. However, CMS believes having a definition is vital to having transparency on the use of ILOSs for oversight purposes and for assisting states in determining if each ILOS is medically appropriate and cost effective. In addition, the agency believes the definition allows for state flexibility, such as to enable states to consider a longer-term substitute.

2. ILOS General Parameters (§§438.16(a) through (d), 457.1201(c) and (e), and 457.1203(b))

Limiting Types of Substitute Services or Settings. CMS believes that limiting the types of substitute services or settings that can be offered as an ILOS would help ensure an ILOS is an appropriate and efficient use of Medicaid and CHIP resources. Therefore, CMS finalizes its proposal to include in §438.16(b) a requirement that each ILOS must be approvable as a service or setting through a state plan amendment, including section 1905(a), 1915(i), or 1915(k) of the Act, or a waiver under section 1915(c) of the Act. As an example, CMS says that personal care homemaker services are approvable as a covered service in a waiver under section 1915(c) of the Act, and therefore would satisfy this requirement and could be an ILOS if it is a medically appropriate and cost-effective substitute for a service or setting covered under the state plan. For separate CHIP, CMS similarly finalizes its proposal that ILOSs would have to be consistent with services and settings approvable under sections 2103(a) through (c), 2105(a)(1)(D)(ii), and 2110(a) of the Act.

Limiting Allowable ILOS Costs to ILOS Cost Percentage. Because ILOSs are provided as substitutes for state plan-covered services and settings, CMS believes it is necessary to ensure there are appropriate fiscal protections for Medicaid and CHIP investments in ILOSs, and that there should be a limit on the amount of expenditures for ILOSs. CMS finalizes its proposal to limit allowable ILOS costs to a portion of the total costs for each managed care program that includes ILOSs (referred to as an ILOS cost percentage).

States claim FFP for the capitation payments they make to managed care plans. Those capitation payments are based on actuarially sound capitation rates[45] (which are developed prospectively based on historical utilization and cost experience) for Medicaid and rates are developed with actuarially sound principles[46] for separate CHIP. Both Medicaid and separate CHIP capitation rates account for utilization and cost associated with ILOSs.

CMS finalizes its policy in §438.16(c) that the ILOS cost percentage be calculated based on capitation rates and capitation payments. The ILOS cost percentage and associated expenditure limit will be measured both on a projected basis when capitation rates are developed (*the*

[45] See §438.2.
[46] See §457.1203(a). Also, to note, unlike under Medicaid, states are allowed for separate CHIP to establish higher capitation rates if necessary to ensure sufficient provider participation or access, or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

projected ILOS cost percentage) and on a final basis after capitation payments are made by states to the managed care plans (*the final ILOS cost percentage*). Both cost percentages will be measured distinctly for each managed care program.

For Medicaid and separate CHIP, CMS finalizes that the projected and final ILOS cost percentage will not be permitted to exceed 5 percent, justifying that 5 percent is a reasonable limit on ILOS expenditures because it is high enough to ensure the ILOSs would be used effectively but low enough to ensure appropriate fiscal safeguards.

Projected ILOS Cost Percentage Calculation: The state's actuary will be required to annually calculate (and annually recalculate) the projected ILOS cost percentage by dividing:

- The portion of total capitation payments that is attributable to all ILOSs (excluding short term stays in an IMD) for each managed care program, 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)).

Final ILOS Cost Percentage Calculation: The state's actuary will be required to annually calculate (and annually recalculate) the final ILOS cost percentage by dividing:

- The portion of total capitation payments that is attributable to all ILOSs (excluding short term stays in an IMD) for each managed care program, 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)).

The same calculations will apply for separate CHIP, but without the references to pass-through payments and state directed payments, since those are not applicable under separate CHIP.

Actuarial Certification: The percentages will need to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. The actuary who certifies the projected ILOS cost percentage will have to be the same actuary who develops and certifies the associated Medicaid capitation rates. Actuarial certification was not proposed, and is not finalized, as a requirement for separate CHIP.

Submissions to CMS: States will be required, at §438.16(c)(5)(i), to annually submit to CMS for review the projected ILOS cost percentage as part of the Medicaid rate certification required in §438.7(a) for each managed care program that includes ILOSs and any subsequent revised rate certification (such as a revised rate certification that changes the ILOSs offered, capitation rates, pass-through payment, or state directed payments). This is not applied for separate CHIP since actuarial certification of capitation rates nor review by CMS is required for separate CHIP.

At §438.16(c)(5)(ii), states will be required to submit to CMS the final ILOS cost percentage report both:

- With the rate certification for the rating period beginning 2 years after the completion of each 12-month rating period that included the ILOS(s) involved; and
- Annually for review as a separate report concurrent with the rate certification submission required in §438.7(a).

For the timing of the required submission with the rate certification, CMS gives the example that the final ILOS cost percentage report for a managed care program that uses a calendar year 2024 rating period would be submitted to CMS with the calendar year 2027 rate certification.

For separate CHIP, current regulations do not require review of capitation rates by CMS, and CMS had not proposed (and is not finalizing) to adopt the requirements at §438.16(c)(5)(ii) for separate CHIP.

In addition, §438.16(c)(4) will require states to prepare and submit 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. The summary report will be required for each managed care program that includes ILOSs, calculated on an annual basis and recalculated annually, certified by an actuary, and submitted concurrently with the final ILOS cost percentage.

CMS had not proposed (and is not finalizing) to apply the submission requirements at §438.16(c)(5)(ii) for separate CHIP since a review of capitation rates is not required under separate CHIP, nor had it proposed (and is not finalizing) to apply the annual ILOS cost report requirements at §438.16(c)(4) to separate CHIP.

Risk-based Approach to Required Documentation: CMS finalizes its policy for a risk-based approach to determine what ILOS documentation states will have to submit to CMS and whether they will need to complete an evaluation. Under this approach, CMS will use the projected ILOS cost percentage as a proxy for identifying states that offer higher amounts of ILOS compared to overall managed care program costs (and therefore as a proxy for having a higher likely impact on federal expenditures) and will vary the documentation and evaluation required of a state based on the state's projected ILOS cost percentage for each managed care program. The documentation requirements for states with a projected ILOS cost percentage that is less than or equal to 1.5 percent will undergo a streamlined review. States with a higher projected ILOS cost percentage will be required to submit to CMS additional documentation (as further explained in section I.B.4.d. of the rule, and II.D.4. below) and an evaluation of ILOSs (as further explained in section I.B.4.g. of the rule, and II.D.7. below). The risk-based approach, requiring additional documentation and evaluation for states with a cost percentage greater than 1.5 percent, will also apply for separate CHIP.

Final Action. CMS finalizes its policies proposed in this section with modifications to the proposed regulatory language to account for its prohibition of separate payment terms for state directed payments outlined in section I.B.2 of the rule by removing references to such separate payment terms that had been in the proposed language.

Selected Comments/Responses. Some commenters did not believe there should be any restrictions on the types of services or settings that could be approved as an ILOS, with some expressing concern that the restrictions could limit the use of ILOSs and prevent innovation. One commenter recommended providing for an exception process to allow states flexibility if they wanted to deviate from the limitation that an ILOS must be approved through another Medicaid authority or wavier. CMS declines to adopt any of the suggestions, asserting that ILOSs are not to be used as a way to avoid compliance with federal law.

There was general support for the policies on the calculation and documentation of projected and final ILOS cost percentages, but some commenters suggested changes. One commenter recommended allowing states with small programs to calculate the ILOS cost percentage across programs or to require integrated programs to calculate the percentages by major services types. Another commenter questioned the need for both the projected and final cost percentages. CMS believes the ILOS cost percentages should be calculated for each managed care program (and not aggregated across multiple programs or calculated by major services category) for reasons including that ILOSs vary by program; each program may include differing populations, benefits, areas, or delivery models; and capitation rates are often developed on a program basis.

Many commenters opposed the 5 percent limit for the ILOS cost percentage or recommended revisions to the limit. Other commenters who supported the limit recommended different percentages for the limit, flexibility for states to determine their own percent, and different types of exceptions to the limit, including suggested exceptions for approved ILOSs, ILOSs focused on HCBS, or ILOSs needed to ensure access to quality care such as HCBS and behavioral health. CMS believes that applying a limit is an appropriate fiscal safeguard necessary to ensure proper and efficient operations, and it believes that a 5 percent limit on ILOS expenditures compared to total program expenditures is a reasonable limit for every managed care program, regardless of size. The agency believes allowing for exceptions would not be equitable and would raise access concerns.

3. Enrollee Rights and Protections (§§438.3(e), 457.1201(e), 457.1207)

CMS notes that it is an option, not a requirement, for managed care plans to offer ILOSs, and that it is an option for an enrollee to use the ILOS as a substitute for the state plan-covered service or setting to which the enrollee is otherwise entitled. CMS believes it is vital to identify and make clear the enrollee rights and protections for enrollees eligible for, offered, or receiving an ILOS.

CMS finalizes its proposal to explicitly state existing enrollee rights and protections at a new §438.3(e)(2)(ii)(A) and (B). Specifically, the finalized policy:

- Explicitly states current rights in the new section that an enrollee who is offered or utilizes an ILOS 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.

- Requires the rights and protections be included in enrollee handbooks if ILOSs are added to a managed care plan's contract.
- Explicitly states 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.
- Requires enrollee rights and protections for ILOSs be documented in managed care plan contracts for Medicaid and separate CHIP.
- Adopts for separate CHIP the enrollee rights and protections at §438.3(e)(2)(ii)(A) and (B), but the enrollee rights and protections reference the existing separate CHIP enrollee rights and protections under subparts K and L of part 457.

4. Medically Appropriate and Cost-effective (§§438.16(d), 457.1201(e))

Managed care plans may cover an ILOS if the state determines the ILOS is a medically appropriate and cost-effective substitute for a covered state plan service or setting. CMS provides several examples.

To ensure appropriate documentation to support a state's determination that an ILOS is a medically appropriate and cost-effective substitute, CMS finalizes its proposal that the following elements must be included (for Medicaid and separate CHIP) in each managed care plan contract that includes ILOSs, as a condition of CMS approval of the contract:

- The name and definition for each ILOS and clear identification of the corresponding state plan-covered service or setting being substituted.
- The clinically defined target population(s) for which each ILOS has been determined to be a medically appropriate and cost-effective substitute by the state.
- A process by which a licensed network or managed care plan staff provider will have to determine that an ILOS is medically appropriate for a specific enrollee. The process will require that the determination of medical appropriateness be documented within the enrollee's records that describes the enrollee's care needs, and the documentation will have to include how each ILOS would be expected to address those needs.

In addition, CMS finalizes that, using the risk-based approach described above, the following additional documentation must be provided concurrent with the managed care plan contract for review and approval for a state with a projected ILOS cost percentage that exceeds 1.5 percent:

- A description of the process and supporting evidence the state used to determine that each ILOS would be a medically appropriate service or setting for the clinically defined target population(s); and
- A description of the process and supporting data that the state used to determine that each ILOS is a cost-effective substitute for a state plan-covered service or setting for the defined target population(s).

If CMS determines that additional information would be pertinent to the review and approval of a contract that includes ILOS(s) (under Medicaid or separate CHIP), the state must provide the additional information.

Selected Comments/Responses. A commenter requested clarification whether a state should identify the clinically defined target populations for ILOSs (as opposed to for managed care plans). In response, CMS explains that each ILOS is a medically appropriate and cost effective substitute for a state plan-covered service or setting, and therefore confirms that a state is responsible for determining the clinically defined target population for which each ILOS is determined to be a medically appropriate and cost effective substitute. CMS finalizes §438.16(d)(1)(iii) with a modification to clarify this. The agency further explains that a state is required to determine the clinically defined target population for which each ILOS is determined to be a medically appropriate and cost effective substitute and must document this population in the managed care plan contract.

5. Payment and Rate Development (§§438.3(c), 438.7, 457.1201(c))

Under §438.3(c)(1)(ii), 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 mental health and substance use disorder parity requirements of part 438 subpart K, 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. Since an ILOS is not a managed care requirement it is not explicitly stated it would be included in the final capitation rates and related capitation payments, according to that existing language, yet ILOS utilization and actual costs are included in rate development.

CMS finalizes its proposal to revise §438.3(c)(1)(ii) to include "ILOS" to ensure clarity, with a cross reference applying the clarification to separate CHIP as well. CMS considers this a technical change since §§438.3(e)(2)(iv) and 438.4(b)(6) clearly denote the inclusion of ILOSs in rate development.

To ensure compliance with the finalized requirements in §438.16(c)(1)(i) and (c)(4)(i), described in section I.B.4.b. of the preamble, which require that the projected ILOS cost percentage documented in the rate certification would not exceed 5 percent, CMS also finalizes its proposal that any contract provision related to ILOSs must be documented in all rate certifications submitted to CMS for review and approval. This was not proposed (and is not finalized) for separate CHIP since rate certifications are not applicable to separate CHIP.

Selected Comments/Responses. A commenter opposed the proposal, believing it would increase administrative expenses and not improve oversight. Disagreeing, CMS explains that when states amend capitation rates, the agency believes states should also be required to calculate a revised projected ILOS cost percentage, which should be accurately accounted for in the revised rate certification. This would be a tool to ensure continued compliance with the finalized requirements in §438.16, including the 5 percent limit for the projected ILOS cost percentage.

6. State Monitoring (§§438.16(d) and (e), 438.66(e), 457.1201(c))

States are required to establish a system to broadly monitor managed care programs' performance. When ILOSs are included in a managed care plan's contract, they must be included in the state's required monitoring activities. States and their managed care plans must also comply with all enrollee encounter data requirements in §§438.242 and 438.818, including reviewing and validating that data collected by, maintained by, and submitted to the state by the managed care plan is a complete and accurate representation of the services and settings provided to enrollees. However, ILOSs are not always easily identifiable in CPT codes and HCPCs.

Therefore, CMS finalizes its proposal to require that states include in contracts with managed care plans a requirement that the plans use specific codes established by the state to identify each ILOS in enrollee encounter data. These new coding requirements are also applied to separate CHIP.

CMS believes that, because §438.66(e)(1) requires states to submit an annual performance report for each managed care program administered by the state (known as MCPAR), states should already be reporting on ILOS in the MCPAR. The agency finalizes its proposal to add an explicit reference to ILOSs within the MCPAR requirement for clarity.

7. Retrospective Evaluation (§§438.16(e) and 457.1201(e))

Overall Policy Finalized. For Medicaid and separate CHIP, CMS finalizes, with modifications to clarify timing and other elements, to require states to submit to CMS retrospective evaluations of ILOSs, if the final ILOS cost percentage exceeds 1.5 percent, but encourages all states that include ILOSs in their managed care plan contracts to conduct such an evaluation of all ILOSs. The evaluation is to be completed separately for each managed care program that includes an ILOS (to account for differing enrollee eligibility criteria, populations, covered benefits, plan types, delivery models, geographic regions, or rating periods among separate programs in a state with multiple programs, and because the ILOS cost percentage would be required for each managed care program) AND is to include all ILOSs in the managed care program.[47]

Timing Elements Involved with Evaluations. The proposed rule had specified that the evaluation must use the 5 most recent years of accurate and validated data for ILOSs; that States' evaluations should be retroactive to the first complete rating period following the effective date of the proposed provision in which the ILOS was included in the managed care plan contracts and capitation rates; and that States would be required to 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 the final rule.

[47] In the proposed rule, CMS had stated its intent to require the retrospective evaluation to include all ILOSs in a managed care program, but the proposed regulatory text had not specified that. In the final rule, CMS modifies the regulatory text to include language expressing that intent.

However, commenters were confused by the timing descriptions in the proposed rule and raised questions about inconsistencies in the preamble and proposed regulatory language. As discussed in further detail within the selected comments and responses below, CMS, therefore, finalizes its intended policy with modifications to the proposed regulatory language to clarify its intent. As finalized, a retrospective evaluation of ILOSs will be required if, during any of the first 5 years following the publication date of the final rule (2025 through 2029), the ILOS final cost percentage exceeds 1.5 percent. If that occurs, then the state will be required to submit to CMS the evaluation not later than 2 years after the later of (1) the completion of the first 5 rating periods that include the ILOS or (2) the rating period that has the final ILOS cost percentage that exceeds 1.5 percent. The evaluation is to 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 managed care plan contract.

Content of Evaluations. To enable CMS and states to accurately measure the impact and programmatic integrity of the use of ILOSs, including if the ILOS is cost effective, CMS finalizes that the retrospective evaluation submitted by a state include at least evaluations by the state, using encounter data, on cost, utilization, access, grievance and appeals, and quality of care for each ILOS. Specifically, as part of the retrospective evaluation, a state is required:

- To evaluate the impact each ILOS had on utilization of state plan-covered services and settings, including any associated savings;
- To evaluate trends in managed care plan and enrollee use of each ILOS;
- To use encounter data to evaluate if each ILOS is a cost-effective and medically appropriate substitute for the identified covered service or setting under the plan or a cost-effective measure to reduce or prevent future need to utilize the covered service or setting;
- To evaluate the impact of each ILOS on quality of care;
- To include the final ILOS cost percentage for each year in the retrospective evaluation period, and a declaration of compliance with the 5 percent threshold;
- To evaluate appeals, grievances, and state fair hearings data, reported separately for each ILOS, including volume, reason, resolution status, and trends; and
- To evaluate the impact of each ILOS on health equity efforts undertaken by the state.[48]

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, including if the evaluation does not show favorable results.

CMS also finalizes an explicit statement of its right to require states to provide additional 5-year retrospective evaluations. CMS believes this may be necessary, including to address deficiencies in initial evaluations, to demonstrate that an ILOS acting as a longer-term substitute is cost effective and medically appropriate, and when a state substantially revises the ILOSs that are options within a managed care program.

[48] CMS notes that managed care plans are required under §§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; and that T-MSIS provides fields for sex, race, ethnicity, disability status, and language spoken.

CMS points to existing EQR activities, including the optional activity finalized at §438.64(c)(7), which is discussed in section I.B.5.c.3 of the rule, that could be used by states (or their EQRO) for assistance with evaluating the impact of ILOSs on quality of care.

Selected Comments/Responses. A couple commenters sought clarification on the timing for when ILOS evaluations would first be expected, and others requested clarification as to the period for which the data is to be reported. CMS agrees the proposed rule was not clear on these points, with inconsistent language in the preamble and proposed regulatory language. CMS clarifies that it is using a risk-based approach to require states to submit a retrospective evaluation only when the final ILOS cost percentage exceeds 1.5 percent (as discussed in section I.B.2.b of the rule). This would not be a rolling evaluation requirement. CMS intended to require states to submit the evaluation to CMS if the final ILOS cost percentage for one of the 5 years following the publication of the final rule exceeds 1.5 percent, unless CMS determines another evaluation is needed. Recognizing that some ILOSs have been used for a while, and while other ILOSs will be new, CMS clarifies the deadline for the evaluation. In the case that the 1.5 cost percentage threshold is exceeded during one of the first 5 years following publication of the final rule, the evaluation will be required to be submitted to CMS not later than 2 years after the later of (1) the completion of the first 5 rating periods that include ILOSs or (2) the rating period that has a final ILOS cost percentage that exceeds 1.5 percent. Plus, CMS would have the right to require the state to submit additional retrospective evaluations. Further, CMS clarifies its intent that the ILOS retrospective evaluation would be required to use ILOS data from the first 5 rating periods that the ILOS is authorized by the state and offered by the managed care plan.

To illustrate the timing requirements, CMS provides examples:

ILOSs That Are New and for Which the Threshold is Exceeded During the 5 Years Following Rule Publication. In the case of a state with a managed care program that has 3 ILOSs first authorized and documented in the managed care plan contracts for the 2027 rating period, the evaluation would be required to be submitted for all 3 ILOSs if the final ILOS cost percentage for 2027, 2028, 2029, 2030, or 2031 exceeds 1.5 percent. The evaluation would need to be submitted to CMS no later than 2 years after the completion of the 5-year period (December 31, 2033, in the example). Plus, CMS would have the right to require the state to submit additional retrospective evaluations. In this example, the evaluation would be required to use ILOS data from 2027, 2028, 2029, 2030, and 2031 (i.e., the first 5 years for which the ILOSs were first authorized and documented in the managed care plan contracts).

ILOSs In Use and for Which the Threshold is Exceeded During the 5 Years Following Rule Publication. In the case of a managed care plan program that has 5 ILOSs that were first authorized by the state and documented in the managed plan contract in 2022, if in 2027 the final ILOS cost percentage is higher than 1.5 percent, the state is required to conduct an evaluation, which would be due to CMS by December 31, 2029 (i.e., 2 years following the completion of the 2027 rating period that had a final ILOS cost percentage that exceeded 1.5 percent). Plus, CMS would have the right to require the state to submit additional retrospective evaluations. In this example, the evaluation would be required to use ILOS data from 2022, 2023, 2024, 2025, and

2026 (i.e., the first 5 years for which the ILOSs were first authorized and documented in the managed care plan contracts).

Threshold Is Exceeded After 5 Years Following Rule Publication. In the case of a state's managed care program with 2 ILOSs that are first authorized and documented in the managed care plan contracts in 2026, if in 2040 the final ILOS cost percentage exceeds 1.5 percent, it is up to CMS to determine whether the state is required to submit a retrospective evaluation, because 2040 is outside of the first 5 years after the date of publication of the rule.

8. State and CMS Oversight (§§438.16(e) and 457.1201(e))

CMS finalizes, with a technical correction, its proposal, for Medicaid and separate CHIP, to require that states notify CMS within 30 days if the state determines that an ILOS is no longer a medically appropriate or cost-effective substitute or if the state identifies another area of noncompliance with part 438 of title 42, Code of Federal Regulations.

CMS finalizes, with modifications, its proposal for a federal oversight process for Medicaid and separate CHIP, which will allow CMS to terminate the use of an ILOS if it determines noncompliance or receives state notification of noncompliance. In the case a managed care plan elects to no longer offer an ILOS, a state terminates an ILOS, or CMS notifies the state it must terminate an ILOS, the state will be required to submit an ILOS transition plan to CMS for review and approval within 30 days (as opposed to 15 days, as proposed) of receipt of the managed care plan notification to the state of no longer offering the ILOS, of receipt of the state notification to the managed care plan of its determination to terminate the ILOS, or of receipt of notice from CMS to the state of its decision to terminate an ILOS, as applicable. Under this policy, states will also be required to prepare a transition plan as part of the implementation process for any new ILOS.

The following elements will be required as part of the transition plan:

- A process to notify enrollees that the ILOS they are receiving will be terminated.
- A transition of care policy, made publicly available and not to exceed 12 months, to arrange for state plan services and settings to be provided timely and with minimal disruption to care for any enrollee receiving the ILOS at the time of termination.
- The administrative actions that the state would take to remove the terminated ILOS from managed care plan contracts and capitation rates.
- An assurance that the state would submit the necessary contract amendment and outline a reasonable timeline for submitting the contract amendment to CMS for review and approval.
- An assurance that the state would submit an adjustment to the capitation rates, as needed, with a reasonable timeline for submission of the revised rate certification to CMS.

In addition, states will be required to remove the ILOS from the applicable managed care plan contracts and submit a modified contract to CMS for review and approval and to adjust the

actuarially sound capitation rates, as needed, to remove utilization and cost of the ILOS from Medicaid capitation rates (consistent with the assurances being required above).

Select Comments/Responses. Some commenters were concerned that the proposed 15-day deadline for the transition plan was not sufficient time for states to collect necessary data from their managed care plans, analyze it, and develop a meaningful plan specific to the ILOS. Suggested alternative deadlines ranged from 45 days to 12 months. CMS agrees that transition plans need to be meaningful and address many issues to be effective. The agency therefore modifies its proposal to allow states up to 30 calendar days to submit an ILOS transition plan to CMS for review and approval, aligning this timeframe with the state notification process so both could occur concurrently.

The agency further clarifies in response to comments that the deadline for the transition plan is tied to the date of the decision to terminate the ILOS and not the termination date itself. CMS makes modifications to its proposed language to clarify that the submission deadline for an ILOS transition plan to CMS for review and approval tolls from the date of receipt of notice from the state to a managed care plan of its decision to terminate an ILOS, of receipt of notice from a managed care plan to the state of its decision to cease offering an ILOS, or of receipt of notice CMS provides to the state of its decision to require the state to terminate an ILOS.

9. Applicability Dates (§§438.3(e), 438.7(g), 438.16(f), 457.1200(d))

CMS finalizes its applicability dates, as proposed.

Not later than the effective date of the final rule, states and managed care plans are required to comply with the finalized provisions in §§438.2 (technical clarifications, including definition of ILOS), 438.3(c)(1)(ii) (clarifying the inclusion of ILOSs in the final capitation rates and related capitation payments), 438.3(e)(2)(i) through (iv) (technical changes to reference the proposed defined term "ILOS"), 438.10(g)(2)(ix) (requiring enrollee rights and protections be included in the enrollee handbooks), 438.66(e)(2)(vi) (clarifying ILOSs are included in MCPR), and applicable cross-references for separate CHIP at §§457.10, 457.1201(c) and (e), and 457.1207.

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, states and managed care plans must comply with the finalized provisions in §§438.3(e)(2)(v) (exception for short term IMD stays), 438.16 (ILOS general requirements, i.e., proposals other than those in the other sections specified in this paragraph or the preceding paragraph), and 438.7(b)(6) (requiring contract provisions related to ILOSs must be documented in all rate certifications submitted to CMS).

E. Quality Assessment and Performance Improvement Program, State Quality Strategies and Extended Quality Review (§§438.330, 438.340, 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, 457.1250)

In accordance with section 1932 of the Act and 42 CFR 438, states that contract with Medicaid managed care plans (MCOs, PIHPs, and PAHPs) must be in compliance with quality assessment and performance improvement requirements, including requiring such plans to have a quality assessment and performance improvement (QAPI) program, a managed care quality strategy for assessing the quality of services furnished by such plans, external quality review (EQR) of the quality of and access to services under managed care contracts, and accreditation reporting.

1. Quality Assessment and Performance Improvement Program (§438.330)

Medicaid managed care plans are required by states to have QAPI programs that include performance improvement projects (PIPs). In 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" 2016 final rule (81 FR 27682) (2016 final rule), CMS implemented a policy to allow states to permit Medicaid managed care plans that exclusively serve dually eligible individuals to use an MA plan's quality improvement project (QIP) under the QAPI instead of a Medicaid PIP. However, in the final rule "Medicare Programs; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program," CMS removed the QIP from the requirements for MA organizations.

CMS finalizes its proposal to replace the outdated reference at §438.330(d)(4) to the removed QIP with a reference that would instead permit the MA organization Chronic Care Improvement Program (CCIP) requirements in §422.152(c) to be used. That is, states may permit plans exclusively serving dually eligible individuals to substitute an MA organization CCIP that meets those requirements for one or more of the PIPs required under §438.330(d). CMS believes the CCIP requirements meet comparable quality improvement standards as are intended for the PIP. This change will not apply to separate CHIP. CMS is modifying the effective date of this policy. Since this change is optional for plans, the change will take effect on the effective date of the final rule instead of the separate proposed applicability date that required states to comply with the update no later than the rating period for contracts beginning after the effective date of the final rule.

2. Managed Care State Quality Strategies (§§438.340, 457.1240)

Currently,[49] states must have a written quality strategy for assessing and improving the quality of health care furnished by Medicaid managed care plans. The process for drafting or revising the quality strategy includes making the draft or revisions available for public comment. States must submit to CMS the initial quality strategy for feedback prior to adoption and resubmit the strategy when there are significant changes to the document or significant changes within the

[49] See §438.340, which also applies to separate CHIP through the cross reference at §457.1240(e).

state's Medicaid program. States are required to review and update their strategy at least once every three years.

To increase transparency and opportunity for ongoing public engagement, CMS finalizes its proposals to revise §438.340(c) to require: (1) states to make their quality strategy available for public comment at the 3-year renewal, regardless of whether or not there are significant changes, in addition to whenever significant changes are proposed to be made; (2) the state Medicaid agency to post on its website the results of its 3-year review, including its full evaluation of the effectiveness of the strategy; and (3) states (prior to finalizing a revised or renewed quality strategy) to submit a copy of the revised strategy to CMS at least every 3 years, following the state Medicaid agency review and evaluation, in addition to when significant changes are proposed to be made.

States will have to comply with the changes for Medicaid and separate CHIP not later than one year after the effective date of the final rule.

3. External Quality Review (§§438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, 457.1250)

States are required to contract with an external quality review organization (EQRO) to conduct an annual EQR on quality, timeliness, and access to services furnished to Medicaid and CHIP beneficiaries under managed care contracts. The EQRO must perform specified mandatory EQR-related activities (including validating MCO PIPs, validating MCO performance measures, reviewing MCO compliance with regulations, and validating MCO network adequacy) and conduct an EQR. States may also require EQROs to conduct optional activities (such as validating encounter data, conducting quality studies, and assisting with quality ratings). The EQR must produce specified information, which must be included in an annual detailed EQR technical report that states must submit to CMS. The technical report must include, among other things, a description of data, including validated performance measurement data for certain mandatory EQR-related activities. The regulations also outline when states may use the results from a Medicare or private accreditation review instead of conducting an EQR for a given managed care entity. These requirements apply to each managed care plan that has a contract with a state Medicaid or CHIP agency as well as certain primary care case management (PCCM) entities whose contract with the state provides financial incentives for improved quality outcomes.

a. Removal of PCCM Entities from Scope of Mandatory EQR

A primary care case manager is 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. A PCCM entity is defined at §§438.2 and 457.10 as an organization that provides, in addition to primary care case management services, an additional specified function, such as intensive case management, development of care plans, execution of contracts with or oversight responsibilities for other FFS providers, and review of provider claims, utilization, and practice patterns. Some PCCM entities

have contracts with the state that provide financial incentives for improved quality outcomes. Such PCCM entities are subject to a number of quality measurement and improvement and EQR requirements to which primary care case managers are not similarly subject.[50] Since states' contracts with PCCM entities vary in the size, structure, and scope of case management and other services provided by risk-bearing PCCM entities, CMS now believes the use of EQR may not be an appropriate oversight tool for all PCCM entities and may deter PCCM entities (especially small provider groups) from entering risk-bearing contracts that are aimed at quality improvement.

CMS finalizes its proposal to exclude PCCM entities from the EQR requirements under §438.350 for Medicaid and separate CHIP. CMS finalizes its policy, mostly as proposed, with a modification to explicitly allow states to choose to perform validation of performance measures and performance improvement projects conducted by PCCM entities. States that choose to conduct these activities may continue to access FFP at the 50 percent rate in accordance with §438.370(b).

b. EQR Review Period

Most EQR activities (for example, validation of performance improvement projects, performance measurement data, and network adequacy activities under §438.358(b)(1) and optional EQR activities under §438.358(c)) are required to be performed using information derived during the "preceding 12 months," but the regulations do not specify when the EQR activity must take place relative to finalization and posting of the annual EQR technical report required to be submitted to CMS. This results in a lack of uniformity in the review periods included in the reports.

To ensure more consistency among states regarding the period represented by data and to align data in the annual reports with the most recently available information used to conduct EQR activities, CMS proposed to define the 12-month review period (i.e., the period from which the data subject to an EQR-related activity is derived) as the 12-month period beginning 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 to require the EQR-related activities be performed in the 12 months preceding the finalization and publication of the annual EQR technical report. The one exception to this proposed period was for the activity described in §438.350(b)(1)(iii), which is the requirement for a review within the previous 3 years.

The agency finalizes this proposal as applied to the mandatory EQR activities. However, based on comments received, CMS does not apply the review period equally between mandatory and optional EQR activities because that would result in the data and information used for optional activities being limited to a 12-month period, which conflicts with the 3-year to 5-year periods required to be evaluated for quality strategies, SDPs, and ILOSs. Therefore, CMS does not apply

[50] For example, states are not required to perform an annual EQR of the state's primary care case managers, but the 2016 final rule provided that states are required to conduct an annual EQR of PCCM entities operating under a risk-bearing contract.

this review period to the optional EQR activities so that states will have flexibility to determine the appropriate review periods for the optional activities they implement.

The updates will also apply to separate CHIP EQR requirements for managed care plans.

States must comply with the updates no later than December 31, 2025.

c. Using an Optional EQR Activity to Support Current and Proposed Managed Care Evaluation Requirements

CMS finalizes, as proposed, its policy to add a new optional EQR activity at §438.358(c)(7), which may be carried out by an EQRO to support states in their evaluation activities related to quality strategies, SDPs, and ILOSs, that pertain to outcomes, quality, or access to services. The scope of the EQR optional activity is limited to an activity permissible under section 1932(c)(2) of the Act, which requires external review of the quality outcomes and timeliness of and access to care in managed care plans and programs. CMS describes that this optional EQR activity could be used to assist in implementing existing evaluation requirements and evaluation requirements described in the final rule (sections I.B.2.j and I.B.4.g) for quality strategies at §438.340(c)(2)(i), SDPs at §438.6(c)(2)(iv) and (v), and ILOSs at §438.16(e)(1). CMS will develop a protocol, which could be used under this optional activity to assist with such evaluation activities. CMS believes the optional activity will provide states with technical assistance (through the protocol) and reminds states they could receive an enhanced match for activities carried out by an EQRO (including under this optional activity) in accordance with section 1903(a)(3)(C)(ii) of the Act.

The optional activity will be available to states for Medicaid and separate CHIP as of the effective date of the final rule.

d. Non-duplication of Mandatory EQR Activities with Medicare or Accreditation Review

States may, at §438.360, exempt managed care plans from EQR-related activities if such activities are duplicative of ones conducted as a part of a Medicare review of an MA plan or a plan accreditation review conducted by a private accrediting organization (PAO) recognized by CMS as applying standards at least as stringent as Medicare (i.e., by a PAO that has been deemed compliant with Medicare requirements under §422.158). CMS believes the requirement to have obtained deemed compliance unnecessarily restricts the availability of the EQR nonduplication option in a manner that is not required under statute.[51]

CMS is therefore finalizing its policy, as proposed, that for purposes of allowing a state to use the results from a private accreditation review conducted by a PAO instead of conducting a

[51] CMS describes that section 1932(c)(2)(B) of the Act, the authorizing basis for the nonduplicative provision, does not require every private independent entity to have obtained MA deeming authority, but rather describes types of organizations that would be eligible to participate in the nonduplication option and provides section 1852(e)(4) organizations (organizations approved as a private national accreditation organization) as one example.

duplicative EQR activity for a managed care entity, the PAO will no longer be required to have obtained MA deeming authority from CMS. However, the review standards used by the PAO must be comparable to standards established through the EQR protocols required under §438.352.

These changes will be effective as of the effective date of the final rule.

e. External Quality Review Results (§438.364)

In addition to the type of information (relating to data validation) currently required to be included in the annual EQR technical report for each EQR-related activity, CMS finalizes its policy, as proposed, that the report include outcomes data and results from quantitative assessments for the applicable EQR activities. CMS also finalizes its proposal that the report 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. These changes will apply to Medicaid and separate CHIP. States will need to comply with these updates not later than 1 year after the date of issuance of the associated EQR protocol.

CMS requires at §438.364(c) that EQR technical reports be completed and available on the state's website not later than April 30 of each year. Most measures in the performance measure validation EQR activity are Healthcare Effectiveness Data and Information Set (HEDIS) measures. In June of each year, data on HEDIS measures from the previous year are audited. CMS proposed (but is not finalizing) to change the April 30 deadline to December 31 so that the EQR performance measurement activity could follow when states and EQROs receive the audited HEDIS data. In response to comments received, the agency acknowledged the burden of changing state and EQRO process for conducting the annual EQR activities and compiling the technical reports and determined that burden outweighed the benefit of the EQR technical reports being posted 4 months earlier. Therefore, the deadline will remain April 30.

Currently states are not required to notify CMS that their EQR technical report has been completed and posted on the state's website. CMS finalizes its proposal to revise §438.364(c)(2)(i) to require that states notify CMS, in a form and manner specified by the agency, not later than 14 calendar days after posting their EQR technical reports on their website. The revision will be effective as of the effective date of the final rule.

States are not currently required to retain on their websites EQR technical reports from prior years. CMS finalizes its proposal to require states to maintain on their website at least the previous 5 years of EQR technical reports. States will be required to comply with the requirement beginning not later than December 31, 2025.

The finalized policies will apply to Medicaid and separate CHIP.

Selected Comments/Responses. Commenters in general supported these changes, including because they believe the changes would make data more accessible and result in more meaningful reports that could support quality improvement, oversight, and stronger managed

care plan performance. In the proposed rule, CMS had sought comment on how it could use future guidance developed in the EQR protocols to support states' efforts to reduce disparities and described potential future guidance in the EQR protocols for states to stratify performance measures reported in the EQR technical reports under the performance measure validation activity to address equity gaps. Several commenters supported such future guidance, while others noted concerns about data reliability and states needing time to develop their data infrastructure.

F. Medicaid Managed Care Quality Rating System (§§438.334 and 457.1240)

1. Background

The Medicaid and CHIP Managed Care Quality Rating System (MAC QRS) requirements[52] are intended to help beneficiaries understand and compare differences in managed care plan performance, including by publicly posting quality ratings on the states' websites. The MAC QRS is the first time that states will be held to a minimum federal standard for their rating systems. CMS, in consultation with states and other interested parties, are required to develop a MAC QRS framework that includes quality measures and a methodology for calculating quality ratings. States may use this developed framework or use their own alternative QRS framework, subject to CMS approval, as long as the alternative framework produces substantially comparable information about plan performance. A minimum set of mandatory quality measures developed by CMS must be used under either type of framework.

CMS describes the extensive consultation and stakeholder interviews it conducted between 2018 and 2022 to inform its proposal for the MAC QRS framework.

In the proposed rule CMS proposed a MAC QRS framework with three components: (1) mandatory measures (which states must use in the CMS framework or in a CMS-approved alternative framework), (2) a rating methodology (either the CMS-developed methodology or an alternative methodology approved by CMS), and (3) a mandatory website display format. States may implement additional measures without implementing an alternative QRS. Also, CMS proposed a subregulatory process for engaging regularly with interested parties before making updates to the components of the MAC QRS framework. CMS emphasized that states would be able to use the optional EQR activity described above to assist with quality rating of MCOs, PIHPs, and PAHPs, and receive an enhanced federal financial participation for certain activities carried out by an EQRO under that optional activity.

As described further below, CMS is finalizing its proposals under this section, but with several modifications to clarify the scope of the alternative QRS and to reduce the implementation resources states need for the MAC QRS. Specifically, CMS is finalizing organizational modifications (that is, placement of provisions) to addresses a few areas of confusion it observed in submitted comments. The modifications are to clarify that its policy (as proposed and as finalized):

[52] These requirements refer to the Medicaid managed care QRS requirements at §438.334, including as applied to separate CHIP through §457.1240.

- Allows states (without CMS approval) to include *additional* measures beyond the CMS-identified mandatory measures for the QRS (not as a replacement for such mandatory measures);
- Allows states (without CMS approval) to include website display features in addition to those newly finalized in the rule (not instead of those newly finalized); and
- Allows states the option to use an alternative to the rating methodology for calculating quality ratings for mandatory measures identified by CMS, subject to CMS review and approval.

In addition, there are 5 modifications made in the final rule in response to comments expressing concern on the overall administrative complexity of implementing the MAC QRS.

- CMS finalizes 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 of the rule. CMS finalizes its proposed 2-phase implementation of the MAC QRS. This means:
    - In phase 1, states must fully comply with all MAC QRS requirements, except for requirements under §438.520(a)(6), by the end of the fourth calendar year following July 9, 2024 – which is by December 31, 2028. The one-year extension, if granted for a state, would extend this phase 1 deadline to December 31, 2029.
    - In phase 2, states must comply with requirements under §438.520(a)(6). CMS will specify the implementation date, but it cannot be earlier than 2 years after implementation of phase 1, meaning no earlier than 2030 or, in the case of a state granted an extension, until at least 2031.
- CMS finalizes a modification that 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 programs established by the states.
- CMS removes the requirement for states to obtain input from the state's Medicaid 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.
- CMS narrows the scope of the requirement for states 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. As finalized, this requirement will apply only to managed care plans that participate in managed care programs with two or more participating plans.
- CMS includes a modification regarding "undue burden". 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 to *the extent feasible without undue burden.*

2. Provisions of the Rule (§§438.334, 438 subpart G, and 457.1240(d))

CMS finalizes its proposal for a new subpart G in 42 CFR 438 to establish the requirements for the MAC QRS framework and the standards that states will need to meet for CMS to approve an alternative QRS. The new provisions are adopted for separate CHIP by cross reference through an amendment to §457.1240(d).

3. Definitions (§438.334, 438.500, and 457.1240(d))

CMS finalizes its proposed definitions for several terms. A couple of the definitions to note include:

- Measurement year: 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.
- QRS framework: 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.

4. General Rule and Applicability (§§438.334(a), 438.505(a) and 457.1240(d))

To provide states more time to make the operational and contractual changes needed to meet the finalized requirements, CMS finalizes its proposal 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 (instead of the 3-year implementation date currently required). Because the final rule is effective on July 9, 2024, states will 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 (based on the measurement and display years discussed in section I.B.6.e.7 of the rule).

However, in response to comments, CMS acknowledges that states may need additional time to fully comply with all MAC QRS requirements and therefore in the final rule adds provisions at §§438.515(d) and 438.520(b) to allow states to request a one-time, one-year extension for 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), respectively. CMS will approve a state's request if the agency determines that the request: (1) includes the required information; (2) demonstrates the state has made a good-faith effort to identify and begin an implementation strategy for complying with the requirement but is unable to comply by the implementation date; and (3) demonstrates the state has an actionable plan to implement the requirements by the end of the one-year extension.

CMS finalizes the requirement that states use the beneficiary support system currently required at §438.71 to provide a support system (such as live consumer assistance through phone or online chat) for beneficiaries and caregivers to understand how to use the MAC QRS to select a

managed care plan. A beneficiary support system is not required for separate CHIP and therefore CMS had not proposed this requirement for separate CHIP.

The MAC QRS framework is currently required by regulation[53] to align with the QHP quality rating system,[54] the MA and Part D quality rating system,[55] and other related CMS quality rating programs. CMS finalizes its proposal to continue such alignment with the specified quality rating systems and other related CMS programs (such as Medicaid and CHIP Scorecard and the CMS Universal Foundation).

The requirements for the MAC QRS (under current requirements and those finalized in section I.B.6 of the rule) apply to each state contracting with an MCO, PIHP, or PAHP for the delivery of covered Medicaid services. Current and newly finalized requirements (except for those on beneficiary support systems, as noted above) apply to separate CHIP. Such current and newly finalized requirements do not apply to PCCM entities nor non-emergency medical transport PAHPs. Also, the newly finalized policy for the MAC QRS framework excludes contracts between states and MA Dual Eligible Special Needs Plans (D-SNPs) if the contract is only for the D-SNP to provide Medicaid coverage of Medicare cost sharing for the D-SNP enrollees.

Select Comments/Responses. Many commenters supported alignment of the MAC QRS with existing CMS quality initiatives, specifically referencing the QHP quality rating system, MA and Part D quality rating system, the Adult and Child Core Sets, and the Universal Foundation. Some concern was raised on the timing for implementation and CMS responds with the addition of allowing states to apply for a one-time, one-year extension with respect to specific requirements.

5. Establishing and Modifying a Mandatory Measure Set for MAC QRS (§§438.334(b), 438.510 and 457.1240(d))

a. Standards for Including Measures in the Mandatory Measure Set (§§438.510(c), 457.1240(d))

CMS finalizes codification of 3 standards for it to apply to determine when to add measures to the mandatory measure set, when to make substantive updates to an existing mandatory measure, and when to remove a measure from the mandatory measure set. The standards are finalized with modifications (i) to the feasibility criterion to take into account burden of data reporting for providers and (ii) to clarify that alignment with other quality initiatives is required to the extent appropriate. A measure is included in the measure set if (based on input CMS receives through the finalized subregulatory process discussed in section I.B.6.e.3 of the rule) it satisfies the measure inclusion criteria standard, balanced representation standard, and burden assessment standard as follows:

- Measure Inclusion Criteria Standard. It meets 5 of the following 6 finalized measure inclusion criteria:

[53] §438.334(b)(1) for Medicaid, and applied by cross-reference at §457.1240(d) for separate CHIP.
[54] The QHP quality rating system is the health plan quality rating system under 45 CFR §156.1120.
[55] The MA and Part D quality rating system is the rating system under subpart D of parts 422 and 423 of title 42, CFR.

    - Usefulness to beneficiaries: The measure is meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan.
    - Alignment: The measure aligns, to the extent appropriate,[56] with other CMS rating programs.
    - Relevance: The measure assesses health plan performance in at least the area of customer experience, access to services, health outcomes, quality of care, health plan administration, or health equity.
    - Actionability: The measure provides an opportunity for managed care plans to influence their performance on the measure.
    - Feasibility: The measure is based on readily available data or data available without undue burden on states, plans, or providers[57] such that it is feasible to report by most states and plans.
    - Scientific acceptability: The measure demonstrates scientific acceptability, i.e., it produces consistent (reliable) and credible (valid) results.
- Balanced Representation Standard. It would contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a set of mandatory measures; and
- Burden Assessment Standard. Burdens to include the measure do not outweigh the benefits to the overall quality rating system framework, based on the 6 inclusion criteria stated above.

A measure will be added to the measure set or updated in accordance with the above standards and will be removed from the set if it no longer meets these standards.

CMS reviews that the overall measure set is to be concise. CMS finalizes 16 measures for the initial mandatory measure set, with flexibility for the number of measures to increase as the set is updated.

Selected Comments/Responses. Many commenters supported the standards for measure selection. In response to a suggestion, the agency modifies its proposed feasibility criterion under the measure inclusion standard to consider whether data are available without undue provider burden (as well as considering state and plan burden, as proposed) for determining if the measure is feasible to report.

Commenters requested clarification on the process that CMS will use to assess a measure in accordance with the standards. CMS agrees additional clarity is needed on how the agency will assess the measure under the balancing standards in order to help inform those who provide input during the subregulatory process finalized in §438.510(b). Therefore, CMS finalizes a new provision in §438.510 to specify considerations of the agency when making the determination of whether a measure satisfies the standards. Specifically, CMS may consider the measure set as a whole, the measure individually, or a comparison of the measure to other measures that assess

[56] CMS adds "to the extent appropriate" as a modification in the proposed rule to better enable inclusion of measures for which there is no existing CMS initiative for which it would be considered for the measure to align.
[57] The consideration of provider burden is added in the final rule in response to comments.

similar aspects of care or performance areas when assessing the measure under the balanced representation and burden assessment standards. By adding these considerations, the agency hopes to encourage participants in the subregulatory process to use the considerations in their analysis.

Several commenters made specific suggestions for additional criteria to be included. One such suggestion was to require measures to be outcomes-based measures. CMS will not add such a criterion because it believes there are instances when a process measure may be a better way to determine the extent to which enrollees of a plan have access to specific services. Also, the agency declines to add a requirement for consensus-based entity (CBE) endorsement because it believes the endorsement criteria overlap with the MAC QRS measure selection criteria and therefore requiring endorsement would be redundant.

CMS also declines a commenter's suggestion to require a pilot period before implementing new measures. The agency believes that benchmarks for quality measures already help plans to assess how well they are performing on the measures, identify any need for improvement, and make educated decisions on how to improve quality. Plus, the agency believes that alignment with other quality initiatives will result in measures that are well-established. However, CMS also notes that if a newly developed measure is added to the mandatory measure set that the rule provides the agency with flexibility to determine the implementation date for the measure, which could allow for a pilot period.

b. Mandatory Measure Set (§§438.510(a), (b), and 457.1240(d))

CMS finalizes an initial set of 16 mandatory measures (instead of 18 mandatory measures, as proposed). States will be allowed to include additional measures. CMS finalizes a modification to clarify that the mandatory minimum measure set includes only measures calculated using the technical specifications identified by CMS in the technical resource manual. To the extent that the manual identifies flexibilities for calculating ratings for MA, if a measure is calculated using such flexibilities it complies with this requirement.

Data from Table 2 of the rule are extracted from the table and replicated below, with slight modification. The table in the rule (as included below) includes non-substantive changes to the measure descriptions, such as to reflect updates implemented by the measure steward that occurred between publication of the proposed and final rules.

Finalized Initial MAC QRS Mandatory Measure Set

CMIT[58] #	Measure Name	Description
743	Use of First-Line Psychosocial Care for Children and	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

[58] The table includes updates to reference the CMS Measures Inventory Tool (CMIT) identifiers instead of the National Quality Forum (NQF, which was the former consensus-based entity) identifiers for the measures.

CMIT[58] #	Measure Name	Description
	Adolescents on Antipsychotics (APP)	
394	Initiation and Engagement of Substance Use Disorder (SUD) Treatment (IET)	The percentage of new SUD episodes that result in treatment initiation and engagement. Two rates are reported: •Initiation of SUD Treatment. 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 the initiation. Ages: 13 and older
672	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
268	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
761	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
123	Child and Adolescent WellCare Visits (WCV)	The percentage of members who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement year. Ages: 3 to 21
93	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
118	Cervical Cancer Screening (CCS)	The percentage of members who were recommended for routine cervical cancer screening who were screened for cervical cancer using either** of the following criteria: • Members 21 to 64 years of age who were recommended for routine cervical cancer screening and had 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

CMIT[58] #	Measure Name	Description
139	Colorectal Cancer Screening (COL-E)	The percentage of members who had appropriate screening for colorectal cancer. Ages: 45 to 75
897	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
166	Contraceptive Care - Postpartum Women (CCP)	Among women who had a live birth, the percentage that: (1) Were provided a most effective or moderately effective method of contraception within 3 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
581	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 measures assesses the following facets of prenatal and postpartum care: (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
148	Glycemic Status Assessment for Patients w.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: • Glycemic status <8.0%. • Glycemic status >9.0%. Ages: 18 to 75
80	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
167	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
151/152	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
151/152	CAHPS – Getting care quickly	Composite of the following items: •The percentage of members who indicated that they always got care for illness, injury, or condition as soon as they needed, in the last six months. •The percentage of members who indicated they always got check-up or routine care as soon as they needed, in the last six months. Ages: 0 to 17 | 18 and older
151/152	CAHPS – Getting needed care	Composite of the following items: •The percentage of members who indicated that it was always easy to get necessary care, tests, or treatment, in the last six months. •The percentage of members who indicated that they always got an appointment with a specialist as soon as needed, in the last six months. Ages: 0 to 17 | 18 and older
151/152	CAHPS – How well doctors communicate	Composite of the following items: •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

CMIT[58] #	Measure Name	Description
151/152	CAHPS – Health plan customer service	Composite of the following items: •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 notation in Table 2 says "either", but since there are 3 criterion listed intent may have been "any".

After consideration of comments, CMS does not finalize inclusion of the following two measures that had been proposed:

Measure Name	Description
MLTSS-1 LTSS Comprehensive Assessment and Update	The percentage of Medicaid MLTSS plan participants who have documentation of a comprehensive assessment in a specified timeframe that includes documentation of core elements. Two performance rates and two exclusions rates are reported for this measure: •Assessment of Core Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) •Assessment of Supplemental Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements and at least 12 supplemental elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) Ages: 18 and older
MLTSS-7: LTSS Minimizing Institutional Length of Stay	The proportion of admissions to an institutional facility (for example, nursing facility, intermediate care facility for individuals with intellectual disabilities (ICF/IID)) for managed long-term services and support (MLTSS) plan enrollees that result in successful discharge to the community (community residence for 60 or more days) within 100 days of admission. This measure is reported as an observed rate and a risk-adjusted rate. Ages: 18 and older

CMS also describes several other measures considered but not proposed or included in the initial mandatory measure set and the reasons for not including such measures.

Selected Comments/Responses. Many commenters suggested additional measures or additional types of measures, including a measure of social determinants of health (SDOH) and measures that reflect quality of care for people with rare disorders, among many other suggestions. Based on assessment of such recommended additional measures according to the standards and criterion for measure inclusion finalized in the rule, and noting overlap with measures finalized in the rule for inclusion, CMS declines to add any further measures at this time and specifies the reasons for declining inclusion of the specific measures suggested. With respect to an SDOH measure, the agency agrees with the importance of such a measure but since there are no existing SDOH measures that have been widely publicly reported at a plan-level, the agency does not believe such a measure is appropriate for inclusion in the initial mandatory measure set. The agency also believes that any measure additions should occur through the subregulatory process finalized in the rule to update the mandatory measure set in order to allow for public notice and comment prior to any decision.

Other commenters did not support specific measures proposed for inclusion and requested removal of specific measures for various reasons. CMS responds to the specific requests for removal with justifications why the specific measure is appropriate for inclusion, often noting

that the assessment purpose of the measure in question is important and the lack of alternative measures. The agency also responds that CBE endorsement is not a requirement for MAC QRS measures.

However, CMS agreed with commenters' suggestions to remove from the initial mandatory measure list two of the proposed measures. Commenters did not support inclusion of the MLTSS-1 measure because of potential burden resulting from its requirement for case management and record review. Commenters did not support inclusion of the MLTSS-7 measure 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. Based on the concerns raised, CMS (as noted above) is not finalizing inclusion of either of these measures, but intends to use the subregulatory process finalized in the rule and to continue evaluating both of the measures and other available MLTSS measures for future inclusion.

Also, in response to comments, the agency clarifies that there is a minimum enrollment threshold that must be met before states are required to collect data to calculate the quality ratings for MAC QRS measures from the state's contracted managed care plans. The minimum enrollment threshold established in §438.515(a)(1)(i) requires 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, though this provision does not provide a standard for the public display of CAHPS survey responses. Managed care plans with less enrollment will therefore not be required under these federal rules to provide this data to the state, but state requirements may impose additional data collection requirements.

c. Subregulatory Process to Update Mandatory Measure Set (§§438.510(b) and 457.1240(d))

CMS reiterates its commitment, consistent with §438.334(b)(2), to consult with interested parties in updating the MAC QRS framework. However, CMS believes that formal rulemaking to add new measures would be overly restrictive and would undermine its ability to adapt the mandatory set in a timely manner. CMS therefore finalizes its proposal to use a subregulatory process to consult with states and other interested parties and obtain expert and public input before adding, updating, or removing measures in the mandatory measure set. Specifically, CMS finalizes the following process (other than for removing measures for specific reasons and non-substantive technical updates to existing measures), noting that it is similar to the QHP quality rating system process and aligns with the Core Sets annual update process:

- First, CMS will engage with states and interested parties to evaluate the mandatory measure set (against the 3 proposed standards described above) and make recommendations for additions, removals, and updates.
- Second, CMS will provide public notice and opportunity to comment, such as through a call letter, after which CMS will publish the modifications in the technical resource manual discussed in section I.B.6.i of the rule.

The subregulatory process will begin with the second display year (i.e., 2029 because the rule is finalized in 2024 and 2028 will be the first display year) and will occur at least biennially thereafter.

In response to some confusion raised in comments, CMS is adopting a modification to its proposal to clarify that the agency will be required to engage in the subregulatory process at least biennially, but it is not required to update the mandatory measure set biennially each time after completing such process. This change is in recognition that the process may identify that updates are not needed.

d. Adding Mandatory Measures (§§438.510 and 457.1240(d))

CMS finalizes its proposal to add mandatory measures using the finalized subregulatory process and finalized criteria and standards. To illustrate how CMS intends for the standards to be applied for adding measures to the measure set using the subregulatory process, CMS details its assessment of two measures (the Follow-Up After ED Visit for Mental Illness (FUM) and the Follow-Up After Hospitalization for Mental Illness (FUH)) it considered for inclusion in its proposed mandatory measure set, which resulted in the FUH measure being included (in the proposed and finalized measure set) but not the FUM measure. CMS walks through analysis of the measures against the 6 inclusion criteria, the balanced representation analysis, and the burden assessment discussed above. Table 3 in the rule specifically shows how each of the measures were assessed against each of the 6 inclusion criteria.

e. Removing Existing Mandatory Measures (§§438.510(d) and 457.1240(d))

CMS finalizes its policy to remove existing mandatory measures from the measure set if, after following the newly finalized subregulatory process, it determines that the measure no longer meets the finalized standards discussed. CMS also finalizes its proposal that it may remove mandatory measures outside of the subregulatory process in 3 cases (which align with the MA and Part D quality rating system process): (1) when a measure steward (other than CMS) retires or stops maintaining a measure, (2) if CMS determines that the clinical guidelines associated with the specifications of the measure change such that they no longer align with positive health outcomes, or (3) if it determines that the measure shows low statistical reliability. Measures removed outside of the subregulatory process will be announced in the proposed annual technical resource manual.

f. Updating Mandatory Measure Technical Specifications (§§438.510(e) and 457.1240(d))

A change made by a measure steward to the measure's technical specifications may result in an update to the measure in the MAC QRS. A change to a measure's technical specifications may be a non-substantive change (such as changes to clarify instructions to identify services) or substantive (such as major changes to the measure calculations). CMS finalizes its proposal that, in alignment with practices under the MA and Part D quality rating system and the Core Sets, it will not use the finalized subregulatory process for changes to measures that address non-substantive technical specification changes, and that it will instead update the technical resource manual to revise the descriptions of measures that undergo such non-substantive changes. CMS provides examples of non-substantive updates and provides details on such examples. Briefly, the examples of non-substantive changes include:

- A change that narrows the denominator or population covered by the measure with no other changes;
- A change that does not meaningfully impact the numerator or denominator of the measure;
- Revisions that are made to the clinical codes without changing the target population or the intent of the measure; and
- A change that provides additional clarifications for reporting, without changing the intent of the measure.

CMS will update a mandatory measure that has undergone a substantive specification update only after going through the finalized subregulatory process.

g. Finalization and Display of Mandatory Measures and Updates (§§438.510(f) and 457.1240(d))

CMS finalizes its proposal to use the technical resource manual described in §438.530 to communicate modifications to the mandatory measure set and the timeline that states would be given to implement the modifications. States will have at least 2 years, from the start of the measurement year immediately following the date the technical resource manual finalizes an addition or substantive update to a measure in the mandatory measure set, to display the measurement results and ratings using the modifications. CMS gives the example that if the technical resource manual finalized updates in August 2026 and the next measurement year after August started in January 2027, states would have, at a minimum, until January 2029 before they would be required to display the ratings for the mandatory measure updates in their MAC QRS. CMS will release the technical resource manual annually.

6. MAC QRS Methodology (§§438.334(d), 438.515, 457.1240(d))

CMS is required to develop, after consulting with interested parties and after public notice and comment, a methodology that states must use in their MAC QRS to calculate the plans' quality ratings. Alternatively, a state may use an alternative methodology approved by CMS as part of an alternative MAC QRS.

CMS finalizes, with modification, its proposal to require states, for Medicaid and separate CHIP, to annually collect (and validate) data from contracted managed care plans that meet a minimum enrollment threshold of 500 or more enrollees, as calculated as described by CMS in the technical resource manual (instead of, as proposed, on July 1 of the measurement year), to calculate and issue quality ratings for the plans for each mandatory measure. States will have flexibility to include plans with fewer than 500 enrollees. CMS modifies the proposal to remove the July 1 marker to better align with the QHP quality rating system and the MA and Part D quality rating system, which do not codify a specific data used for determining the overall minimum enrollment threshold. However, the agency notes that it intends to require states (in the technical resource manual) to use plan enrollment at the time of January 1 and July 1 as markers.

CMS also finalizes, with modifications, its proposal requiring states to collect available data from the state's Medicaid FFS program and Medicare, as applicable, if all necessary data cannot be provided by the managed care plans for the measures and to the extent feasible without undue burden on the state. For example, this would be necessary in the case that a measure requires data on services that are split by the state between managed care and FFS delivery systems, or in the case of a measure that uses data with respect to dually eligible individuals. CMS clarifies that a state would not under this policy calculate or assign quality ratings to Medicaid FFS or Medicare plans. The agency finalizes this proposal with a modification to clarify that collecting necessary data and calculating performance rates may be performed by the state, the plan, or an EQRO (that is, not necessarily performed directly by the state, as proposed). However, the plans will not be able to validate the data or perform an external quality review activity. The quality ratings must be issued by the state (not the plan or EQRO). The agency includes another modification to require that the validation of data must not be performed by an entity with a conflict of interest, including managed care plans.

CMS finalizes its proposal in §438.515(a)(3) that states use the validated data to calculate, for each mandatory measure, a performance rate for each managed care plan whose contract includes a service or action being assessed by the measure, as identified by the state. In the case of a state that delivers Medicaid services through different managed care programs, data necessary to calculate the measure performance rate for a measure may be collected from more than one managed care plan. In the final rule, CMS adopts a modification that for data collected from sources outside of Medicaid managed care, these requirements apply *to the extent feasible without undue burden*.

CMS also includes, as a modification in the final rule, a new paragraph (a)(8) in §438.535 to require states to include the following data if data necessary to calculate a measure cannot be provided by the managed care plan (because of the "extent feasible without undue burden" standard that is added): (i) a description of Medicare data and Medicaid FFS data that cannot, without undue burden, be collected, validated, or used to calculate a quality rating for the measure, 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, 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).

Currently, §438.334(d) requires states to issue a single annual quality rating to each managed care plan using the Medicaid managed care quality rating system. CMS finalizes its proposal to revise that to require states to issue for each plan a quality rating (which would be expressed as a measure performance rate) for each mandatory measure for which the plan is accountable.

Testing conducted by CMS suggested that displaying quality ratings at both the individual measure and domain levels (such as domains for behavioral health, chronic conditions, infant and children, and preventive care) would be most desirable to beneficiaries, balancing those who prefer big picture information with those who prefer detailed information, but CMS did not significantly test domain level quality ratings and therefore proposed additional consultation with interested parties before consideration of future potential proposals requiring domain level

ratings. CMS finalizes that states must ensure that the quality ratings include data for all beneficiaries (including dually eligible beneficiaries) covered under a managed care plan for a service for which data are required to calculate the rating. In the technical resource manual, CMS intends to provide guidance on which beneficiaries must be included in data informing the quality ratings for each MAC QRS mandatory measure.

CMS clarifies in the final rule that states must include data on dually eligible enrollees in quality ratings for a Medicaid managed care plan when the state determines that the service or action assessed by the MAC QRS measure is covered by the plan's contract with the state. That means a state is not required to include dually eligible individuals in quality ratings for a MAC QRS measure if the service or action assessed by the measure is provided to the individual through Medicare (and not the plan for which the rating is being calculated). In determining if the service or action is covered by the plan's contract, CMS recommends the state consider if the service or action is performed by the plan and whether the plan should be held accountable for the service or action assessed by the measure. A state has the flexibility to choose to issue quality ratings for MAC QRS measures, even in cases in which the state is not required to do so.

In addition, states will be required to calculate quality ratings at the plan level by program. That is, in the case of states that cover Medicaid services through multiple managed care programs (i.e., programs that differ by the population served and the benefits covered), a managed care plan that participates in more than one such program will receive separate quality ratings under each program. These separate quality ratings will be calculated from data for only those beneficiaries enrolled in the managed care plan under the given program.

In response to concerns raised by commenters that states would be required to collect and validate data for measures that assess services not covered through the state's managed care programs, CMS makes modifications in the final rule 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. States will be required to include those mandatory measures that assesses performance of their managed care plans and report that plan level performance by managed care program. States will have to report under the requirement finalized at §438.535(a)(1) a list of any mandatory measures identified as not applicable along with an explanation of why.

Selected Comments/Responses. Several commenters supported, and several other commenters opposed, the use of Medicaid FFS and Medicare data, in addition to Medicaid managed care data, as needed to calculate mandatory measures if such data can be used without undue burden. Those in opposition raised concerns about the availability of data outside of Medicaid. The agency recognizes the concerns raised, but believes the MAC QRS data and quality ratings should, if possible, be inclusive of all managed care beneficiaries, which means inclusion of data outside of Medicaid. CMS also believes that since data collection from non-Medicaid managed care sources is required to the extent that such collection of data does not result in undue burden (i.e., includes a "without undue burden" standard), that this allows for a gradual implementation

of contract and systems changes needed to collect the data from such additional sources, including if that means a timeline that extends past the implementation date finalized.

In response to comments raising concern about challenges in using non-Medicaid managed care data to validate collected data and use the validated data to calculate and issue quality ratings, CMS finalizes clarifications that for Medicare data and Medicaid FFS data the requirements in §438.515(a)(1)(ii), (a)(2), and (a)(3) (relating to the collection of data from sources outside Medicaid MCOs, validation of such data, and calculation of ratings using such data) apply to the state in its administration of its MAC QRS only "to the extent feasible without undue burden."

Many questions and concerns were raised with respect to the inclusion of data on dually eligible individuals for performance ratings. The agency responds with clarifications and modifications discussed above, including regarding the "undue burden" standard. The agency also references the opportunity for states to request a one-time, one-year extension to the requirement in §438.515(b) (as described in the summary above), which could (if approved by CMS) apply to the requirement that all data for applicable enrollees, including dually eligible individuals, be included in each plan's quality rating. CMS is finalizing a deadline of September 1 of the fourth year following the effective date of the final rule for submission to CMS of requests for a one-year extension. This would provide enough time for the agency to review and approve the requests before December 31, 2028 (the MAC QRS implementation deadline).

7. MAC QRS Website Display (§§438.334(e), 438.520, 457.1240(d))

CMS finalizes, with modifications, its policy at §438.520 that states must 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 allow users to tailor specific information (such as by formulary, provider directory,[59] and quality ratings) based on their entered data; (3) standardized information so that users can compare managed care programs and plans; (4) information that promotes beneficiary understanding of and trust in the displayed quality ratings; and (5) access to Medicaid and CHIP enrollment and eligibility information, either directly on the website or through external resources.

In the final rule, CMS includes clarifying language that the required website display information must be immediately and easily available to the public; therefore, states are not permitted to require log-in credentials for accessing the information. States may have such a requirement for accessing more tailored and detailed information than the level of information required in the rule as long as it is possible for a member of the public who is not enrolled in the managed care program to view the required website display information. If users are requested to input user-specific information, the state must provide an explanation of why the information is requested,

[59] As discussed in the selected comments and responses below, CMS modifies the requirement for a user to be able to search available managed care plans that provide coverage for a drug identified by the user and plans that include within their networks a provider identified by the user, so that such search tools would only be required for managed care programs with more than one plan.

how it will be used, and whether it is optional or required to access a QRS feature or type of information.

The proposed website display requirements will be implemented in two phases:[60]

- The first phase will be implemented by the end of the 4th year following release of the final rule. This phase satisfies the one-stop-shop goal for accessing information needed in decision-making, but would not include interactive tools. States must develop the website, display quality ratings, and ensure that users can access information on plan providers, drug coverage, and view quality ratings stratified by sex, race, ethnicity, and dual eligibility status.
- In the second phase, states will be required to modify the website to provide an interactive user experience, allowing for the user to tailor the display to their needs and search for plans without leaving the MAC QRS website.

Selected Comments/Responses. Almost all commenters supported the agency's inclusion of a website display with the clearly defined components identified by CMS. But some of them also expressed concern about the resources that would be required to develop the website with each of the stated components. Some requested an exemption from the requirements for states with a small number of managed care plans. CMS replies that enhanced FFP (as part of FFS available for the state's Medicaid Enterprise System (MES)) may be available for the state's MAC QRS website, and the data infrastructure that supports it, when necessary to comply with the new MAC QRS website requirements, and encourages states to seek information from their MES State Officer for assistance on which operational elements of the MAC QRS implementation may be eligible. CMS also intends to provide technical assistance for the design and implementation of the website and to issue a design manual with additional guidance.

In response to commenters' request for exemptions for states with small numbers of managed care plans, CMS responds that it believes each requirement is important to achieve its goals for the MAC QRS, regardless of number of managed care plans of a state. However, it acknowledges that the specific requirement for the website display to include 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 would only be useful for managed care programs with at least two plans offering different drug formularies and provider networks. Therefore, the agency finalizes the requirement with modifications to require these specific search tools for only managed programs with more than one plan.

Some commenters suggested additional required features for the website. CMS declines including additional requirements, but clarifies that states are able to include websites features in addition to those being required in the rule.

[60] CMS refers to two sample MAC QRS prototypes: a simple website (Prototype A) that represents the information to be required for phase 1 and another MAC QRS prototype (Prototype B) that represents an interactive website for phase 2, both of which can be found at https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/qualityrating-system/index.html. In addition, CMS states its intent to release a MAC QRS design guide following the final rule.

In response to comments raising concern about complying with the website display requirements by the implementation deadlines, CMS finalizes (as discussed in the summary above) at §438.520(a)(2)(v) and (a)(6) that states may submit a request for a one-time, one-year extension for certain MAC QRS requirements. Certain features of the website display requirements are among the requirements for which a state may apply for such an extension. Specifically, states will be able to request such extension for: (1) the requirements at §438.520(a)(2)(v), which require the display of quality ratings for each managed care plan for mandatory measures stratified by dual eligibility status, race and ethnicity, and sex, and (2) the requirements at §438.520(a)(6), which require states (i) to include interactive search tools that enable users to identify available managed care plans that provide coverage for a drug identified or include within their network a provider identified by the user and (ii) to stratify quality ratings by certain additional factors identified by CMS. The deadlines for submissions for an extension request are relative to whether the respective requirements are within phase 1 or phase 2 of implementation. Requests for extensions for requirements specified in §438.520(a)(2)(v) must be submitted by September 1, 2028. Requests for extensions for requirements specified in §438.520(a)(6) must be submitted no later than four months before the implementation date specified by the Secretary for those requirements.

a. Navigational and Orienting Information (§§438.334(e), 438.520(a)(1) and (5), 457.1240(d))

Through testing, CMS found that if initial upfront clear background information was provided describing the purpose of the MAC QRS and how beneficiary information would be used, users positively responded to and became more comfortable using features of the website.

CMS finalizes its proposal to require that states provide users with information necessary to understand and navigate the MAC QRS display, including by providing users with information on the MAC QRS purpose, relevant information on dual eligibility and enrollment through Medicare, Medicaid and CHIP, an overview of how the website can be used to select a managed care plan, how information provided would be used, information or hyperlinks that direct users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan, and (only with respect to Medicaid and not for separate CHIP) information on how to access the beneficiary support system required under existing §438.71 to answer questions related to the MAC QRS.

b. Tailoring of MAC QRS Display Content (§§438.334(e), 438.520(a)(2) and (a)(6), and 457.1240(d))

CMS finalizes its proposal to require states to display provider directory and drug coverage information for each managed care plan, with a modification that these requirements apply to managed care plans that participate in managed care programs with at least two participating plans.[61] In phase 1, this requirement could be satisfied by providing hyperlinks. For phase 2,

[61] This information is already required to be available from managed care plans under §438.10(h)(1) and (2) and §438.10(i).

states will be given at least two additional years after a state's initial implementation of their MAC QRS to display provider directory and drug coverage information for managed care plans through an integrated, interactive search feature that allows users to identify plans that cover certain providers and prescriptions.[62]

CMS also finalizes its proposal to require each state's website to allow users to view available plans for which the user may be eligible based on the user's age, geographic location, and dual eligibility status, as well as other demographic data that will be identified by CMS in future guidance. Phase 1 will require states to display the ratings that reflect the quality of care furnished to all of a plan's enrollees, as well as quality ratings stratified by dual eligibility status, race and ethnicity, and sex. States must display this information by the general MAC QRS implementation date (the 4th year following release of the final rule). Phase 2 requires accessing the information through an interactive tool, which will allow beneficiaries to view and filter quality ratings based on the stratification factors required in phase one and which will be available no earlier than two years after the general MAC QRS implementation date. As mentioned above, as finalized, a state may apply for a one-time, one-year extension of requirements at §438.520(a)(2)(v) and §438.520(a)(6).

c. Plan Comparison Information (§§438.334(e), 438.520(a)(3), and 457.1240(d))

CMS finalizes its proposal to require states to display, for each managed care plan, standardized information identified by CMS that allows users to compare available managed care plans and programs, including (i) the name, website, and customer service telephone hot line of each managed care plan; (ii) premium and cost sharing information; (iii) a summary of covered benefits; (iv) certain metrics of managed care plan access and performance that states must make available under subparts B and D of part 438 of title 42, CFR, including certain data most recently reported to CMS on each managed care program under §438.66(e) (Medicaid only) and the results of secret shopper surveys at §438.68(f), described in section I.B.1.c. of the rule; and (v) whether the managed care plan offers an integrated Medicare-Medicaid plan or highly or fully integrated MA D-SNP, and if it does (under both phase 1 and phase 2) a link to the plan's rating under the MA and Part D quality rating system.

In response to commenters' suggestions, CMS adds to its policy explicit authority for the agency to require states to include on the MAC QRS website, in addition to a comparative summary of benefits available from the managed care plans, other information on benefits such as whether access to the benefit requires prior authorization.

[62] CMS believes burden on managed care plans would be minimized since under §431.60(a) of the May 2020 CMS Interoperability and Patient Access final rule, states are already required to implement an application programming interface (API) that permits third party retrieval of certain data specified by CMS, and these requirements are applied in Medicaid managed care to MCOs, PIHP, and PAHPs under §438.242(b)(5) and (6).

d. Information on Quality Ratings (§§438.334(e), 438.520(a)(4) and (c), and 457.1240(d))

CMS finalizes its proposal (without modification) that states provide plain language descriptions (i.e., a simple explanation) of the importance and impact of each quality measure.[63] In addition, states will be required to indicate the measurement period for which data were produced to calculate the displayed quality ratings, and when, how, and by whom quality ratings were validated.

CMS will periodically consult with interested parties, including MAC QRS users, to maintain and update the website display requirements for the information to be required.

e. Display of Additional Measures Not on the Mandatory Measure Set (§§438.334(e), 438.520(c), and 457.1240(d))

CMS finalizes its proposal that states may display measures beyond those included in the mandatory measure set if each of the following standards are met:

- The state obtains input from prospective MAC QRS users, including beneficiaries and caregivers (and, if the state enrolls American Indians/Alaska Natives in managed care, the state consults with Tribes and Tribal Organizations in accordance with the state's Tribal consultation policy); and
- The state documents the input received from prospective MAC QRS users on the additional measures, modifications made to the proposed additional measures in response to input, and the rationale for not accepting input, and such documentation is reported as part of the proposed MAC QRS annual report.

8. Alternative Quality Rating System (§§438.334(c), 438.525, and 457.1240(d))

Currently, states may, with CMS approval, implement an alternative QRS that uses different quality measures or applies a different methodology than the CMS-developed MAC QRS framework if certain conditions are met, including that the measure or methodology be substantially comparable to those under the framework.

CMS finalizes its proposal to allow states to add measures that are not mandatory measures without prior approval from CMS. The agency clarifies in the final rule that this does not permit states to substitute mandatory measures with different measures. Ratings for the mandatory measures must be published when the mandatory measures are applicable to the state's managed care program. How the ratings are calculated under the state's MAC QRS may be changed using an alternative methodology, subject to CMS approval. The state will not be required to consult

[63] CMS includes example explanations for each of the mandatory measures it had proposed in the two sample MAC QRS prototypes (Prototype A and B), which can be found at https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care-quality/qualityrating-system/index.html. CMS intends 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 rule, which states may choose to use.

with the Medicaid Advisory Committee or engage in a public notice process before seeking approval from CMS of the state's alternative QRS methodology.

CMS finalizes, with modifications, its policy to further define the criteria and process for determining if an alternative methodology is substantially comparable to the MAC QRS methodology. The agency finalizes its proposal requiring states to submit documents and evidence that demonstrate compliance with the substantial comparability standards, as part of their request to implement an alternative QRS, and permitting states to submit supporting documentation in addition to that which is required.

Some commenters raised confusion about the scope of flexibility provided to states when establishing an alternative QRS, including believing this policy enabled states to substitute measures for mandatory measures, which is not the case. In response to this confusion about the scope of the authority for an alternative rating methodology, CMS reorganizes the regulation it had proposed for clarification and includes the policy in §438.515 where the CMS methodology is codified (but finalizes the substance of the policy proposed). To further address confusion, the agency also finalizes a new provision at §438.515(c)(3) to clarify that CMS will not review or approve requests to implement a MAC QRS that does not comply with requirements to include mandatory measures, the general requirements for calculating quality ratings established in §438.515(a)(1) through (4), or the requirements to include the website features identified in §438.520(a)(1) through (6).

9. Annual Technical Resource Manual (§§438.334, 438.530, and 457.1240(d))

CMS finalizes, with modifications, its policy that it will develop a Medicaid managed care quality rating system technical resource manual that will be updated. The manual will include the mandatory measure set, the measure steward technical specifications for measures in the set, and information on applying the proposed methodology requirements to the calculation of quality ratings for mandatory measures; specific MAC QRS measures added or removed from the prior year's set; a summary of public comment received; a timeline for implementation; the rationale for recommendations/feedback; and the subset of mandatory measures that must be stratified.

CMS had proposed releasing each updated technical resource manual at least 5 months before the measurement period for which the manual would apply. However, several commenters requested releases 9 to 12 months before the measurement period. Though CMS responded it would not be feasible to maintain such schedule and include the necessary information, it believes that the agency can get the identified information to states sooner than proposed by releasing the information in installments as available throughout the year (as opposed to releasing all information in one document, as proposed). Therefore, CMS finalizes that the agency may publish the technical resource manual information in installments throughout the year.

Also, to ensure that the technical specifications for initial measurement year in 2026 align with the measure steward technical specifications for the same year, CMS notes that it will not be able to release the technical specification earlier than 2027 and therefore modifies its proposed initial

release date for the resource manual. By no later than August, 1, 2025, as proposed, CMS will publish the information on (i) the initial mandatory measure set, (ii) any measures removed from the set before August 2025, and (iii) the subset of initial mandatory measure that must be stratified and by which stratification factors. However, the initial release date for the first annual technical resource manual with other information required in this section will now be no later than 2027, as opposed to the proposed August 1, 2025 initial release date.

10. Reporting (§§438.334, 438.535, and 457.1240(d))

CMS finalizes, with modifications, its proposal that requires states to submit to CMS, upon request (but not more frequently than annually, and with at least 90 days' notice), information on their MAC QRS to support oversight of compliance with the MAC QRS requirements. The report will include (as proposed): (i) a list of all measures included in the MAC QRS, (ii) an attestation that the displayed quality ratings for mandatory measures were calculated and issued in compliance with §438.515, (iii) a description of the methodology used to calculate any additional measures when it deviates from the CMS framework methodology and a description of any additional quality measures, (iv) the date on which the state publishes or updates the quality ratings, (v) a link to the state's MAC QRS website, (vi) any technical specification adjustments to the mandatory measures, and (vii) if applicable, a summary of any alternative QRS approved by CMS.

Also, in the final rule, the agency includes the additional reporting requirements discussed in section I.B.6.f of the final rule (relating to Medicare and Medicaid data not included in the MAC QRS quality ratings) and adds the following required content to the report: (i) identification of mandatory measures that are not included in a state's MAC QRS because they are not applicable to the state's Medicaid managed care program; (ii) 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 (iii) for any measure identified as applicable to the state's managed care program, the managed care programs to which the measure is applicable.

11. Technical Changes (§§438.334, 438 Subpart G, 438.358, and 457.1240(d))

CMS describes several technical changes to conform the regulations with other parts of the rule, which would also apply for separate CHIP.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), CMS is required to provide 60-day notice in the Federal Register and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The final rule shows the CMS estimates of its information collection requirements (ICRs) from this rule.

The annual burden estimates for all of the proposed provisions are shown separately for Medicaid and CHIP in Table 5 and Table 6, respectively. To estimate the burden for the

Medicaid requirements (part 438), CMS utilized state submitted data for enrollment in managed care plans for CY 2021:

- 67,655,060 enrollees in MCOs,
- 36,285,592 enrollees in PIHPs or PAHPs, and
- 5,326,968 enrollees in PCCMs.

This totals 77,211,654 Medicaid managed care enrollees, reflecting 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.

To estimate the burden for the CHIP requirements (part 457), CMS utilized state submitted data for enrollment in managed care plans for CY 2017:

- 4,580,786 Medicaid expansion CHIP managed care enrollees, and
- 2,593,827 separate CHIP managed care enrollees.

These data also showed that 32 states used managed care entities for CHIP, contracting with 199 MCOs, PIHPs and PAHPs, as well as 17 PCCMs.

The burden estimates apply to states and private-sector entities (plans). For Medicaid, CMS estimates the total burden—that is, the annual costs plus the one-time costs—to be $136,346,234, based on 1,529,955 hours. The vast majority of the burden is for annual costs. The annualized one-time burdens are estimated at $7,130,225.

For CHIP, CMS estimates the total burden—that is, the annual costs plus the one-time costs—to be $32,600,895, based on 350,401 hours. The annualized one-time burdens are estimated at $3,767,861.

For Medicaid and CHIP combined (Table 7), CMS estimates the total burden—that is, the annual costs plus the one-time costs—to be $168,947,129, based on 1,880,356 hours. The annualized one-time burdens are estimated at $10,898,086.

IV. Regulatory Impact Analysis

The federal government has a number of standards and sources defining a significant regulatory action. This rule has an annual effect on the economy of $200 million or more in any 1 year and thus qualifies as a significant regulatory action, which requires the federal government to produce a Regulatory Impact Analysis, summarized here. CMS focuses on the provisions with the potential for a significant economic impact, particularly SDPs, MLR reporting standards, and ILOS due to the impact these provisions could have on managed care payments.

SDPs. CMS calculates that SDP payments in 2023 were $78.1 billion, comprising approximately 15.6 percent of total Medicaid managed care payments in 2023 and 9.0 percent of total Medicaid benefit expenditures. Of the 39 states reporting the use of one or more SDPs in 2022, the highest percentage of Medicaid managed care spending paid through SDPs was 58 percent.

CMS describes how SDPs were a significant factor in Medicaid expenditure growth from 2016 through 2022. CMS cannot estimate how much of the SDP growth was attributable to states transitioning pass-through payments to SDPs or transferring spending from FFS payments (for example, supplemental payments) to SDPs. However, based on its experience working with states, the agency believes that while much of the earlier SDP spending was largely existing Medicaid spending transitioned to managed care SDPs, most SDP spending in recent years reflects new expenditures. CMS' current-policy projections show even more growth, with the share of managed care payments through SDPs increasing to 16.5 percent by 2029, or $99 billion.

The provision that is 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, NF services, and qualified practitioner services at AMCs. CMS' high spending scenario shows total SDP spending reaching about 22.8 percent of managed care spending in 2027, and then decreasing to 21.5 percent in 2028 as the financing provisions go into effect.[64] This assumes many states increase their SDPs up to the ACR limit, mostly for hospitals and AMCs. Of that $35.8 billion increase in 2028, CMS projects the federal government would pay $23.0 billion and the non-federal share would be $12.8 billion (Table 10 of the rule).[65]

The other SDP proposals with cost implications are expected to have relatively small impacts going in both directions.

MLR. One part of this rule's MLR policies would permit to be included as "incurred claims" only those provider incentives and bonuses that are tied to clearly defined, objectively measurable, and well-documented clinical or quality improvement standards. In states that require plans to pay remittances back 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. Based on various assumptions and using MLR data from 2018, CMS estimates that the policy clarification would increase remittances paid by managed care plans to states by approximately $12 million per year (total computable).

Such remittances to states might also increase due to the policy that only expenditures directly related to activities that improve health care quality may be included in QIA expenses for MLR reporting. Based on a variety of assumptions and the Medicaid MLR data for 2018, CMS projects that this policy change would increase remittances paid by managed care plans to states by approximately $49.8 million per year.

CMS is not able to estimate the effects of other MLR proposed policies.

[64] In the proposed rule, CMS' low-end estimate of the changes was zero—that is, future growth in SDPs would proceed as projected under current policy. Since some states already indicated to CMS that they would increase SDPs with the clarification that CMS would allow effective payment rates up to ACR, the agency believes it is more accurate to estimate for the low case that there are some increases in spending—for example, an $8.0 billion increase in 2028 above the current law estimate (Table 9 of the rule).
[65] The amount actually paid directly by states may depend on their use of IGTs and provider taxes.

ILOS. Similar to SDPs, ILOS spending projections due to the final rule range from zero to a high scenario estimated by CMS. The high scenario is based on assumptions that (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. Under its high scenario, ILOS spending in 2028 is projected to increase by $3.0 billion, of which $1.9 billion would be federal (Table 12 of the rule).

Accounting statement. Table 13 of the final rule shows the amount of transfers for the 2024-2028 period, using 2024 dollars discounted at 3 percent and 7 percent. Using the 3 percent discount rate, CMS shows the following transfers and the "primary estimate" for each:

- $9.9 billion from the federal government to providers
- $5.4 billion from states to providers
- $0.5 billion from the federal government to beneficiaries
- $0.3 billion from states to beneficiaries
- $0.02 billion from managed care plans to the federal government
- $0.01 billion from managed care plans to states