CMS Finalizes Medicaid Managed Care Rule

On April 22nd, CMS released the *Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality* Final Rule. The rule makes broad reforms to the Medicaid Managed Care landscape, with significant changes to quality standards and reporting, financial requirements, and program integrity / oversight.

NOTE: Page numbers refer to the pdf page numbers in the unofficial published inspection document made available on the federal register prior to the official publication of the rule.

Contents

1. Access (42 CFR 438.2, 438.10, 438.66, 438.68, 438.206, 438.207, 438.214, 438.602, 457.1207, 457.1218, 457.1230, 457.1250, and 457.1285)

Enrollee Experience Surveys (§§ 438.66(b), 438.66(c), 457.1230(b) and 457.1207) (pg. 15)

Finalized Changes
CMS finalized changes to enrollee experience surveys largely as proposed. Specifically, CMS finalized an exemption for Medicaid managed care plans in which all enrollees are enrolled in a Medicare Advantage dual eligible special needs plan (D-SNP) subject to the condition in § 422.107(e)(1)(i). This exemption allows states to utilize existing annual experience surveys, such as CAHPS surveys for enrollees in D-SNPs, reducing the risk of survey fatigue. Additionally, CMS encouraged states to consider including provider surveys and additional survey topics suggested by commenters to enhance monitoring and oversight efforts.

CMS finalized an implementation date of 2 years after the effective date of the final rule for the proposals at §§ 457.1230(b) and 457.1207. They also finalized §§ 438.66(b), (c), and (f) as proposed, with an exception of an implementation date of 2 years after the effective date of the final rule for the proposals at §§ 457.1230(b) and 457.1207. Additionally, they finalized § 438.66(c)(5) to permit States to use a CAHPS survey as required for Medicare Advantage D-SNPs.

Background/Rationale
Commenters noted widespread support for CMS's proposal to implement annual enrollee experience surveys, recognizing enrollees as valuable sources of feedback for improving care quality. Many expressed agreements with the requirement for written survey materials to adhere to accessibility standards, facilitating broader participation. Additionally, commenters favored the inclusion of survey results in the Medicaid managed care program annual report (MCPAR) and timely posting on state websites. Some commenters, however, expressed concerns about potential survey fatigue among enrollees and suggested flexibility in survey frequency and alignment with other existing surveys. Others recommended specific survey enhancements, such as targeting marginalized populations, shortening survey length, and offering multiple distribution methods. CMS responded by acknowledging these concerns and finalized an exemption for Medicaid managed care plans with all enrollees in Medicare Advantage dual eligible special needs plans, reducing survey burden. They also encouraged states to consider provider surveys and additional survey topics suggested by commenters to enhance monitoring and oversight efforts.

Commenters presented diverse perspectives on CMS's proposal regarding enrollee experience surveys. Some advocated for a specific survey instrument like CAHPS®, while others favored granting states flexibility to choose surveys tailored to their programs. Concerns were raised about potential survey fatigue, low response rates to standardized surveys like CAHPS, and the need for surveys to capture program-specific nuances. Suggestions included defining characteristics of acceptable surveys, aligning survey expectations with existing measures like National Core Indicators (NCI), and providing technical guidance on survey methodology. CMS emphasized the importance of capturing program-specific information and chose not to mandate a specific survey instrument, aiming to balance standardization with flexibility. They acknowledged concerns about survey fatigue and administrative burden, finalizing exemptions for certain Medicaid managed care plans. Additionally, CMS agreed to

extend the implementation timeline for posting CHIP CAHPS survey results, recognizing the need for sufficient preparation time and technical assistance.

Appointment wait time standards (§§ 438.68(e) and 457.128) (pg. 28)

Finalized Changes
CMS finalized revisions to § 438.68(b)(1) and (2), replacing the requirement for States to set time and distance standards with a more flexible requirement for quantitative network adequacy standards for specified provider types. This change encourages States to utilize various quantitative measures in combination to ensure access to services for enrollees. Additionally, CMS proposed a new quantitative network adequacy standard, including setting appointment wait time standards for specific services and provider types. The proposed maximum appointment wait times for routine outpatient mental health and substance use disorder appointments, primary care, and OB/GYN appointments were informed by standards for individual health insurance coverage and feedback from interested parties.

Outpatient Mental Health and SUD, adult and pediatric	within State-established timeframes but no longer than 10 business days from the date of request
primary care, adult and pediatric	longer than 15 business days from the date of request
obstetrics and gynecological	within State-established timeframes but no longer than 15 business days from the date of request
State-selected	chosen in an evidence-based manner within State-established timeframes

CMS acknowledged concerns regarding consistency in implementing appointment wait time standards and interpreting results. While declining to adopt a universal definition of "routine," CMS encouraged States to work with managed care plans to develop consistent definitions. CMS also declined to define "urgent" and "emergent," emphasizing that the standards focus on less time-sensitive appointments initially. However, CMS agreed to review data from secret shopper surveys to inform potential future rulemaking. CMS supported the suggestion to include incentives for providers meeting wait time standards but stressed the importance of remedy plans for addressing access concerns. Regarding hold harmless provisions in provider contracts, CMS deferred to States and managed care plans. CMS agreed to use "services" instead of "provider types" for clarity in the standards, allowing for variations in wait time standards as long as they adhere to maximum timeframes. States were encouraged to consider additional standards for specific services or providers, provided they do not exceed established limits.

CMS declined to use "calendar days" instead of "business days" for appointment wait time standards, stating that business days are appropriate for routine appointments and align with other standards, though it noted future considerations for HCBS. Regarding exceptions for rural areas or HPSAs, CMS emphasized the importance of implementing standards while acknowledging challenges and existing exception processes. CMS addressed concerns about appointment wait time standards' efficacy, stressing their positive impact when coordinated efforts are made. It also highlighted opportunities for managed care plans to ease provider burden and the flexibility for States to customize standards. The

applicability date for appointment wait time standards was finalized to balance enrollee needs with implementation efforts. CMS clarified provisions regarding behavioral health PIHPs and PAHPs and emphasized States' autonomy in setting higher standards.

Background/Rationale
Many commenters supported the proposals related to appointment wait time standards but suggested that 10- and 15-business days may not be appropriate standards. Some recommended longer timeframes, such as 30 business days, citing alignment with Medicare Advantage or the need for data verification. Commenters emphasized the importance of feasibility and meaningfulness in setting standards and suggested collecting data to establish baselines. In response, CMS acknowledged the comments and explained its rationale for proposing the 10- and 15-business day standards, considering the significance of outpatient mental health, substance use disorder, primary care, and OB/GYN appointments in preventing the need for urgent or emergent care. CMS also emphasized the potential benefits of aligning with standards from Federally Facilitated Marketplaces (FFMs) and agreed on the importance of monitoring data over time to assess the effectiveness of the standards.

Some commenters recommended that CMS define “routine” for appointment wait time standards for consistency in implementation and results, while others supported letting States define it to reflect their local markets. There were also suggestions to define “urgent” and “emergent” appointments and include them in the standards. Additionally, commenters recommended refining the standards by specifying existing patient appointments separately from new patient appointments. One commenter questioned how the standards apply to Dual Eligible Special Needs Plans (D-SNPs) and their intersection with existing Medicare requirements.

Some commenters suggested using “calendar days” for ease of application, while others recommended exceptions for rural areas or HPSAs due to provider shortages. Concerns were raised about the burden of appointment wait time standards and their impact on access, particularly in rural areas, HPSAs, and for mental health and SUD services. Commenters advocated for regional autonomy in setting standards and partnerships to address provider shortages. Suggestions were made for revising compliance dates and strengthening requirements for pediatric specialists in CHIP managed care plans. One commenter questioned CMS's authority to set national standards, while others supported including appointment wait time standards in MCO, PIHP, and PAHP contracts.

Secret shopper surveys (§§ 438.68(f), 457.1207 and 457.1218 (pg. 51)

Finalized Changes
CMS finalized the requirement for States to use secret shopper surveys to validate compliance with appointment wait time standards and verify the accuracy of provider directory data. States must use an independent entity apart from the state Medicaid agency to administer the surveys. CMS declined to modify the definition of "independence." Additionally, CMS clarified that network adequacy standards do not apply to services primarily covered by Medicare for dually eligible individuals.

CMS confirmed that secret shopper surveys required at § 438.68(f) are to collect information within the scope and intent of the final rule, specifically focusing on the performance of MCOs, PIHPs, and PAHPs in meeting wait time standards. They clarified that appointment wait time standards do not necessarily require appointments to be offered by a specific provider listed in the directory, as long as a routine appointment within established timeframes is offered by any provider in the practice. Additionally, CMS

finalized the timeframes for transmitting directory data errors identified in secret shopper surveys to States and managed care plans, specifying that the 3-business day timeframes are for data transmission, not correction of erroneous data. Furthermore, CMS rejected the suggestion to delay the implementation of secret shopper surveys pending further decisions on the development of a National Directory of Healthcare Providers and Services, emphasizing the importance of addressing inaccurate directory data promptly. Finally, CMS declined to adopt additional requirements for disaggregating appointment wait time data by key social, demographic, and geographic variables, leaving such considerations to the discretion of individual states.

Background/Rationale
Many commenters expressed support for using secret shopper surveys, believing they would provide valuable information and promote improvements in network accuracy and specificity. Some commenters advocated for the use of independent entities to conduct these surveys, emphasizing the need for impartiality and reliability. Suggestions were made to include "any direct or indirect relationship" in the definition of "independence," but CMS declined to adopt this suggestion, citing differences between secret shopper surveys and enrollment broker functions. Some commenters recommended revealed shopper surveys or standardized definitions and methodologies, but CMS declined, stating that secret shopper surveys capture unbiased information. Commenters also provided feedback on the compliance threshold, with varying opinions on the feasibility of a 90 percent compliance rate and suggestions for lower initial rates. Additional recommendations included revisions to include more services in the surveys or allow State-derived studies instead of specifying provider types. Some commenters raised concerns about the frequency of surveys and the impact of seasonality, suggesting adjustments to address these issues.

One commenter urged CMS to clarify that the surveys should only collect information related to the rule's scope and not extend to reproductive health care services. Another group of commenters sought clarification on whether appointments needed to be offered by specific providers or any provider within the practice. CMS clarified that appointments by any provider in the practice would suffice, emphasizing the goal of assessing access to care. Additionally, commenters raised concerns about the timeframe for correcting directory data errors and the burden of secret shopper surveys on states and providers. CMS defended the need for secret shopper surveys, citing ongoing issues with network adequacy and access. There were also suggestions for improving survey methodologies and reporting of survey results. Despite some opposition, CMS decided to proceed with the implementation of secret shopper surveys as proposed.

Assurances of adequate capacity and services – Provider payment analysis (§§ 438.207(b) and 457.1230(b)) (pg. 75)

Finalized Changes
CMS finalized changes to § 438.207(b)(3) regarding managed care plan payment analysis as proposed. CMS will require MCOs to submit annual documentation to the state that demonstrates a payment analysis showing their level of payment for certain services. It would rely on paid claims data from the immediate prior rating period.

CMS agreed with commenters that transparency on provider payment rates is crucial and acknowledged an oversight in the proposed regulation text. To address this, CMS finalized adjustments to ensure the payment analysis includes the total amount paid for specific services and the percentage

in relation to published Medicare payment rates. These changes aim to provide greater insight into how Medicaid provider payment levels impact access to care.

CMS finalized several provisions based on public comments. They approved Sections 438.207(b)(3) and (g), and 457.1230(b) as initially proposed. Additionally, a minor wording correction was made in § 438.207(b)(3)(i). Notably, CMS incorporated habilitation services into § 438.207(b)(3)(ii) following feedback. This adjustment reflects the inclusion of habilitation services in the payment analysis alongside other specified services.

Background/Rationale
Commenters raised concerns regarding the proposal, suggesting that States should have more flexibility in evaluating relevant factors for access and determining useful comparative data. Some were worried about the potential misleading nature of the analysis and its impact on provider participation in Medicaid programs. In response, CMS emphasized the importance of consistency in analyses and disagreed with concerns about misleading information, stating that the scope of required results is limited. They also assured that providers would be able to interpret the data appropriately, and technical assistance would be available if needed.

Comments were made regarding the requirement for States to publicly disclose provider payment analyses, suggesting annual instead of triennial reporting to alleviate burden. The response clarified existing documentation posting requirements and emphasized the need for annual analyses due to contract cycles, acknowledging a discrepancy in the proposed rule. Concerns were raised about the burden on Medicaid agencies for conducting payment analyses and the necessity of actuarial services, which the response addressed by clarifying that such analyses are the responsibility of managed care plans. Suggestions to reconsider timelines for reporting provider rates and to use Medicaid Fee-For-Service (FFS) rates instead of Medicare rates were dismissed by CMS. Comments supported including habilitation services in the payment analysis, which CMS agreed with, making revisions accordingly. Other comments addressed the lack of Medicaid FFS rates in some cases, suggesting alternatives like average unit cost reporting, with CMS clarifying guidelines for conducting payment analyses and reporting data by managed care plans. Concerns about the scope of services included in payment analyses and the statutory basis for the requirement were raised, with CMS defending the statutory basis and outlining how the analyses contribute to quality assessment. Overall, the proposed rules were finalized with minor adjustments.

Assurances of adequate capacity and services reporting (§§ 438.207(d) and 457.1230(b)) (pg. 97)

Finalized Changes
CMS finalized the proposal to have States incorporate their review and analysis of managed care plan provider payment analyses required in § 438.207(b)(3) (secret shopper survey) into their assurance and analysis reporting, citing it as the least burdensome approach and ensuring transparency across all managed care programs. Additionally, CMS acknowledged support for specifying the timing of submission of the NAAAR in § 438.207(d)(3) to improve consistency among States. However, a commenter highlighted potential duplicity in submitting the NAAAR for new managed care plans simultaneously with readiness review information and suggested giving States more time for submission. In response, CMS agreed to revise § 438.207(d)(3)(i) to require the submission of the NAAAR in advance of contract approval, allowing managed care plans to address deficiencies identified in

readiness reviews and enabling States to report current network adequacy and access information, ultimately benefiting newly contracted plans, States, and CMS.

Background/Rationale
Commenters raised suggestions for additional requirements, such as having States submit their NAAAR reports to interested parties' advisory groups, which CMS declined to adopt but encouraged States to consider. Another commenter supported the specificity on the timing of NAAAR submission but noted potential duplicity in simultaneous submission with readiness review information for new managed care plans. CMS acknowledged this concern and revised § 438.207(d)(3)(i) to require NAAAR submission before contract approval, aiming to provide managed care plans and States with adequate time for adjustments and ensuring the most current information for contract approval decisions. Overall, while CMS finalized most proposals as initially suggested, adjustments were made based on commenter feedback to improve efficiency and effectiveness.

Remedy plans to improve access (§438.207(f)) (pg. 102)

Finalized Changes
CMS finalized the proposal to require States to submit remedy plans to address access areas in need of improvement, aiming to enhance collaboration between States and managed care plans in developing solutions. When the state MCO, PIHP, PAHP, or CMS identifies any access issues, including any access issues with the standards specified in §§438.68 and 438.206, the state would be required to submit a plan to remedy the access issues.

While many commenters supported this requirement, some suggested including specific steps, timelines, and payment adequacy information in remedy plans. CMS acknowledged the value of remedy plans in improving access to care and declined to specifically require payment adequacy information but encouraged States to consider incorporating relevant analyses. Additionally, commenters recommended including input from a wide array of interested parties in remedy plans, which CMS agreed with, emphasizing the importance of collaborative efforts in addressing access issues. However, concerns were raised about the administrative burden of meeting the 90-day deadline for remedy plan submission, with some suggesting a longer timeframe. CMS acknowledged these concerns but maintained that the 90-day timeframe is appropriate, citing States' experience in addressing program areas in need of improvement and the need for structured and accountable processes.

Background/Rationale
Many commenters expressed support for requiring States to submit remedy plans to address access areas in need of improvement, emphasizing that it would enhance transparency and accountability. Suggestions were made to include specific steps, timelines, and payment adequacy information in these plans. Others recommended incorporating input from various interested parties and considering factors like claim denial rates and prior authorization requests. Concerns were raised about the administrative burden and the feasibility of the 90-day deadline for plan submission, with some suggesting an extension to 180 days due to the anticipated volume of information. In response, CMS emphasized the collaborative nature of remedy plans, encouraging input from multiple sources and acknowledging the challenges but maintaining the importance of the 90-day timeframe for submission, considering existing monitoring activities and the need for structured improvement efforts.

Transparency (§§ 438.10(c), 438.602(g), 457.1207, 457.1285) (pg. 112)

Finalized Changes
CMS finalized changes to mandate that States' managed care websites contain all required information on one easily navigable page, a proposal supported by many commenters who emphasized the need for improved usability. CMS also clarified existing regulations regarding website requirements and addressed concerns raised by commenters, including the recommendation to post direct links to relevant documents on managed care plans' sites. CMS created a more complete list of required information that must be posted to a state website at 438.602(g).

Additionally, CMS responded to suggestions for aligning transparency requirements for Medicaid and CHIP managed care organizations, aiming to ensure consistency across programs. In another aspect, CMS finalized changes to replace the term "behavioral health" with "mental health" and "SUD" throughout relevant regulations, responding to support from commenters who favored clearer terminology for regulatory clarity and efficiency.

Background/Rationale
Commenters expressed support for CMS's proposal to enhance the usability of States' managed care websites, emphasizing the importance of clear, easily accessible information for interested parties. They particularly highlighted the challenges users face in navigating State websites and endorsed the proposed requirements as a significant improvement. In response, CMS acknowledged the support and underscored the critical role of State managed care websites as sources of information.

Additional comments raised questions and suggestions regarding the implementation of website requirements. Some commenters recommended direct links to relevant documents on managed care plans' sites, seeking clarity on the applicability of requirements to State versus managed care plan websites. CMS responded by clarifying existing regulations, stating that while requirements apply to State websites, States can extend them to managed care plan websites through contracts.

Furthermore, comments addressed concerns about the complexity of required reports and the administrative burden associated with website features like chat functions. CMS clarified its stance, emphasizing the importance of balancing required content with usability and suggesting approaches to assist readers with technical information. Lastly, comments supported aligning transparency requirements for Medicaid and CHIP managed care organizations, to which CMS responded by affirming alignment efforts while ensuring relevance to each program's context.

Terminology (§§ 438.2, 438.3(e), 438.10(h), 438.68(b) and 438.214(b)) (pg. 123)

Finalized Changes
CMS received support for revising the term "behavioral health" to "mental health" and "SUD" as appropriate throughout part 438 regulations. In response, CMS appreciated the endorsement and confirmed the finalization of this change in various sections to enhance clarity and eliminate ambiguity. After considering public feedback, CMS finalized the revisions as proposed in sections 438.2, 438.3(e), 438.10(h), 438.68(b), and 438.214(b).

Background/Rationale

CMS proposed changes to replace the term "behavioral health" throughout 42 CFR part 438 with more precise language, such as "mental health and substance use disorder," to better encompass the full scope of conditions intended. This proposal aimed to address concerns about the imprecision of the term and ensure clarity in regulatory text. Specifically, CMS suggested revisions in various sections, including the definition of PCCM entity and provider directories, network adequacy standards, and credentialing policies. Additionally, CMS proposed changing "psychiatric" to "mental health" in certain sections to better reflect the services provided in institutions for mental disease. These proposals were authorized by section 1902(a)(4)(A) of the Act to improve the proper and efficient operation of the plan by employing clear and unambiguous terminology in regulatory text.

2. State Directed Payments (SDPs) (§§ 438.6, 438.7 and 430.3) (pg. 124)

Contract Requirements Considered to be SDPs (Grey Area Payments) (§ 438.6(c)(1)) (pg. 133)

Finalized Changes
CMS amended § 438.6(c)(1) to add the phrase "in any way" after "…The State may not…" to make the regulation more explicit that any State direction of an MCO's, PIHP's or PAHP's expenditures is impermissible unless it meets the requirements set forth in § 438.6(c).

Background/Rationale
CMS requested comments on whether additional clarification about grey area payments is necessary, or if revision to the regulation text would be helpful. Some commenters supported CMS's restatement of their existing policy that any State direction of a managed care plan's payments to providers, regardless of specificity or even if tied specifically to utilization and delivery of services, is prohibited unless § 438.6(c) or (d) permits the arrangement, and that "grey area payments" are prohibited.

Some commenters opposed CMS's interpretation. These commenters encouraged CMS to revise the Federal regulatory requirements to instead indicate that broad contract requirements that direct managed care plans to move a set percent of provider payments into value-based arrangements do not trigger SDP provisions. CMS noted that continue to believe that their current policy is reasonable and appropriate and decline to revise the regulation to allow flexibility for States to continue directing general increases to payments without using an SDP to ensure that payments are tied to utilization of service. However, CMS noted they recognize that their intent as outlined in the proposed rule preamble (88 FR 28113) would be clearer if they included a minor modification to § 438.6(c)(1).

Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c)(1)(iii)(B), (c)(2) and (c)(5)(iii)(A)(5)) (pg. 138)

Finalized Changes
CMS finalized their proposal to exempt SDPs that adopt a minimum fee schedule based on total published Medicare payment rates from written prior approval as it would be unnecessary and duplicative. They propose to amend § 438.6(c) to provide specifically for SDPs that require use of a minimum fee schedule using FFS Medicare payment rates.

CMS finalized their proposal to require the managed care plan contract to include certain information about the Medicare fee schedule used in the SDP, regardless of whether the SDP was granted an exemption from written prior approval under § 438.6(c)(1)(iii)(B). That is, for SDPs which use total published Medicare payment rates, the contract would need to specify which Medicare fee schedule(s) the State directs the managed care plan to use and any relevant and material adjustments due to geography, such as rural designations, and provider type, such as Critical Access Hospital or Sole Community Hospital designation.

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

A few commenters recommended that CMS allow other SDPs to be exempt from prior approval requirements. Some of these commenters suggested CMS exempt from the prior written approval requirement any SDP that adopts minimum fee schedules, particularly those for behavioral health services and HCBS. CMS disagreed that additional types of SDPs should be exempted from written prior approval of preprints. SDPs that use minimum fee schedules other than State plan approved rates or 100 percent of the total published Medicare payment rate, as well as uniform increases, must continue to be reviewed by CMS and receive written approval via a preprint, to ensure the payment rates are reasonable, appropriate, and attainable, in addition to ensuring compliance with § 438.6(c).

Non-Network Providers (§ 438.6(c)(1)(iii)) (pg. 151)

Finalized Changes
CMS finalized their proposal to remove the term "network" from the descriptions of SDP arrangements in current (and revised as proposed) § 438.6(c)(1)(iii). Under this proposal, the permissible SDPs are described as payment arrangements or amounts "for providers that provide a particular service under the contract" and this will permit States to direct payments under their managed care contracts for both network and non-network providers, subject to the requirements in paragraph (c).

Background/Rationale
Many commenters supported CMS' proposal to remove "network" from § 438.6(c)(1)(iii) noting that the revision would remove barriers to access to quality care for enrollees and provide more flexibility for States to direct managed care plan payment to a wider array of providers. Several commenters stated support for removing "network" from § 438.6(c)(1)(iii) and requested that CMS permit SDPs that require network providers to be paid higher payment amounts than out-of-network providers. CMS noted that states are permitted to direct payment in any of the ways suggested by commenters, subject to all the requirements in § 438.6(c) and applicable law. Unless limited or circumscribed by a requirement for how a Medicaid managed care plan pays certain noncontracted providers, states could choose to utilize network status as the basis on which to define provider classes or subclasses for an SDP under § 438.6(c)(2)(i)(B)

SDP Submission Timeframes (§§ 438.6(c)(2)(viii) and 438.6(c)(2)(ix)) (pg. 158)

Finalized Changes
CMS finalized that States must complete and submit all required documentation for each SDP for which written approval is required before the specified start date of the SDP. Required documentation includes at least the completed preprint and as applicable, the total payment rate analysis and the ACR demonstration as described in § 438.6(c)(2)(iii) and the evaluation plan as required in § 438.6(c)(2)(iv). The deadline the Agency is finalizing means before the first payment to a provider under the SDP (not merely prior to the State's request for FFP for the State's payments to its managed care plans that incorporate the SDPs). CMS is finalizing that all amendments to SDP preprints must be submitted before the start date of the SDP amendment.

if the required documentation – meaning a complete SDP preprint or complete amendment to the preprint (inclusive of at least the completed preprint and, as applicable, the total payment rate analysis, the ACR demonstration and the evaluation plan)- is not submitted before the start date specified in the preprint, the SDP or SDP amendment will not be eligible for approval.

CMS finalized their proposal to require the submission of related contract requirements and rate certification documentation no later than 120 days after the start of the SDP or the date granted written prior approval of the SDP, whichever is later.

Background/Rationale
Some commenters supported requiring States to submit preprints to CMS at least 90 days prior to end of the rating period as this proposal would provide States the most flexibility. Commenters stated concern with States waiting so late into the rating period to submit an SDP preprint for CMS approval, and noted this would very often trigger retroactive contract and capitation rate adjustments, which creates more burden and uncertainty for States, managed care plans, providers, and CMS.

Many commenters supported CMS' proposal in § 438.6(c)(2)(ix)(A) for SDP preprint amendments to be submitted prior to the end of the rating period, but some did not support their proposal in § 438.6(c)(2)(ix)(B) as they noted the differing timeframes by SDP approval duration disadvantaged States using multi-year SDPs such as VBP arrangements.

Some commenters had overall concerns with the complexity of CMS' proposals on submission timeframes for SDP preprints and preprint amendments and stated that this could lead to States inadvertently missing submission deadlines, particularly during certain situations such as natural disasters.

CMS noted that the comments they received persuaded them that their proposal could inadvertently make submission timeframes overly complicated which could exacerbate rather than alleviate submission compliance and hinder States' efforts to respond to unexpected issues. 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. However, they also continue to believe that it is important for States to be timely with submissions of SDPs as much as possible to align with contract and rate certification reviews, as well as to facilitate efficient implementation of SDPs by managed care plans.

Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for Certain SDPs and Expenditure Limit for All SDPs (§ 438.6(c)(2)(ii)(I) and (c)(2)(iii)) (pg. 171)

Finalized Changes

Standard for Total Payment Rates for each SDP

CMS finalized a new standard at § 438.6(c)(2)(ii)(I) to codify their current policy that each SDP ensure that the total payment rate for each service, and each provider class included in the SDP is reasonable, appropriate, and attainable; upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class.

Proposed Payment Rate Limit for Inpatient Hospital Services, Outpatient Hospital Services, Qualified Practitioner Services at Academic Medical Centers, and Nursing Facility Services (pg. 181)

CMS finalized their proposal to include four services – inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services – in § 438.6(c)(2)(iii) and limit the projected total payment rate for each of these four services to ACR for any SDP arrangements described in paragraphs (c)(1)(i) through (iii), excluding (c)(1)(iii)(A) and (B), that are for any of these four services. The total payment limit would apply across all SDPs in a managed care program; States would not be able to for example, create multiple SDPs that applied, in part or in whole, to the same provider classes and be projected to exceed the ACR.

Average Commercial Rate Demonstration Requirements (pg. 191)

CMS finalized their proposal in § 438.6(c)(2)(iii) that States provide two pieces of documentation: (1) an ACR demonstration; and (2) a total payment rate comparison to the ACR. The ACR demonstration would be submitted with the initial preprint submission (new, renewal, or amendment) following the applicability date of this section and then updated at least every 3 years, so long as the State continues to include the SDP in one or more managed care contracts.

CMS finalized their proposal to specify the requirements for demonstration of the ACR if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. This demonstration must use payment data that: (1) is specific to the State; (2) is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section; (3) is specific to the service(s) addressed by the SDP; (4) includes the total reimbursement by the third party payer and any patient liability, such as cost sharing and deductibles; (5) excludes payments to FQHCs, RHCs and any non-commercial payers such as Medicare; and (6) excludes any payment data for services or codes that the applicable Medicaid managed care plans do not cover under the contracts with the State that will include the SDP. CMS finalized their proposal to require States to use data that is specific to the service type(s) included in the SDP.

CMS finalized their proposal to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. Under this proposal, the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which

written prior approval is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as defined in § 438.6(a) as a percentage of the average commercial rate, demonstrated pursuant to § 438.6(c)(2)(iii)(A), for each of the four categories of services (that is, inpatient hospital services, outpatient hospital services, nursing facility services or qualified practitioner services.

Average Commercial Rate Demonstration and Total Payment Rate Comparison Compliance
CMS finalized their proposal at § 438.6(c)(2)(iii)(C) to require States to submit the ACR demonstration and the total payment rate comparison for review as part of the documentation necessary for written prior approval for payment arrangements, initial submissions or renewals, starting with the first rating period beginning on or after the effective date of this rule.

CMS finalized their proposal to require that States update the ACR demonstration once every 3 years as long as the State continues to seek to include the SDP in the MCO, PIHP, or PAHP contract. CMS finalized at § 438.6(c)(8)(ii) the applicability date of the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as proposed.

Background/Rationale
Standard for Total Payment Rates for each SDP
Some commenters supported the proposal at § 438.6(c)(2)(ii)(I) that each SDP must ensure that the total payment rate for each service and provider class included in the SDP must be reasonable, appropriate, and attainable but recommended that the standards of "reasonable, appropriate, and attainable" be further defined to avoid confusion between States, managed care plans and CMS. Some commenters requested clarification on the State documentation requirement demonstrating the total payment rate by service and provider class specified in § 438.6(c)(2)(ii)(I). CMS does not believe or anticipate that they would request a State to conduct and provide a total payment rate analysis at the CPT code level when exercising their authority under § 438.6(c)(2)(ii)(I) to request documentation demonstrating the total payment rate for each service and provider class.

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

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

CMS noted that in establishing a total payment rate limit, it was not their intent to restrict States' ability to effectively use SDPs to further the State's overall Medicaid program goals and objectives. Their goal was to balance the need for increased transparency and fiscal integrity with the need for State flexibility to accomplish State policy objectives, such as increasing access to care. Their internal analysis indicates that establishing a total payment rate limit less than the ACR could result in reductions in total payment rates from existing total payment rate levels for some SDPs, particularly given the number of States with approved SDPs that exceed the Medicare rate.

Average Commercial Rate Demonstration Requirements

Commenters supported the proposals outlined in § 438.6(c)(2)(iii)(C) regarding the submission process for the ACR demonstration and the total payment rate comparison, including the requirement for these to be provided with the initial SDP preprint and then updated at least once every 3 years thereafter. These commenters believe these proposals would allow for State flexibility and lessen the administrative burden to implement and report on ACR demonstrations since § 438.6(c)(2)(iii) does not require specific data sources or templates.

Several commenters requested clarification on the data sources that should be utilized for ACR demonstrations and total payment rate comparisons proposed in § 438.6(c)(iii)(A) and (B). Some commenters noted that commercial rate data are difficult for States to provide absent an all-payer claims database. Other commenters noted it was unclear if the data in the ACR demonstration and total payment rate comparison will be collected in a way to clearly identify non-Medicaid covered services in commercial payments or third-party liability amounts. Commenters requested that CMS provide guidance and technical assistance about the data sources that would be appropriate for States to utilize for the ACR demonstrations and total payment rate comparisons.

CMS reiterated that they are not requiring States to use specific data sources at this time (88 FR 28126) for the SDP submissions of the information required by § 438.6(c)(2)(iii). They agree that all-payer claims databases are good sources of data, though not all State Medicaid agencies have access to such data. Additionally, commercial data are often proprietary and to our knowledge, there are no publicly available data sources for commercial data.

Average Commercial Rate Demonstration and Total Payment Rate Comparison Compliance

One commenter suggested that CMS allow Medicaid agencies to increase the ACR level used to set the payment amounts in an SDP between ACR demonstrations submitted to CMS, so that the State could direct increased payments to account for inflation. While the commenter supports only requiring States to submit an ACR demonstration every three years in § 438.6(c)(2)(iii)(C) to reduce State burden, they noted that medical inflation trends are not static over three-year periods (meaning, between ACR demonstration submissions). The commenter recommended that CMS allow States to account for medical inflation within their jurisdiction in their ACR during the three-year period without requiring States to revise the ACR demonstration. One commenter requested that CMS delay implementation of § 438.6(c)(2)(iii) for 1 year after the effective date of this final rule. The commenter believes States will need more time than the proposed applicability date, the first rating period after the effective date of the final rule, provides. CMS noted that this requirement is largely in alignment with existing practices and should not cause significant burden for States to implement.

Financing (§ 438.6(c)(2)(ii)(G) and (c)(2)(ii)(H)) (pg. 227)

Finalized Changes
CMS finalized its proposal to revise § 438.6(c)(2)(ii) to add a new paragraph (c)(2)(ii)(G) to require State directed payments (SDPs) to explicitly comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, as part of the CMS review process.

CMS also finalized its proposal to revise § 438.6(c)(2)(ii) to ensure transparency regarding the use of SDPs and to ensure that the non-Federal share of SDPs is funded with a permissible source. States will be required to ensure that each participating provider in an SDP arrangement attests that it does not participate in any hold harmless arrangement with respect to any healthcare-related tax as specified in § 433.68(f)(3) in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount. These hold harmless arrangements include those that produce a reasonable expectation that taxpaying providers would be held harmless for all or a portion of their cost of a healthcare-related tax. Furthermore, 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 will comply with this newly finalized requirement by obtaining each provider's attestation or requiring the Medicaid managed care plan to obtain each provider's attestation. After reviewing comments, the finalized proposal will include a modification explicitly stating 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.

CMS is finalizing its proposal at § 438.6(c)(2)(ii)(H) to require that the State ensure that such attestations are available upon request by CMS, with the modification that States may, as applicable, provide an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations. This rule's effective date is no later than the first rating period for contracts with MCOs, PIHPs, and PAHPS beginning on or after January 1, 2028.

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

Background/Rationale
In recent years, CMS has identified instances in which States appear to be funding the non-Federal share of Medicaid SDP payments through healthcare-related tax programs that appear to involve an impermissible hold harmless arrangement. These arrangements appear designed to redirect Medicaid payments away from the providers that furnish the greatest volume of Medicaid-covered services toward providers that provide fewer, or even no, Medicaid-covered services, with the effect of ensuring that taxpaying providers are held harmless for all or a portion of their cost of the healthcare-related tax.

In the arrangements, a State or other government unit imposes a health-care-related tax, then uses the tax revenue to fund the non-Federal share of SDPs that require Medicaid managed care plans to pay the provider taxpayers. The taxpayers appear to enter a pre-arranged agreement to redistribute the Medicaid payments to ensure that all taxpayers when accounting for both their original Medicaid payment (from the State through a managed care plan) and any redistribution payment received from another taxpayer(s) or other entity, receive back (and are thereby held harmless for) all or at least a portion of their tax amount.

CMS is concerned that the current regulations' failure to explicitly require written prior approval of an SDP on the State demonstrating compliance with applicable Federal requirements for the source(s) of non-Federal share potentially compromises CMS' ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Given the growing number of SDPs that raise potential financing concerns and the growing number of SDPs generally, CMS believes it is important to be explicit in the regulations governing SDPs.

The current lack of transparency for SDPs prevents both CMS and States from having the information necessary for reviewing both the proposed non-Federal share financing source and the proposed payment methodology to ensure they meet Federal requirements. However, States have cited challenges with identifying and providing details on redistribution arrangements when CMS has requested such information during the review of SDPs, but CMS is only interested in any business arrangements among private entities that could result in a violation of Federal statutory and regulatory requirements.

CMS recognizes that healthcare-related taxes can be critical tools for financing payments that support the Medicaid safety net but emphasizes that they must be implemented in accordance with applicable statutory and regulatory requirements. This proposed rule would ensure that CMS and States have the necessary information about any arrangements in place that would redistribute Medicaid payments and make clear that CMS has the authority to disapprove proposed SDPs if States identify the existence of such an arrangement or do not provide the required information or ensure the attestations are made and available as required.

The finalized new attestation requirements help ensure appropriate transparency regarding the use of Medicaid payments and any relationship to the non-Federal share source(s) and aim to do so without interfering with providers' normal business arrangements.

Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§438.6(c)(2)(vii)) (pg. 261)

Finalized Changes

CMS is finalizing its proposal to revise § 438.6(c) to address how different types of SDPs must be based on the utilization and delivery of covered services.

CMS is finalizing its proposal to codify its previous rule clarification in a new section, § 438.6(c)(2)(vii)(A) for SDPs about minimum fee schedules, maximum fee schedules, and uniform increases. CMS would require that all payments made under the SDP are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only. This would preclude States from making any SDP payment based on historical or any other basis that is not tied to the delivery of services to the rating period itself.

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

CMS is finalizing its proposal to prohibit the use of post-payment reconciliation processes for SDPs. Specifically, States establishing fee schedules under § 438.6(c)(1)(iii) cannot require that plans pay providers using a post-payment reconciliation process.

Background/Rationale
A fundamental requirement of SDPs is that they are payments related to the delivery of services under the contract. The current regulations require that states demonstrate in writing that SDPs that require prior written approval are based on the utilization and delivery of services to Medicaid enrollees covered under the managed care plan contract. Requiring SDPs to be based on the utilization and delivery of services is a fundamental and necessary requirement for ensuring the fiscal and program integrity of SDPs, but CMS believes further clarification is necessary due to the variety of payment mechanisms that States use in their SDP arrangements.

Under the prior rule, States could not, under CMS' interpretation of the requirement, require managed care plans to make payments for services that were delivered outside of the approved rating period. However, in working with States, CMS found that this was not always understood, and thus, it seeks to clarify this rule further.

CMS has also seen States have their actuaries submit an amendment to adjust the amount paid to plans after reconciliation. These amendments typically come near to or after the close of the rating period and are most common when the reconciliation would result in increased costs to the plan absent the adjustment. As a result, the risk is removed from the managed care plans in the SDP. CMS is concerned with this practice as they believe tying payments in an SDP, even interim payments, to utilization from a historical time period outside of the rating period approved for the SDP is inconsistent with prospective risk-based capitation rates that are developed for the delivery of services in the rating period.

CMS believes requiring managed care plans to make interim payments based on historical utilization and then reconciling to actual utilization instead suggests an intent by the State to ensure payment of a specific aggregate amount to certain providers or, in some cases, removal of all risk-related to these SDPs from managed care plans. Further, CMS believes prohibiting this practice and removing post-payment reconciliation processes as proposed would alleviate actuarial and oversight concerns and restore program and fiscal integrity to these kinds of payment arrangements.

Value-Based Payments and Delivery System Reform Initiatives (§ 438.6(c)(2)(vi)) (pg. 272)

Finalized Changes

CMS finalized changes to redesignate current paragraph (c)(2)(iii) as paragraph (c)(2)(vi) with a revision to remove the phrase "demonstrate in writing" to be consistent with the effort to ensure that

SDP standards apply to all SDPs, not only those that require prior approval. CMS also finalized changes to redesignate current paragraph (c)(2)(iii)(A) as paragraph (c)(2)(vi)(A).

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

1. Remove the existing requirements at § 438.6(c)(2)(iii)(C) that currently prohibit States from setting the amount or frequency of the plan's expenditures.
2. Remove the existing requirements at § 438.6(c)(2)(iii)(D) that currently prohibit States from recouping unspent funds allocated for these SDPs.
3. Redesignate § 438.6(c)(2)(iii)(B) with revisions and clarifications to § 438.6(c)(2)(vi)(B). The provision addresses how performance in these types of arrangements is measured for participating providers.
4. Adopt a new § 438.6(c)(2)(vi)(C) to establish requirements for use of population-based and condition-based payments in these types of SDP arrangements.

Performance-Based Payments

At § 438.6(c)(2)(vi)(B)(1), CMS finalized to codify our interpretation of this policy by requiring payments to providers under SDPs that are based on performance not be conditioned upon administrative activities, such as the reporting of data, nor upon the participation in learning collaboratives or similar administrative activities.

CMS finalized at § 438.6(c)(2)(vi)(B)(3), that a payment arrangement that is based on performance must define and use a performance period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered.

At § 438.6(c)(2)(vi)(B)(4), CMS finalized to require that all SDPs that condition payment on performance include a baseline statistic for all metrics that are used to measure the performance that is the basis for payment from the plan to the provider; these are the metrics (including, per proposed paragraph (c)(2)(iv)(A)(2), at least one performance measure, as that term is proposed to be defined in § 438.6(a)) that are specified by the States in order to comply with proposed § 438.6(c)(2)(vi)(B)(2).

At § 438.6(c)(2)(vi)(B)(5), CMS finalized to require that all SDPs that condition payment on performance use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the payment arrangement applies, that demonstrate improvement over baseline data on all metrics selected in § 438.6(c)(2)(vi)(B)(2).

Population-Based Payments and Condition-Based Payments CMS finalized to define a "population-based payment" at § 438.6(a) as a prospective payment for a defined Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group. CMS also finalized to define a "condition-based payment" as a prospective payment for a defined set of Medicaid service(s), that are tied to a specific condition and delivered to Medicaid managed care enrollees.

CMS finalized § 438.6(c)(2)(vi)(C)(1) to require that population-based and condition-based payments be based upon either the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution of a covered enrollee to a provider during the rating period.

CMS finalized § 438.6(c)(2)(vi)(C)(3) to require that population-based payments and condition-based payments replace the negotiated rate between a plan and providers for the Medicaid covered service(s) being delivered as a part of the SDP to prevent any duplicate payment(s) for the same service. Also, at § 438.6(c)(2)(vi)(C)(3), CMS finalized a requirement that prevents payments from being made in addition to any other payments made by plans to the same provider on behalf of the same enrollee for the same services included in the population- or condition-based payment.

CMS finalized new § 438.6(c)(2)(vi)(C)(4) to require that States include at least one performance measure that measures performance at the provider class level as a part of the evaluation plan outlined in proposed § 438.6(c)(2)(iv). CMS also finalized a provision that States be required to set the target for such a performance measure to demonstrate improvement over baseline.

Approval Period

CMS finalized § 438.6(c)(3)(i) to add that a multi-year written prior approval for SDPs that are for VBP initiatives described in paragraphs (c)(1)(i) and (ii) may be for of up to three rating periods to codify our existing policy. Requiring States to renew multi-year SDPs at least every 3 years will allow us to monitor changes and ensure that SDPs remains aligned with States' most current managed care quality strategy. CMS finalized minor revisions in paragraphs (c)(3)(i)(A) through (C) to use the term "State directed payment" as appropriate and to revise paragraph (c)(3)(ii) to specify it is about written prior approvals. Finally, CMS redesignated paragraph (c)(2)(F) to new paragraph (c)(3)(iii) to explicitly provide that State directed payments are not automatically renewed.

Background/Rationale

Many commenters were broadly supportive of the proposed changes to the VBP initiative SDP provisions (currently at § 438.6(c)(2)(iii)), including the proposals to remove existing requirements (currently at § 438.6(c)(2)(iii)(C) and (D)) that prevent States from setting the amount and frequency of payments or from recouping unspent funds from VBP initiative SDPs, respectively. Commenters stated support for removing barriers to allow for flexible collaboration and innovation. Some commenters encouraged CMS and States to engage with interested parties to determine if there are additional barriers to implementation of VBP initiative SDPs described in paragraphs (c)(1)(i) and (ii).

Some commenters supported the removal of the prohibition on States recouping unspent funds from VBP initiative SDPs but requested that CMS provide further direction and requirements for how recouped funds can be spent. CMS did not propose and are not finalizing spending requirements for recouped unspent State funds that were initially designated for payment of VBP initiative SDPs. CMS reminds States that any recoupments made from plans as a part of VBP initiative SDPs are subject to the return of the Federal share via the CMS-64.

Many commenters supported the provisions for performance-based VBP initiative SDPs at proposed § 438.6(c)(2)(vi)(B). Specifically, commenters showed support for requiring that performance-based VBP initiative SDPs use measurable and understandable performance targets as well the proposed expansion of the performance measurement period to up to 12 months prior to the start of the contract rating period.

Several commenters either opposed the proposal that performance-based VBP initiative SDPs must not condition payment on administrative activities, such as the reporting of data, or they suggested revisions to the provision so that "pay-for-reporting" would be allowed at least in the initial years of a performance-based VBP initiative SDP. Because payment for performance-based VBP initiative SDPs must be based on provider performance tied to the delivery of covered services under the Medicaid managed care contract for the rating period, CMS has never allowed these types of SDPs to be based on "pay-for-reporting." The rationale has been and remains that the act of reporting is an administrative activity and not a covered service.

Some commenters suggested revisions to the proposal that the performance measurement period must not precede the start of the rating period by more than 12 months; commenters suggested extending the period of time for which the performance period could precede the baseline to 18 or 24 months to allow for an adequate claims runout period, provider reporting, and data analysis. CMS believes that the flexibility to use a performance period that precedes the rating period by 12 months is sufficient to allow adequate time for claims runout and for States time to collect and analyze performance data for use in the payment arrangement.

Quality and Evaluation (§ 438.6(c)(2)(ii)(C), (c)(2)(ii)(D), (c)(2)(ii)(F), (c)(2)(iv), (c)(2)(v) and (c)(7)) (pg. 292)

Finalized Changes

CMS is finalizing § 438.6(c)(2)(ii)(D), (c)(2)(iv) and (v) as proposed. CMS is finalizing § 438.6(c)(7) with modifications to be consistent with the policy decision at § 438.6(c)(6) that prohibits separate payment terms. CMS is finalizing § 438.6(c)(2)(ii)(F) with a revision to clarify that 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.

Specifically, at t § 438.6(c)(2)(iv)(A), CMS proposed that the evaluation plan must identify at least two metrics that will be used to measure the effectiveness of the payment arrangement in advancing the identified goal(s) and objective(s) from the State's managed care quality strategy on an annual basis. At § 438.6(c)(2)(iv)(A)(1), CMS proposed that the metrics must be specific to the SDP and attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the SDP applies and at § 438.6(c)(2)(iv)(A)(2), CMS proposed to require that at least one of the selected metrics be a performance measure.

At § 438.6(c)(2)(iv)(B), CMS proposed to require States to include baseline performance statistics for all metrics that will be used in the evaluation since this data must be established in order to monitor changes in performance during the SDP performance period.

CMS proposed to amend § 438.6(c)(2)(ii)(D) to further require the evaluation plan include all the elements outlined in paragraph (c)(2)(iv).

CMS proposed add new § 438.6(c)(2)(v) to require that States provide commitment to submit an evaluation report if the final State directed payment cost percentage exceeds 1.5 percent. As proposed in § 438.6(c)(2)(v), the evaluation reporting requirement is limited to States with SDPs that require prior approval and exceed a certain cost threshold.

CMS proposed to define final State directed payment cost percentage" in § 438.6(a) as the annual amount calculated, in accordance with paragraph (c)(7)(iii) of the section, for each State directed payment and each managed care program. In § 438.6(c)(7)(iii)(A), CMS proposed for SDPs requiring prior approval that the final SDP cost percentage numerator be calculated as the portion of the total capitation payments that is attributable to the State directed payment and, actual total amount that is paid as a separate payment term described in § 438.6(c)(6), for each managed care program.

At § 438.6(c)(7), CMS proposed that unless the State voluntarily submits the evaluation report, the State must calculate the final State directed payment cost percentage, and if the final State directed payment cost percentage is below 1.5 percent, the State must provide a final State directed payment cost percentage report to CMS.

CMS proposed to adopt three requirements in § 438.6(c)(2)(v)(A).
1. Evaluation reports must include all the elements approved in the evaluation plan required in § 438.6(c)(2)(iv).
2. States must include the 3 most recent and complete years of annual results for each metric in § 438.6(c)(2)(iv)(A).
3. States must publish their evaluation reports on their public facing website as required under § 438.10(c)(3).

At § 438.6(c)(2)(v)(B), CMS proposed to require States to submit the first evaluation report no later than 2 years after the conclusion of the 3-year evaluation period and that subsequent evaluation reports would have to be submitted to CMS every 3 years after.

At § 438.6(c)(2)(ii)(F), CMS proposed that all SDPs must result in achievement of the stated goals and objectives in alignment with the State's evaluation plan.

At § 438.358(c)(7), CMS proposed to include a new optional EQR activity to support evaluation requirements, which would give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs.

Background/Rationale
CMS proposed several regulatory changes to enhance CMS's ability to collect evaluations of SDPs and the level of detail described in the evaluation reports. CMS's intent is to shine a spotlight on SDP evolution and use evaluation results in determining future approvals of State directed payments.

Throughout this section, CMS highlights their recognition that performance is a broad term and that the approach to evaluation quality in health care is evolving. In addition, they recognize the importance of preserving States' flexibility to identify performance measure(s) that are the most appropriate for evaluation the specific SDP. CMS encourages States to implement SDPs for primary care, maternal heath, and behavioral health to improve access to these services. They also encourage States to include measures that focus on primary and behavioral health care in their evaluation plans when relevant.

Overall, CMS believes the proposed regulations at § 438.6(c)(2)(iv) would ensure that States collect and use stronger data for developing and evaluating payment arrangements to meet the goals of their Medicaid programs and that States would also be responsive to recommendations for more clarity for SDP evaluation plans. They recognize and share the concerns over the limited availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care.

Several commenters were broadly supportive of CMS's proposed SDP valuation plan policies at § 438.6(c)(2)(iv) and CMS's goal to incentivize quality improvement efforts through SDP evaluations. Some commenters opposed the proposed standard at § 438.6(c)(2)(ii)(F) requiring all SDPs to result in the achievement of the stated goals and objectives identified in the State's evaluation plan(s) for the SDPs, noting concern that it will result in States setting overly modest targets to avoid putting initiatives at risk if performance does not meet the established targets. CMS replied that they believe States should have the flexibility to choose meaningful targets based on the goals of the payment arrangement within their Medicaid managed care program and its quality strategy. They encouraged States to request technical assistance from CMS. In addition, some commenters are 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. Some commenters stated concern about the administrative burden of the evaluation plans and suggested that CMS implement either an optional requirement or a minimal level of monitoring for SDPs that do not require CMS written prior approval of associate preprints.

Contract Term Requirements (§ 438.6(c)(5) and 438.7(c)(6)) (pg. 314)

Finalized Changes
CMS is finalizing § 438.6(c)(5)(i), (ii) and (iv) as proposed; finalizing § 438.6(c)(5)(iii) as proposed with grammatical minor edits to (§ 438.6(c)(5)(iii)(B) and (C) to remove, "the contract must include the following"; not finalizing the proposed provision (proposed at paragraph (c)(5)(v)) related to contract terms for separate payment terms; finalizing, at new § 438.6(c)(5)(v), a requirement for submission of minimum contract documentation for an SDP to CMS no later than 120 days after the SDP start date but not the proposal for submission within 120 days of CMS's written prior approval if that is later than the start date of the SDP; and finalizing § 438.7(c)(6) to require submission of rate certifications that includes an SDP no later than 120 days after the start date of the SDP but not the proposal for submission within 120 days of CMS's written prior approval if that is later than the start date of the SDP. See sections I.B.2.l. and I.B.2.m. of this final rule for further discussion of separate payment terms and rate certifications related to SDPs.

Background/Rationale
Some commenters stated support for accurate documentation of SDPs in the applicable managed care plan contracts and noted that timely incorporation of this SDP documentation, and associated submission of the contracts to CMS is essential to ensure efficient and proper administration of the Medicaid program. A few commenters suggested that CMS consider making § 438.6(c)(5) applicable sooner than proposed.

A few commenters supported CMS's proposal to require States to submit managed care plan contracts and rate certifications that include SDPs no later than 120 days of the start date or approval date while other commenters questioned the feasibility of the contract submission timeframes proposed in § 438.6(c)(5)(vi). Some commenters stated that using a "later of" submission date scheme was

unnecessarily complicated, prone to error, and would leave managed care plans and providers unclear on final details about the SDP for too long. A few commenters noted that contracts and rate certifications should be submitted at the same time as the SDP preprint to ensure they are all consistent. A few commenters stated it is critical that managed care plans receive timely information about SDPs as delays in programming managed care plans claims processing and reporting systems accurately have the potential to delay payments to providers.

Similar to their reasoning for revising the SDP submission time in § 438.6(c)(2)(viii), CMS was persuaded by comments that their proposal was overly complex with the "later of "submission timelines. They believe that there needs to be consistently between the final regulations at § 438.6(c)(5)(vi) for contract submission and § 438.7(c)(6) for rate certification submission given their relationship to each other's approval. Further, CMS believes simplification of the timeframes for submission of the contract and rate certifications inclusive of SDPs is needed to prevent unnecessary delays for States, managed care plans, and providers.

Including SDPs in Rate Certifications and Separate Payment Terms (§§ 438.6(c)(2)(ii)(J) and (c)(6), and 438.7(f)) (pg. 327)

Finalized Changes

CMS is redesignating the existing regulatory requirement at § 438.6(c)(2)(i) as (c)(2)(ii)(J) to require that each SDP must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. CMS is removing the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices.

CMS has amended § 438.6(a) to define "separate payment term" as a pre-determined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a specific SDP for which the State has received written prior approval.

CMS is instituting a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms. CMS is instituting a new § 438.6(c)(6)(i) to require that all separate payment terms to be reviewed and approved as part of the SDP review process in § 438.6(c)(2). They are also implementing a new requirement at § 438.6(c)(6)(ii) that would expressly prohibit States from using separate payment terms to fund SDPs that are exempted from the written prior approval process – specifically, minimum fee schedules using State plan approved rates in § 438.6(c)(1)(iii)(A) and minimum fee schedules using approved Medicare fee schedules, as proposed in § 438.6(c)(1)(iii)(B).

CMS is finalizing a rule at § 438.6(c)(6)(iii), to require that each separate payment term be specific to both an individual SDP approved under § 438.6(c)(2)(i) and to each Medicaid managed care program to provide clarity in the contract for the plan and facilitate State and Federal oversight of such terms.

CMS is finalizing a new requirement at § 438.6(c)(6)(iv) that the separate payment term not exceed the total amount documented in the written prior approval for each SDP for which CMS has granted written approval.

CMS is requiring as part of § 438.6(c)(6)(v), that States document the separate payment term in the State's managed care contracts no later than 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later.

CMS is finalizing a rule at § 438.6(c)(6)(v)(A) to prohibit States from amending the separate payment term after CMS approval except to account for an amendment to the payment methodology that was first approved by CMS as an amendment to the approved State directed payment.
CMS is requiring that CMS approve the amendment to the preprint before the separate payment term could be amended. CMS is including four pieces of information that must be documented in the State's Medicaid managed care plan contracts: (1) the total dollars that the State would pay to the plans for the individual SDP that CMS gave written prior approval; (2) the timing and frequency of payments that would be made under the separate payment term from the State to the plans; (3) a description or reference to the contract requirement for the specific SDP for which the separate payment term would be used; and (4) any reporting that the State required to ensure appropriate reporting of the separate payment term for purposes of MLR reporting under § 438.8.

CMS is adding § 438.7(f) requiring the State, through its actuary, certify the total dollar amount for each separate payment term as detailed in the State's Medicaid managed care contract.

CMS is finalizing a rule in § 438.7(f)(1), requiring that the State pay each MCO, PIHP, or PAHP a different amount under the separate payment term compared to other MCOs, PIHPs, or PAHPs so long as the aggregate total dollars paid to all MCOs, PIHPs, and PAHPs did not exceed the total dollars of the separate payment term for each respective Medicaid managed care program included in the Medicaid managed care contract.

CMS is requiring, in § 438.7(f)(2), that the State, through its actuary, must provide an estimate of the impact of the separate payment term on a rate cell basis, as paid out per the SDP approved by CMS under § 438.6(c)(2)(i).

CMS is finalizing a rule, in § 438.7(f)(3), that no later than 12 months following the end of the rating period, the State must submit documentation to CMS that includes the total amount of the separate payment term in the rate certification consistent with the distribution methodology described in the State directed payment for which the State obtained written prior approval to facilitate oversight and monitoring of the separate payment term.

CMS is finalizing a rule, at § 438.7(f)(4), that requires States to submit a rate certification or rate certification amendment incorporating the separate payment term within 120 days of either the start of the payment arrangement or written prior approval of the SDP, whichever is later.

Background/Rationale
CMS did not receive any comments on §438.6(c)(2)(ii)(J) and finalized as proposed.
CMS is concerned that the use of separate payment terms for SDPs erodes the risk-based nature of payment to managed care plans and fiscal integrity in Medicaid managed care. As a response, CMS is adopting a new provision at paragraph (c)(6) requiring that all SDPs be incorporated into Medicaid managed care capitation rates as adjustments to base capitation rates and prohibiting the use of separate payment terms.

Many commenters noted that eliminating separate payment terms would be a notable departure from current practice. CMS 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 in order to give states time to transition.

SDPs included through Adjustments to Base Capitation Rates (§§ 438.6(c)(6), and § 438.7(c)(4) through (c)(6)) (pg. 354)

Finalized Changes
CMS added a new regulatory requirement at § 438.7(c)(5) specifying that retroactive adjustments to capitation rates resulting from an SDP must be the result of an approved SDP being added to the contract, an amendment to an already approved SDP, a State directed payment described in § 438.6(c)(1)(iii)(A) or (B), or a material error in the data, assumptions, or methodologies used to develop the initial rate adjustment such that modifications are necessary to correct the error.

CMS added a new regulatory requirement at § 438.7(c)(4) that States must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under § 438.7(a) for any special contract provisions related to payment in § 438.6 not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.

Background/Rationale
Some commenters stated that there are circumstances not related to a material error when retroactive adjustments to capitation rates are appropriate. In response, CMS recommended that States implement risk-sharing arrangements such as 2-sided risk corridors in response to the uncertainty.

Appeals (§ 430.3(e)) (pg. 360)

Finalized Changes
CMS added a new § 430.3(d) that would explicitly permit disputes that pertain to written disapprovals of SDPs under § 438.6(c) to be heard by the Health and Human Services (HHS) Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

Background/Rationale
Some commenters believed this rule would deny a potential appellant access to the courts. CMS disagreed that anything in this rule would do so and emphasized that administrative appeals process is a timelier and more cost-effective path to resolution than the court system. CMS generally believes the Board is the best equipped and efficient to handle these matters.

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)) (pg. 369)

Finalized Changes
CMS has finalized 457.1203(e) to exclude any references to SDPs in State MLR reporting.

CMS has added a new rule requiring that, under §§ 438.8(e)(2)(iii)(C) managed care plan expenditures to providers that are directed by the State under § 438.6(c), including those that do and do not require prior CMS approval, must be included in the MLR numerator. In § 438.8(f)(2)(vii), CMS is requiring that State payments made to Medicaid MCOs, PIHPs, or PAHPs for approved arrangements under § 438.6(c) be included in the MLR denominator as premium revenue. CMS is also finalizing a rule requiring that States and managed care plans are required to comply with these changes in § 438.8(e)(2)(iii)(C) and

(f)(2)(vii) 60 days after the effective date of the final rule. The rule was modified to use the newly defined term "State directed payment" and to clarify the scope of the provisions.

CMS established a new requirement at § 438.6(c)(4) that States must annually submit data, no later than 180 days after each rating period, to CMS's T-MSIS, and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs that were in effect for the rating period, including amounts paid to individual providers.

CMS finalized § 438.6(c)(4) with revisions to modify the 180-day timeframe to "1 year" and add ", as applicable" At the end of the introductory text in § 438.6(c)(4). CMS also finalized 438.6(c)(4)(v) with a technical edit to remove "the amount for any pass-through payments under paragraph (d) of this section,"

CMS is not finalizing the proposed §§ 438.8(k)(1)(xiv) through (xvi) or §438.74(a)(3) through (4) to require SDP line-level reporting in the State summary and managed care plan specific MLR report.

Background/Rationale
Some comments expressed concern that requiring plans and States to report SDPs on a line-item basis would require extensive State and plan administrative work, as well as CMS technical assistance. CMS agreed and modified the rule in acknowledgement. Some commenters believed that MBES would be the more appropriate system for reporting SDP data since it is already used to collect provider-level data on UPL payments. CMS disagreed because MBES does not classify by amounts paid by the managed care plan to a provider for a service delivered to a specific Medicaid managed care enrollee. Many commenters had wide views on the level of administrative reporting CMS should impose. CMS appreciated the comments and committed to further revising T-MSIS reporting in the future to better enable States to report more complex SDP data easily and effectively.

Applicability Dates (§§ 438.6(c)(4) and 438.6(c)(8), and 438.7(f)) (pg. 378)

Finalized Changes
CMS finalized a rule requiring that States and managed care plans have to comply with § 438.6(a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) through (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv), and 438.7(c)(4), (c)(5), and (f)(1) through (3) upon the effective date of this final rule.

CMS is also requiring that States and managed care plans comply with § 438.6(c)(2)(iii), (vi)(B), (vi)(C)(1) and (2) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of this final rule.

CMS is requiring that States and managed care plans comply with § 438.6(c)(2)(ii)(H), (c)(2)(vi)(C)(3) and (4), (c)(2)(vii), (c)(2)(viii) and (ix), and (c)(5)(i) through (v) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after the effective date of the final rule

CMS is also requiring that States and managed care plans comply with § 438.6(c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v), and (c)(7) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of this final rule.

CMS is requiring that States and managed care plans comply with §§ 438.6(c)(5)(vi) and (c)(6)(v), and 438.7(c)(6) and (f)(4) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after the effective date of this final rule.

CMS is requiring that States must submit the initial TMSIS report after the first rating period following the release of CMS guidance on the content and form of the report.

CMS modified the T-MSIS reporting deadline in § 438.6(c)(4) from 180 days to 1 year to acknowledge the time needed for more accurate and complete encounter data reporting.
CMS also modified the applicability date for § 438.6(c)(2)(vii) to no later than 3 years after the effective date of the final rule to align with the applicability date for the prohibition on separate payment terms in § 438.6(c)(6).

Background/Rationale
Some commenters noticed the array of new documentation required and requested an extension on applicability deadlines. CMS recognized their concern and modified the T-MSIS deadline and the applicability date for § 438.6(c)(2)(vii).

3. Medical Loss Ratio (MLR) Standards (§§ 438.8, 438.3 and 457.1203) (pg. 396)

Standards for Provider Incentives (§§ 438.3(i), 438.8(e)(2), 457.1201 and 457.1203) (pg. 398)

Finalized Changes
CMS finalized changes at § 438.8(e)(2) as proposed, which require that for the provider bonus or incentive to be included in the MLR numerator, they must be clearly linked to an objectively measurable, well-defined, and documented clinical or quality improvement standard. However, CMS extended the implementation timeframe at § 438.3(v) from "on or after 60 days following the effective date of the final rule" to "on or after 1 year following the effective date of the final rule." CMS is also finalizing revised text at § 438.3(i)(3)(iii) to mirror the performance metrics text in the private market regulations at 45 CFR 158.140(b)(2)(iii).

CMS also finalized a change to the proposal at § 438.3(i)(3)(iv) requiring incentive payment contracts to specify a dollar amount that can be clearly linked to successful completion of performance metrics to also allow a percentage of a verifiable dollar amount in the contract, as an alternative to a specific dollar amount. The effective date for this provision is the first rating period beginning on or after July 9, 2025 for the provider incentive changes in §§ 438.3(i), 438.608(e), and the existing cross-references at § 457.1200(d) for separate CHIP. CMS also clarifies that the finalized revisions are equally applicable to separate CHIP through the existing cross-reference at § 457.1201(h).

Background/Rationale
CMS extended the implementation timeline at § 438.3(v) after acknowledging comments that 60 days may not be long enough to allow managed care plans to engage with contracted providers and

complete the legal review necessary to implement new provider incentive arrangements. Regarding the revised text at § 438.3(i)(3)(iii), CMS is making this technical revision to standardize language used in different sections of the 2023 managed care proposed rule ("well-defined quality improvement performance metrics" versus "clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards") (§ 438.3(i)(3)(iii) and § (438.8(e)(2)(iii)(A)) and to align with similar requirements in the private market.

The finalized policy change at § 438.3(i)(3)(iv) is intended to provide additional flexibility that would better align with current incentive payment practices.

Prohibited Costs in Quality Improvement Activities (QIAs) (§§ 438.8(e)(3) and 457.1203(c)) (pg. 415)

Finalized Changes
CMS finalized as proposed § 438.8(e)(3)(i) and corresponding 457.1203(c), which add a reference to Marketplace regulation that prohibits inclusion of overhead or indirect expenditure that are not related to health care quality improvement in MLR calculation.

Background/Rationale
CMS refuted comments implying that the QIA requirements will present undue administrative burden to managed care plans, resulting in either a reluctance to implement QIAs or higher administrative cost. CMS instead stated that "many indirect costs such as office space and human resources would be incurred even if the managed care plan did not implement QIA."

Additional Requirements for Expense Allocation Methodology (§§ 438.8(k)(1)((vii) and 457.1203(f)) (pg. 424)

Finalized Changes
CMS finalized as proposed § 438.8(k)(1)(vii) and corresponding 457.1203(f)), requiring Medicaid managed care plans to provide a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes, licensing or regulatory fees, and other non-claims costs, as described in § 158.170(b).

Background/Rationale
CMS noted that a recent state-level Medicaid MLR review found that many managed care MLR reports did not include information about expense allocation methodologies. CMS believes that the finalized regulation will improve expense allocation reporting from managed care plans and disagreed with comments implying that this would be a difficult change to implement.

Credibility Factor Adjustment to Publication Frequency (§§ 438.8(h)(4) and 457.1203(c)) (pg. 430)

Finalized Changes
CMS finalized as proposed § 438.8(h)(4) and corresponding 457.1203(c) which remove the text "on an annual basis," effectively removing the requirement that credibility factors be updated annually.

Background/Rationale
These factors are applied to plans with fewer enrollees to adjust for the higher impact of claims variability on smaller plans. Since the publication of the credibility adjustment factors in 2017, the factors

have not changed. The credibility factors developed using the 2017 model were not expected to change annually, therefore CMS is removing that requirement. However, CMS plans to continue to review these factors and update them if needed.

MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (§§ 438.8(m) and 457.1203(f)) (pg. 431)

Finalized Changes
CMS decided not to finalize the proposed changes at § 438.8(m) and corresponding § 457.1203(f), which would have specified that an MCO, PIHP, or PAHP would only be required to resubmit an MLR report to the State when the State makes a retroactive change to capitation rates.

Background/Rationale
After considering comments opposing the proposed changes, and the impacts of the resumption of Medicaid and CHIP eligibility redetermination across States, CMS decided that by restricting managed care plan MLR resubmissions to when States make capitation rate changes, the MLRs may not be accurate and therefore, did not finalize the proposal.

Level of MLR Data Aggregation (§§ 438.74 and 457.1203(e)) (pg. 433)

Finalized Changes
CMS finalized as proposed §438.74 and corresponding §457.1203(e), which state explicitly that State MLR summary reports must include the required elements for each MCO, PIHP, or PAHP that is contracted with the State. CMS does this by replacing "the" with "each" before "report(s)" at 438.74(a)(1) and by adding language at

Background/Rationale
CMS is finalizing this policy to address confusion among states about what is required for these reports.

Contract Requirements for Overpayments (§§ 438.608(a)(2) and (d)(3) and 457.1285)) (pg. 435)

Finalized Changes
CMS finalized § 438.608(a)(2) and (d)(3) with a few modifications. CMS finalized a change to § 438.608(a)(2) instructing States to require managed care plans to define "prompt" as within 30 calendar days of identifying or recovering an overpayment, as opposed to 10 business days in the proposed rule. This change also applies to corresponding § 457.1285.

CMS is also finalizing a change at § 438.608(d)(3) (and corresponding 457.1285) to clarify that all overpayments (identified or recovered) must be reported by Medicaid or CHIP managed care plans annually to the State.

The finalized effective date for both of these changes will be the first rating period beginning on or after July 9, 2025, as opposed to the proposed 60 days following the effective date of the final rule.

Background/Rationale
After considering comments asking for an extension, CMS believes 30 calendar days will provide a managed care plan sufficient time to investigate an overpayment and determine whether the

overpayment is due to potential fraud or other causes, but they also make clear that states could implement shorter timeframes.

Regarding § 438.608(d)(3) and corresponding § 457.1285, CMS believes that requiring reporting of all overpayments, whether identified or recovered, to the States will provide managed care plans and States with more consistency in the overpayment reporting requirements.

4. In Lieu of Services and Settings (ILOSs) (§§ 438.2, 438.3(e), 438.16, 457.10, 457.1201(c) and 457.1201(e)) (pg. 447)

Overview of ILOS requirements (§§ 438.2, 438.3(e), 438.16, 457.10, 457.1201(c) and 457.1201(e)) (pg. 447)

Finalized Changes

CMS finalized their proposal to revise the regulatory requirements for ILOSs to specify the nature of the ILOSs that can be offered:

- CMS finalized their 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) and acknowledge that an ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize State plan-covered service or setting.
- CMS finalized their proposal to align the ILOS definition for CHIP by adding the definition provided in § 438.2 to § 457.10.
- CMS finalized their proposal to make several conforming changes in § 438.3(e)(2) to align the language with the proposed definition in § 438.2. CMS finalized their proposal to make the same conforming changes to the CHIP managed care plan contract requirements through the existing cross-reference at § 457.1201(e).
- CMS finalized their proposal to create a new section § 438.16 titled *ILOS requirements for Medicaid*, and the agency finalized their proposal to amend § 457.1201(c) and (e) to include cross-references to § 438.16 to adopt for separate CHIP.
- CMS finalized their proposal to add § 438.3(e)(2)(v) to explicitly provide an exception from the applicability of § 438.16 for short term stays, as specified in § 438.6(e), for inpatient mental health or substance use disorder treatment in an institution for mental diseases (IMD). CMS does not propose to adopt the IMD exclusion for separate CHIP.

Background/Rationale

Many commenters offered widespread support for CMS' proposed ILOS policies as they believe the proposed policy direction and the flexibility to offer expanded ILOSs supported States and managed care plans in their efforts to strengthen access to care, improve enrollee's health care outcomes, and lower overall health care costs in Medicaid and CHIP. Many commenters also supported the proposed definition of an ILOS and stated that this definition appropriately accounted for immediate or longer-term substitutes for a covered service or setting under the State plan, noting that it supports efforts to address enrollees' physical, behavioral, and health-related social needs, improve population health, and advance health equity.

Some commenters raised concerns that the additional guardrails and reporting requirements could increase State and plan burden and disincentivize them from expanding ILOSs. A few of these commenters recommended that CMS not finalize the proposed provisions, but rather focus additional oversight only on more novel or non-traditional ILOSs and allow approved ILOSs to continue without additional guardrails. CMS noted that while they recognize that defining an ILOS will add guardrails, they believe that finalizing a definition of ILOS is vital to ensuring clarity and transparency on the use of ILOSs to ensure appropriate and efficient use of Medicaid and CHIP resources, and that these investments advance the objectives of the Medicaid and CHIP programs.

ILOS general parameters (§§ 438.16(a) through (d), 457.1201(c), and €, and 457.1203(b)) (pg. 457)

Finalized Changes

CMS finalized their proposals to add several requirements in § 438.16 that ILOSs would have to meet:

- CMS finalized in § 438.16(b), that an ILOS must be approvable as a service or setting through a State plan amendment or a waiver under section 1915(c) of the Act. Similarly for CHIP, CMS finalized their proposal that ILOSs must be consistent with services and settings approvable under sections 2103(a) through (c), 2105(a)(1)(D)(ii), and 2110(a) of the Act as well as the services and settings identified in § 438.16(b).
- CMS finalized their proposal to establish an ILOS cost percentage to limit allowable ILOS costs to a portion of the total costs for each managed care program that includes ILOS(s). Specifically, CMS finalized their proposal in § 438.16(c), that the ILOS cost percentage must be calculated based on capitation rates and capitation payments. Further, CMS finalized their proposal to define both a "projected ILOS cost percentage" and "final ILOS cost percentage" in § 438.16(a) as the amounts for each managed care program that includes ILOS(s) using the calculations proposed in § 438.16(c)(2) and (3), respectively. In § 438.16(c)(2), CMS finalized their proposal that the projected ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that would be attributable to all ILOSs, excluding short term stays in an IMD, for each managed care program (numerator) by the projected total capitation payments for each managed care program and the projected total State directed payments that are paid as a separate payment term (denominator). In § 438.16(c)(3), CMS finalized their proposal that the final ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD, for each managed care program (numerator) by the actual total capitation payments for each managed care program and the actual total State directed payments that are paid as a separate payment term (denominator). For CHIP, CMS finalized their proposal to align with the projected and final ILOS cost percentage calculations by amending § 457.1201(c) to include cross-references to § 438.16(c)(2) through (3). However, since pass-through payments and State directed payments are not applicable to separate CHIP, CMS propose to exclude all references to passthrough payments and State directed payments at § 457.1201(c).
- CMS finalized their proposal, at § 438.16(c)(1)(i), to require that the projected ILOS cost percentage could not exceed 5 percent and the final ILOS cost percentage could not exceed 5 percent. For CHIP, CMS finalized to amend § 457.1203(b) to adopt 5 percent ILOS cost percentage limits by amending § 457.1201(c) to include a new cross-reference to § 438.16(c)(1).
- CMS finalized their proposal, in § 438.16(c)(1)(ii), that the State's actuary would have to calculate the projected ILOS cost percentage and final ILOS cost percentage on an annual basis and recalculate these projections annually. CMS finalized at § 438.16(c)(1)(iii) to require that the

projected ILOS cost percentage and the final ILOS cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. For CHIP, CMS finalized their proposal to amend § 457.1201(c) to exclude requirements for certification by an actuary.

- CMS finalized their proposal to require, at § 438.16(c)(5)(i), that States annually submit to CMS for review the projected ILOS cost percentage for each managed care program as part of the Medicaid rate certification required in § 438.7(a). CMS finalized, at § 438.16(c)(5)(ii), to require that States must submit the final ILOS cost percentage report to CMS with the rate certification for the rating period beginning 2 years after the completion of each 12-month rating period that included an ILOS(s). CMS finalized, in § 438.16(c)(4), that States provide to CMS a summary report of the actual managed care plan costs for delivering ILOSs based on claims and encounter data provided by the managed care plans to States.
- CMS finalized their proposal that the ILOS documentation States would have to submit to CMS, as well as an evaluation States would have to complete, would vary based on a State's projected ILOS cost percentage for each managed care program. CMS finalized their proposal that documentation requirements for States with a projected ILOS cost percentage that is less than or equal to 1.5 percent would undergo a streamlined review, while States with a higher projected ILOS cost percentage would have more robust documentation requirements. Additionally, CMS finalized their proposal that States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS.

Background/Rationale

Commenters generally supported the proposal that an ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i) or 1915(k) of the Act, as they believe it would implement ILOS guardrails and provide leeway under the proposed definition to include services and supports to support SDOH and HRSN efforts. Many commenters suggested revisions to the proposal that an ILOS must be approvable through another Medicaid authority or waiver. One commenter recommended revising § 438.16(b) to include services and settings approvable under Money Follows the Person while another commenter recommended using a similar set of eligibility criteria for Special Supplemental Benefits for the Chronically Ill (SSBCI) offered by Medicare Advantage plans. Some commenters stated that there should be no restriction on the types of services or settings that could be approved as an ILOS while another recommended creating an exception process for States that wanted to deviate from § 438.16(b).

CMS noted they do not believe it is appropriate to include services and settings that are approvable in Money Follows the Person as it is a demonstration program with unique funding and eligibility criteria. SSBCI is a supplemental benefit option in Medicare Advantage specifically for the certain chronically ill SSBCI-eligible plan enrollees, so they do not believe it is relevant for ILOS policy as ILOSs are not limited to a target population of the chronically ill nor a supplemental benefit. While recognizes that requiring an ILOS to be approvable as a service or setting under the State plan or waiver under section 1915(c) of the Act will place restrictions on allowable ILOSs, they believe the proposal strikes the right balance to encourage innovation while ensuring appropriate use of Medicaid and CHIP resources.

Generally, there was support for the proposed calculation and documentation of projected and final ILOS cost percentages, including the exclusion of short-term IMD stays that are ILOSs, and the summary report of managed care plans' ILOS costs. Many commenters also indicated that the definitions for the ILOS cost percentages were reasonable and appropriate.

Some commenters suggested revisions to the proposed calculations and documentation for ILOS cost percentages. CMS acknowledged that the calculation of projected ILOS cost percentages and final ILOS cost percentages will be a new State administrative burden; however, they believe it is a necessary tool to ensure appropriate Federal oversight.

Many commenters recommended revisions to the proposed 5 percent limit for the ILOS cost percentage or were in opposition to the limit. Some commenters supported a 5 percent limit on ILOS expenditures but recommended other exceptions to this limit which varied by commenter or to focus the limit on novel ILOSs. Other commenters opposed any limit of the projected ILOS cost percentage or final ILOS cost percentage. These commenters raised concerns that a fiscal limit could discourage utilization of ILOSs, reduce the use of existing ILOSs, remove State flexibility and create inequities in the ILOSs offered across States.

CMS noted that they believe that there must be appropriate and consistent fiscal guardrails on the use of ILOSs in every managed care program to ensure proper and efficient operations in Medicaid, and efficient and effective health assistance in CHIP. While they recognize that any limit imposed on ILOS expenditures in comparison to overall program expenditures will limit State and managed care plan use of ILOSs to some degree, they believe that they have an obligation to implement appropriate fiscal constraints for Medicaid and CHIP investments in ILOSs, and it is appropriate to set a limit for each managed care program so that ILOS expenditures do not grow unfettered.

Several commenters supported the annual reporting of managed care plans' ILOS costs. Some commenters supported the use of a risk-based approach for States' ILOS documentation and evaluation requirements as they believe the proposals struck the right balance between Federal oversight and State administrative burden.

Enrollee rights and protections (§§ 438.3(e), 438.10(g), 457.1201(e) and 457.1207) (pg. 484)

Finalized Changes

- CMS finalized to specify, in § 438.3(e)(2)(ii)(A), that an enrollee who is offered or utilizes an ILOS would retain all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they would retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option.
- CMS also finalized their proposal to revise § 438.10(g)(2)(ix) to explicitly require that the rights and protections in § 438.3(e)(2)(ii) be included in enrollee handbooks if ILOSs are added to a managed care plan's contract. For separate CHIP, CMS proposes to amend § 457.1207, (which includes an existing cross-reference to § 438.10) to reference instead to the separate CHIP enrollee rights and protections under subparts K and L of part 457.
- CMS finalized their proposal to add § 438.3(e)(2)(ii)(B) to ensure that an ILOS would not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and a managed care plan may not deny an enrollee access to a service or setting covered under the State plan on the basis that an enrollee has been offered an ILOS as a substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past. For separate CHIP, CMS proposes to adopt the enrollee rights and protections at § 438.3(e)(2)(ii)(A) and (B) through an existing cross-reference at § 457.1201(e) and to amend §

457.1201(e) to acknowledge that the CHIP enrollee rights and protections are unique from those offered to Medicaid enrollees and are instead located under subparts K and L of part 457.
- CMS finalized requiring clear documentation of enrollee rights and protections in States' managed care plan contracts in § 438.16(d)(1)(v). For separate CHIP, CMS proposes to adopt this requirement in managed care plan contracts by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(1)(v).

Background/Rationale
Many commenters supported the proposed enrollee rights and protections and the inclusion of these in managed care plan contracts and enrollee handbooks if ILOSs are authorized and identified in managed care plan contracts as commenters noted they believe these were reasonable and appropriate guardrails.

A few commenters recommended that CMS require States to develop a public list of available ILOSs, related targeting criteria and the managed care plans who offer them, and to conduct outreach to providers and enrollees, so that providers and enrollees understand what ILOS options may be available. CMS noted that information on ILOSs authorized by the State that their managed care plans may elect to offer, and that enrollee may choose at their option to utilize will be in the managed care plan contracts which, as required in §§ 438.602(g)(1) and 457.1285 for Medicaid and separate CHIP respectively, must be posted on their websites. They do not believe it is necessary to further mandate the use of specific education and outreach mechanisms as States are in the best position to determine what efforts are appropriate for the target population for each ILOS.

Medically appropriate and cost effective (§§ 438.16(d) and 457.1201(e)) (pg. 489)

Finalized Changes

In §438.16(d) CMS interprets medically appropriate and cost-effective substitutes in §438.3(e)(2)(i) to mean ILOSs can function as short- or long-term substitutes for State covered services or settings or when the ILOS is expected to prevent or reduce the need for State covered services or settings. This section also sets ILOS documentation requirements on ILOS contract coverage and capitation rates per §4383.(e)(2)(iv). These documentation requirements include the name and definition of each ILOS contracted, the State covered service or setting the ILOS was determined to be medically appropriate and a cost-effective substitute for, and the clinically defined target populations. While States may determine target populations, CMS requires States to outline a process for providers to determine medical eligibility for enrollees on a case-by-case basis based in sound evidence.

CMS finalized the requirement that States with ILOS cost percentages greater than 1.5% have greater required documentation and evaluation compared to States at or below an ILOS cost percentage of 1.5%. This is outlined further in final rule sections I.B.4.d and I.B.4.g. This documentation is required to be submitted alongside manage care contracts. Additionally, CMS reserves the rights to request additional documentation from States if the documentation is determined to be pertinent to the contract review and approval process.

§457.1201(e) was amended so that separate CHIPs meet the same requirements for managed care program reporting. Additionally, separate CHIPs must adopt enrollee rights and protections which is

now referenced in §438.3(e)(2)(ii)(A) and §438.3(e)(2)(ii)(B). CMS also added language to §457.1201(e) to note that separate CHIP employee rights and protections are unique from Medicaid enrollees and is outlined in §457(k) and §457(L).

Background/Rationale
Under §438.3(e)(2)(i), States may allow managed care plans to cover ILOSs if they are medically appropriate and a cost-effective substitute to existing programs. To monitor ILOS use, protect enrollee rights, ensure fiscal accountability, and promote transparency, CMS requires ILOS documentation. Historically, CMS has received insufficient detail from States when reviewing managed care plan contracts. Thus, CMS defines necessary components of contract agreements to promote transparency and accountability.

To balance fiscal safeguards and enrollee protections, CMS took a risk-based approach to required ILOS documentation and evaluation. CMS believes that ILOS cost percentage is a reasonable proxy for ILOSs in comparison to overall managed care program cost. Thus, States with an ILOS cost percentage greater than 1.5% have additional reporting requirements alongside a more robust CMS review whereas States with an ILOS cost percentage at or below 1.5% would undergo streamlined review.

Payment and rate development (§§ 438.3(c), 438.7 and 457.1201(c)) (pg. 500)

Finalized Changes
States are required to ensure ILOS utilization and actual costs are accounted for in the benefit component of capitation under §438.3(e)(2)(iv) and for separate CHIP coverage through cross-reference under §457.1201(c). §438.7(b)(6) and §438.7(c)(4) were revised such that all rate certifications submitted to CMS include contract provisions related to ILOSs. CMS also advises States' actuaries to determined and update risk adjustments appropriately if ILOS utilization is higher than initially anticipated.

Background/Rationale
Previous CMS regulation was unclear if ILOSs should be included in States' capitation rates as the regulation's language was ambiguous. Under 1902(m)(2)(A)(iii) of the Act, CMS established actuarially sound capitation rates that explicitly include ILOSs. Given ILOSs are not a requirement of managed care plans, ILOSs will not be covered under contractual requirements in §438.3(c)(2)(ii).

CMS requires contract previsions related to ILOSs are included in rate certifications so that compliance with §438.16(c)(1)(i) and §438.16(c)(5)(i) which require ILOS cost percentage to not exceed 5% of the documented rate certification. This requirement does not apply to separate CHIPs as rate certifications are not required.

State Monitoring (§§ 438.16(d) and (e), 438.66(e) and 457.1201(e)) (pg. 504)

Finalized Changes
When ILOSs are included in a managed care contract, the State must include monitoring activities of ILOSs in required activities under §438.66(b) and §438.66(c). CMS requires managed care contracts with States to include provisions allowing for enrollee encounter level data to be sent to the State at a

frequency determined by the State and CMS. Following 1903(m) of the Act, States must review and validate encounter data sent to the State completely and accurately represents the care provided.

Additionally, States are required under §438.16(d)(1)(vi) to require managed care plans to use unique CPT and HCPCS codes or modifiers to identify ILOS encounters. While reporting is not required for separate CHIPs, CMS encourages CHIPs adopt the new coding requirements.

CMS revised §438.66(e)(2)(vi) to include an explicit reference to ILOS data for inclusion in annual MCPAR performance reports.

Background/Rationale
In the 2016 final rule, CMS clarified States and CMS's oversight responsibilities in §438.66. § 438.66(b) identifies required collected data and §438.66(c) clarifies expectations for State data usage for performance and improvement. CMS is building on this oversight to include oversight of ILOSs to protect delivery of ILOSs, especially when large numbers of beneficiaries undergo coverage transition.

Specific CPT or HCPCS codes are required to ensure ILOS data is easily identifiable in T-MSIS data, support program integrity activities, and enable information to be publicly available as required. Additionally, unique CPT or HCPCS codes may make ILOS data easily identified from base data in development of capitation rates and ILOS cost percentage calculations.

The State must submit an annual performance report to CMS evaluating the accessibility and availability of covered services in each Medicaid managed care program administered by the State, referred to as the MCPAR. Given ILOSs are substitutes for State plan-covered services and settings and MCPAR content must include accessibility and availability of services in managed care plans, ILOS data should be included in MCPAR. To improve clarity to States, CMS included explicit language on ILOS data inclusion in MCPAR reports.

Retrospective evaluation (§§ 438.16(e) and 457.1201(e)) (pg. 509)

Finalized Changes
Under 1902(a)(4), 1902(a)(6), 2101(a), and 2107(b)(1) of the Act, CMS is requiring States to evaluate and demonstrate the cost-effectiveness, medical appropriateness, and efficiency of ILOSs for Medicaid and CHIP programs. CMS proposes a risk-based approach to documentation requirements based on States' ILOS cost percentage. In §438.16(e)(1) for Medicaid and cross-reference in §457.1201(e) for CHIP, CMS requires retrospective evaluations for each managed care plan that has an ILOS if the overall ILOS cost percentage is greater than 1.5% and encourages all States to conduct retrospective evaluations regardless of ILOS cost percentage. Retrospective evaluations would use data from the previous 5 years on ILOSs under §438.16(e)(1)(ii) for Medicare and cross reference in §457.1201(e) for separate CHIP. §438.16(e)(2)(ii) grants CMS the power to require States to terminate the use of ILOSs if the State is out of compliance, including if the retrospective evaluation shows unfavorable results for ILOS usage. In §438.16(e)(1)(iv) for Medicaid and with cross-reference in §457.1201(e) for separate CHIP, the States' first retrospective evaluation is to be completed beginning the first full rating period in which the ILOS was

included in the managed care contract and capitation rate following the effective date of this regulation. CMS also encourages states to consider creating a preliminary ILOS evaluation plan when making significant changes to ILOS, including implementation of new ILOS.

§438.16(e)(1)(iii) for Medicaid and cross-reference §457.1201(e) for separate CHIP requires States to use data to assess enrollee use, access, cost, appeals, complaints, and quality for each ILOS. Subsection A requires States to evaluate the impact of ILOSs on State-plan covered services or settings including cost-savings and diminished utilization of services and settings. Subsection B requires States to evaluate managed care plan trends and enrollee usage of ILOSs to evaluate enrollee access. Subsection C requires States to use encounter data 5 years after the original determination to evaluate if each ILOS is still medically accurate and a cost-effective substitute. Subsection D requires States to use validated measure sets, when possible, to evaluate quality of care of ILOSs. Subsection E requires States to provide the final ILOS cost percentage annually in their retrospective analysis required in §438.16(c)(5)(ii) with the declaration of compliance with the 5% allowable threshold required in §438.16(c)(1)(I). Subsection F requires States to evaluate grievences, appeals, and State fair hearing data separately for each ILOS. Subsection G requires States to evaluate the impact of ILOSs on health equity to mitigate health disparities by requiring managed care plans to submit enrollee encounter data that includes sex, sexual orientation, race, ethnicity, disability status, rurality, and language spoken.

§438.16(e)(1)(iv) for Medicaid with cross reference in §457.1201(e) for separate CHIP requires States to submit a retrospective evaluation of ILOSs after 2 years following the conclusion of the first 5 rating periods.

§438.16(e)(1)(v) for Medicaid with cross reference in §457.1201(e) for separate CHIP allows CMS to require States to submit additional 5-year retrospective evaluations, particularly when the initial evaluation demonstrated deficiencies.

Background/Rationale

Medicaid and CHP programs are regularly required to submit evaluations to CMS on cost or cost savings, enrollee health outcomes, or enrollee experiences for specific benefits, demonstrations, or managed care programs. Additionally, there are existing quality requirements on States who contract with managed care organizations. In line with this federal oversight, CMS is requiring States to evaluate and demonstrate ILOS quality, cost effectiveness, and medical appropriateness.

CMS acknowledges variation in ILOSs including eligible enrollees, covered services, managed care plan types, and geographic regions. Thus, CMS decided to require independent retrospective evaluations for each managed care plan with ILOSs to strengthen evaluation rigor and results. The decision determining if evaluations should be completed for each managed care plan, across managed care plans, each managed care plan contract, or at a level decided by the State was also informed by public comment.

CMS considered evaluation time frames of 1, 3, 5, and 10 years. CMS had concerns about sufficient data for meaningful analysis for the 1-year and 3-year timeframes. CMS determined a 10-year time frame was unreasonably long to obtain efficiency and effectiveness information. CMS moved forward with a

5-year reporting timeline as they believe this will offer managed care plans and enrollees time to utilize the services to generate data and offer enough time to generate robust data on cost-effectiveness and medical appropriateness for longer-term substitutes.

Other reporting periods for scope of ILOS retrospective evaluation were considered. CMS considered allowing States to identify a 5-year timeframe for evaluation but was ultimately concerned about States being incentivized to find and report on favorable timeframes to avoid termination. CMS also evaluated requiring retrospective evaluations in the year following ILOS cost percentage exceeding 1.5%, however CMS would like to identify early and baseline impacts of new ILOSs over time. The final scope is believed to be in line with best practices and CMS requested comment on timing of the evaluation period.

CMS believes that evaluation of utilization, cost, access, appeals, grievences, and quality of care will provide accurate measurements of ILOS integrity and impact and follows similar elements for programs under sections 1915(b) and 1915(c) of the Act.

Under §438.16(e)(1)(iii)(D) for Medicaid with cross reference §457.1201(e) for separate CHIP, CMS considered requiring States to use independent evaluators to evaluate ILOS quality outcomes. Ultimately, CMS was concerned about undue burden on States to procure independent evaluators partially due to the timing of final ILOS cost submissions.

CMS notes requirements to partner with EQRO under §438.364(a) and §457.1250(a) may assist States in ILOS reporting requirements and reduce administrative burden.

Under §438.16(e)(1)(iii)(F), CMS's goal with this data is to ensure enrollees' experiences with ILOSs are consistent and equitable compared to State plan services and settings. Also, CMS acknowledges some data collected in this section must be submitted through MCPAR. However, the data required in this section only pertains to ILOSs and requires more detail.

§438.16(e)(1)(iii)(G) is consistent with obligations for managed care plans under §238.242(c)(3), §457.1233(d), and §438.818. CMS also notes T-MSIS currently has fields for sex, race, ethnicity, disability status, and language spoken.

§438.16(e)(1)(v) is designed to offer States flexibility to demonstrate ILOS effectiveness for longer periods of time.

CMS recognizes the mechanism for retrospective managed cost evaluation for separate CHIP is annual which does not align with the 5-year ILOS retrospective evaluation. CMS considered requiring separate CHIP to include ILOS evaluation in the CHIP Annual Report Template System (CARTS) rather than a standalone report.

State and CMS oversight (§§ 438.16(e) and 457.1201(e)) (pg. 530)

Finalized Changes

In § 438.16(e)(2)(i)(A) and (B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, CMS finalized to require that States notify CMS within 30 calendar days if the State determines that an ILOS is no longer a medically appropriate or cost effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance in this proposed section.

In § 438.16(e)(2)(iii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, CMS finalized a process for termination of an ILOS that will apply when a State terminates an ILOS, a managed care plan elects to no longer offer an ILOS to its enrollees, or CMS notifies the State that it must terminate an ILOS. In § 438.16(e)(2)(iii)(A) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, CMS finalized to require that States establish a process to notify enrollees that the ILOS they are currently receiving will be terminated as expeditiously as the enrollee's health condition requires. CMS also finalized, in § 438.16(e)(2)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States create and make publicly available a transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to the care for any enrollees receiving an ILOS at the time of termination.

CMS finalized, in § 438.16(e)(2)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to direct States to remove the ILOS from the applicable managed care plan contracts and submit a modified contract to CMS for review and approval as required for Medicaid in § 438.3(a). Similarly, CMS permitted States, through §§ 438.3(e)(2)(iv) and § 457.1201(e), to account for the utilization and actual cost of ILOSs in developing the component of the capitation rates that represents the covered State plan services, unless a statute or regulation explicitly required otherwise.

CMS finalized in § 438.16(e)(2)(iii)(D) to direct States to adjust the actuarially sound capitation rate(s), as needed, to remove utilization and cost of the ILOS from Medicaid capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2). For separate CHIPs, States must develop capitation rates consistent with actuarially sound principles as required at § 457.1203(a).

Summarize the general themes of the comments and CMS' response to them (e.g., why did CMS change something from how it was proposed? Why did they not choose to?) You do not need to summarize every comment and response, but just those that represent bigger themes (e.g., those with several commentors). For this reason, CMS finalized to adopt § 438.16(e)(2)(iii)(D) for separate CHIP through a new cross-reference at § 457.1201(e). However, CMS notes that the requirements at § 438.7 are not applicable for part 457.

Background/Rationale
Some commenters supported the proposed State notification requirements when a State determines that an ILOS is no longer a medically appropriate or cost-effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance. The commenters stated the proposal ensured adequate notice and transparency. Many commenters also supported a required transition plan for terminated ILOS and prompt enrollee notification when an ILOS is terminated, and indicated it was appropriate oversight and transparency. CMS appreciates the support for these provisions which they believe are critical to ensure appropriate Federal oversight of ILOSs to ensure they advance the objectives of the Medicaid and CHIP programs, and properly safeguard the health and safety of Medicaid and CHIP enrollees. CMs also notes that both States and CMS can determine that an

ILOS is no longer a medically appropriate or cost-effective substitute for a State plan-covered service or setting. Further, both States and CMS can identify other areas of noncompliance.

Some commenters raised concerns with CMS's proposal that States must submit a transition plan to CMS within 15 calendar days. Several commenters indicated that 15 calendar days is not a reasonable timeframe to develop and submit a transition plan because States would struggle to collect necessary data from their managed plans, and analyze it quickly enough to develop a meaningful transition plan for the specific ILOS. CMS proposed that an ILOS transition plan be submitted within 15 calendar days of the decision by a State, managed care plan or CMS to terminate an ILOS believing that to be the most appropriate timeframe to address potential health and safety concerns. However, CMS realizes that monitoring for and addressing health and safety concerns is a routine part of managed care plan operations and is done through multiple methods such as grievance monitoring, encounter data analysis, and utilization management. After consideration of the comments, CMS is finalizing § 438.16(e)(2)(iii) to allow States up to 30 calendar days to submit an ILOS transition plan to CMS for review and approval to align with the State notification process so both of these activities, when pertinent, could occur concurrently within the same 30-day timeframe.

Applicability dates (§§ 438.3(e), 438.7(g), 438.10(g)(2)(ix), 438.16(f) and 457.1200(d)) (pg. 540)

Finalized Changes
CMS finalized as proposed that States and managed care plans would be required to comply with the provisions outlined in §§ 438.2, 438.3(c)(1)(ii) and (e)(2)(i) through (iv), 438.10(g)(2)(ix), 438.66(e)(2)(vi), and applicable cross-references for separate CHIP at §§ 457.10, 457.1201(c) and (e), and 457.1207 no later than the effective date of the final rule. Additionally, CMS finalized as proposed that States and managed care plans would comply with §§ 438.3(e)(2)(v), 438.16, and 438.7(b)(6) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule as CMSs believe this is a reasonable timeframe for compliance. CMS finalized as proposed to revise § 438.3(v) to add this proposed date, remove "July 1, 2017," and update "2015" and referenced citations; and add §§ 438.7(g)(1) and 438.16(f). Lastly, CMS finalized as proposed to adopt the applicability date at § 438.16(f) for separate CHIP by adding § 457.1200(d).

Background/Rationale
Some commenters requested that CMS delay the proposed applicability dates for ILOS provisions as they noted additional time was needed to make necessary contractual and operational changes. A few of these commenters requested delay of all ILOS provisions, one commenter requested delay of §§ 438.16(d) and 438.16(e), another recommended delay of § 438.66(c)(1), and one commenter recommended delay of § 438.66(e)(2)(vi). Other commenters were unclear which ILOS provisions they recommended be delayed. Additionally, we received commenters who requested CMS delay enforcement of the associated guidance published on January 4, 2023 until the effective date of the final rule.

CMS continues to believe that the proposed applicability dates give States ample time to comply with the proposed regulatory changes for ILOSs. On January 4, 2023, CMS published guidance to clarify the existing option for States to pursue efforts to address enrollees' unmet HRSNs, strengthen access to care, improve population health, reduce health inequities, and lower overall health care costs in Medicaid through the use of ILOSs. As the regulatory changes are generally consistent with the ILOS

guidance, CMS believes States have had ample notice and should actively be making the necessary contractual and procedural changes.

5. Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review (§§ 438.330, 438.340, 438.350, 438.354, 438.358, 438.360, 438.364, 357.1201, 457.1240 and 457.1250)

Quality assessment and performance improvement program (§ 438.330) (pg. 542)

Finalized Changes

The finalized changes to the regulations at § 438.330(d)(4) involve updating references to reflect the removal of the Quality Improvement Project (QIP) requirement and its replacement with the Chronic Care Improvement Program (CCIP) for Medicaid managed care plans exclusively serving dually eligible individuals. This update aligns with previous changes made in the 2019 Final Rule, which eliminated the QIP requirement for Medicare Advantage (MA) organizations, recognizing the complexity and redundancy of the QIP and CCIP requirements. Consequently, the regulation now allows States to permit these Medicaid managed care plans to substitute an MA plan's CCIP, conducted under § 422.152(c), for one or more Performance Improvement Projects (PIPs) mandated under § 438.330(d). This change is effective immediately upon the final rule's enactment, eliminating the need for a separate applicability date since the substitution is optional for plans.

Background/Rationale

The rationale behind these regulatory changes stems from the evolution of quality improvement requirements for Medicare and Medicaid managed care plans. Initially, MA organizations were required to implement both Quality Improvement Projects (QIPs) and Chronic Care Improvement Programs (CCIPs). However, due to the complexity and overlapping nature of these programs, the Centers for Medicare & Medicaid Services (CMS) removed the QIP requirement in the 2019 Final Rule. Despite this removal, an outdated reference to the QIP persisted in § 438.330(d)(4) for Medicaid managed care plans serving dually eligible individuals. The proposed rule aimed to rectify this by allowing these plans to use a CCIP instead of a PIP, thereby reducing unnecessary duplication and increasing flexibility. Public comments largely supported this update, emphasizing the benefits of streamlined and efficient quality improvement processes. This change ensures that Medicaid managed care plans can maintain robust health improvement initiatives for dually eligible individuals without the burden of redundant requirements.

Managed Care State Quality Strategies (§§ 438.340 and 457.1240) (pg. 546)

Finalized Changes

The finalized changes to § 438.340 involve several updates to increase transparency and enhance public engagement in the development and revision of States' Medicaid managed care quality strategies. States must now make their quality strategies available for public comment every three years, regardless of whether significant changes are proposed. Additionally, States must post the full results of their three-year evaluation of the quality strategy on their website and submit these evaluations to CMS at least every three years. A technical correction was made to § 438.340(c)(3)(ii), replacing an incorrect internal citation to ensure accuracy. These changes apply equally to separate

CHIP through existing cross-references and must be implemented no later than one year from the final rule's effective date.

Background/Rationale

The rationale for these updates is to foster greater transparency and ensure ongoing public and CMS engagement in the continuous improvement of managed care quality strategies. Previously, States were only required to seek public comment when significant changes were made, potentially allowing important revisions to occur without public input. By mandating public comment every three years and requiring the posting of evaluation results, the new regulations aim to keep quality strategies dynamic and responsive to changing needs. These measures also provide CMS with regular opportunities to review and suggest improvements to States' quality strategies, further aligning them with federal standards and expectations. Public feedback generally supported these proposals, emphasizing the need for greater clarity and accountability in the quality strategy process. Despite some concerns about potential burdens on States, the changes were finalized as proposed, with the belief that they enhance the effectiveness and transparency of managed care programs.

External Quality Review (§§ 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240 and 457.1250) (pg. 550)

Finalized Changes

(1) Removal of PCCM entities from scope of mandatory External Quality Review

The finalized changes remove Primary Care Case Management (PCCM) entities from the mandatory scope of External Quality Review (EQR) requirements. Previously, PCCM entities, defined as organizations providing additional case management functions under risk-bearing contracts, were subject to annual EQRs, similar to managed care entities. The 2016 rule had required this due to the financial risk these entities bore. However, the final rule now exempts PCCM entities from mandatory EQR activities, including performance measure validation and performance improvement projects. Instead, the updated regulations allow States the discretion to monitor these entities, including the option to continue using EQR methods if desired. Conforming amendments were made to various sections of the regulations to reflect these changes, emphasizing the optional nature of performance measure validations for PCCM entities and ensuring independent reviews by EQROs where applicable.

(2) EQR review period

The finalized changes aim to standardize the review period for External Quality Review (EQR) activities to enhance consistency and the use of recent data in annual EQR reports. A new paragraph (§ 438.358(a)(3)) defines a 12-month review period for most EQR activities, starting from the beginning of the most recent contract or calendar year. This applies to mandatory activities such as the validation of performance improvement projects, performance measurement data, and network adequacy activities. The final rule mandates that these EQR activities be performed in the 12 months preceding the finalization and publication of the annual report, promoting the use of the most up-to-date information. However, in response to public comments, optional EQR activities are exempted from this 12-month review period, allowing States flexibility in determining appropriate review periods for these activities. Conforming changes were made to various sections, and the new requirements must be implemented by December 31, 2025, for both Medicaid and CHIP programs.

(3) Using an optional EQR activity to support current and proposed managed care evaluation requirements

The finalized changes introduce a new optional External Quality Review (EQR) activity aimed at assisting states in evaluating quality outcomes, timeliness, and access to care within managed care plans and programs. This activity, detailed in § 438.358(c)(7), supports the evaluation of state quality strategies, State Directed Payments (SDPs), and In Lieu of Services or Settings (ILOSs) as mandated in the final rule. States can now utilize an EQR organization (EQRO) to perform these evaluations, leveraging the expertise of EQROs in research design, statistical analysis, and quality assessment. This optional activity is expected to provide technical assistance, enhance transparency, and improve quality, while also offering an enhanced federal funding match for states that opt to use EQROs for this purpose. While states have the flexibility to conduct these evaluations themselves, the protocol developed by CMS will aid those that choose to engage EQROs. The rule clarifies that this does not necessitate a new competitive procurement for EQRO contracts, provided compliance with state procurement laws. The finalized changes are effective immediately, with the new evaluation requirements incorporated into the existing EQR structure for both Medicaid and separate CHIP.

(4) Non-duplication of mandatory EQR activities with Medicare or accreditation review

The finalized changes remove the requirement for Private Accreditation Organizations (PAOs) to obtain Medicare Advantage (MA) deeming authority from CMS in order for states to use their accreditation reviews in place of mandatory EQR activities. Previously, under § 438.360(a)(1), states could exempt MCOs, PIHPs, or PAHPs from duplicative EQR activities if the plan accreditation was conducted by a PAO recognized by CMS with MA deeming authority. The new regulation at § 438.360(a)(1) eliminates this prerequisite, thus reducing the administrative burden on CMS and PAOs, and allowing states more flexibility in leveraging PAO accreditation reviews for non-duplication of mandatory EQR activities. Conforming changes were also made to § 438.362(b)(2) to remove references to MA deeming authority, ensuring a streamlined process for states to use accreditation data.

(5) External quality review results (§ 438.364)

(a) Data included in EQR technical reports

CMS has finalized changes to § 438.364(a)(2)(iii) to expand the scope of data included in the EQR technical reports. The revised regulation now requires the reports to include outcomes data and results from quantitative assessments, in addition to validated performance measurement data for PIPs and network adequacy. These updates aim to provide more meaningful reports that support quality improvement and oversight in managed care. CMS also sought comment on adding guidance in the EQR protocols for stratifying performance measures, which received support for enhancing health disparity monitoring and aligning with Medicaid and CHIP Core Sets requirements.

(b) Revising the date annual EQR technical reports must be finalized and posted

CMS has decided not to finalize the proposed changes to § 438.364(c)(1) regarding the due date for EQR technical reports. The current requirement remains in place, requiring that these reports be completed and available on the State's website by April 30th of each year. CMS initially proposed changing this date to December 31st annually to better align with the availability of finalized HEDIS performance measures, but concerns raised in public comments regarding the feasibility and operational burden of this change led to the decision to maintain the current due date.

(c) Notifying CMS when annual EQR technical reports are posted

CMS has finalized the requirement that States must notify CMS within 14 calendar days of posting their EQR technical reports on their website, as proposed in § 438.364(c)(2)(i). This change aims to facilitate CMS's review and aggregation of required data for the annual report to the Secretary, as mandated by section 401 of the Children's Health Insurance Reauthorization Act (CHIPRA) of 2009 and section 2701 of the ACA. This requirement will apply to separate CHIP through an existing cross-reference at § 457.1250(a).

(d) Revising website requirements for historical EQR technical reports

CMS has finalized the requirement that States maintain at least the previous 5 years of EQR technical reports on their website, as proposed in § 438.364(c)(2)(iii). This change aims to enhance transparency and administrative efficiencies by providing historical data for review during managed care program and plan performance evaluations, contract renewals, and waiver renewals.

Background/Rationale

(1) Removal of PCCM entities from scope of mandatory External Quality Review

The rationale behind removing PCCM entities from mandatory EQR requirements stems from the variability in the size, structure, and services provided by these entities, which questioned the appropriateness and effectiveness of EQR as an oversight tool. Many PCCM entities are small providers, and the burden and cost of mandatory EQR could disincentivize them from engaging in risk-bearing contracts aimed at improving quality and outcomes. Additionally, the existing quality monitoring tools, such as Quality Assessment and Performance Improvement (QAPI) program reviews and other oversight mechanisms, were deemed sufficient. Public comments supported this removal, citing flexibility for States and reducing administrative burdens.

(2) EQR review period

The rationale for these changes stems from the need to address inconsistencies in the review periods reported in States' annual EQR technical reports. Previously, the regulations did not specify which 12-month period should be used for EQR activities, leading to significant variability in reporting periods. This lack of uniformity diminished the utility of EQR reports for quality improvement and oversight. The proposed changes were intended to align the review periods with the most recent data, enhancing the relevance and comparability of the reports. Public comments supported the use of recent data and standardization of review periods, although concerns were raised about the feasibility of completing some EQR activities within 12 months. Consequently, the final rule retains the 12-month period for mandatory activities but allows flexibility for optional activities to accommodate longer evaluation periods required for certain quality strategies.

(3) Using an optional EQR activity to support current and proposed managed care evaluation requirements

The rationale behind these changes is to address the identified challenges states face in evaluating SDPs and ILOSs, and to provide additional support in implementing effective quality strategies. CMS reviews and stakeholder feedback revealed that states often struggle with evaluation plans and results, indicating a need for greater technical assistance. By adding this optional EQR activity, CMS aims to offer states a structured, protocol-based approach to these evaluations, ensuring more robust and meaningful assessments. The competencies of EQROs, such as research design and quality improvement methodologies, make them well-suited to support these evaluations. The inclusion of this optional activity also responds to public comments emphasizing the importance of flexibility for states and the capability of existing EQRO vendors.

(4) Non-duplication of mandatory EQR activities with Medicare or accreditation review

The rationale for this change is to address the unnecessary administrative burdens imposed by the previous regulation. CMS observed that requiring PAOs to obtain and periodically renew their MA deeming authority created inefficiencies and restricted the availability of the EQR non-duplication option for states. Additionally, CMS believes the requirement was not mandated by statute. Section 1932(c)(2)(B) of the Act allows states to use private accreditation reviews to avoid duplicative EQR activities but does not explicitly require PAOs to have MA deeming authority. By removing this

requirement, the change aligns the regulation more closely with the statutory intent, which is to facilitate the use of PAO reviews in lieu of duplicative EQR activities.

(5) External quality review results (§ 438.364)

(a) Data included in EQR technical reports

Section 438.364 currently outlines the content requirements for EQR technical reports, including validated performance measurement data for PIPs and the public availability of these reports. CMS identified limitations in the existing regulations, which focused primarily on data validation rather than outcomes of PIPs and network adequacy. The proposed changes were designed to address these limitations by ensuring that the reports include outcome data and quantitative assessment results. Public comments generally supported these changes, citing potential improvements in report utility and data accessibility for quality improvement purposes.

(e) Revising the date annual EQR technical reports must be finalized and posted

Currently, § 438.364(c) mandates that EQR technical reports must be completed and posted on the State's website by April 30th of each year. CMS proposed changing this date to December 31st to better align with the availability of HEDIS performance measures, which are finalized in June annually. The rationale behind the proposal was to ensure that the EQR technical reports include the most recent data possible, improving their utility for States, CMS, and other interested parties. However, public comments highlighted significant challenges associated with the proposed change, including increased costs, potential data reporting lags, and the tight timeline for completing EQR activities. Based on these comments, CMS has decided not to proceed with the proposed change and will explore other means to enhance the timeliness and actionability of EQR reports in the future.

(f) Notifying CMS when annual EQR technical reports are posted

CMS currently does not require States to notify CMS when their EQR technical reports are posted on their website. To align with statutory requirements and improve efficiency, CMS proposed revising § 438.364(c)(2)(i) to mandate that States notify CMS within 14 calendar days of posting their reports. Public comments generally supported this proposal, noting it would enhance transparency and streamline the review process.

(g) Revising website requirements for historical EQR technical reports

Currently, States are encouraged but not required to retain EQR technical reports from previous years on their websites. CMS proposed to require States to maintain at least the previous 5 years of these reports to improve transparency and allow for historical analysis of plan performance. Public comments supported this change, suggesting it would aid in tracking responses to recommendations and monitoring changes in quality performance. While some commenters requested extending the requirement to 10 years, CMS decided to finalize the requirement at 5 years for now, considering the variable length and content of EQR reports across States.

6. Medicaid Managed Care Quality Rating System (§§ 438.334 and 457.1240) (pg. 573)

Definitions (§§ 438.334, 438.500 and 457.1240(d)) (pg. 582)

Finalized Changes

In the final rule, several technical and other terms were defined for both Medicaid and separate CHIP programs, with additional details provided later in the document for relevant proposals. Definitions included terms like "Measurement period" and "Measurement year" related to data collection, as well as

frameworks such as the "Medicaid managed care quality rating system" and the "Medicare Advantage and Part D 5-Star Rating System." Corrections were made to ensure consistency, such as updating "Qualified health plan rating system" to "Qualified health plan quality rating system." These definitions were finalized without public comment, and CHIP managed care programs will adhere to the same quality rating system rules as Medicaid, except where explicitly noted, as cross-referenced in the final rule.

General Rule and Applicability (§§ 438.334(a), 438.505(a) and 457.1240(d)) (pg. 584)

Finalized Changes

CMS finalized several key aspects regarding the implementation and operation of the Medicaid and CHIP Quality Rating System (MAC QRS). Firstly, CMS extended the implementation timeline for the MAC QRS by an additional year, providing states with four calendar years following the publication of the final rule to fully comply. Secondly, CMS introduced provisions allowing states to request a one-time, one-year extension for specific MAC QRS requirements, such as methodology and website display, in cases where states faced identified barriers to implementation. Detailed plans outlining steps taken and remaining, along with explanations for the inability to comply by the original deadline, were required for extension requests. Additionally, CMS clarified the scope of flexibility for states regarding the methodology used in the QRS and affirmed states' ability to display additional quality measures and website features beyond the mandatory minimum measures specified by CMS. Lastly, CMS emphasized the severability of provisions within the MAC QRS, ensuring continued functionality even if specific aspects faced legal challenges or were deemed invalid.

Background/Rationale

CMS received various comments regarding the implementation timeline and alignment of the Medicaid and CHIP Quality Rating System (MAC QRS) with existing CMS quality measurement and rating initiatives. Many commenters supported the proposal to extend the implementation date for the MAC QRS, expressing concerns about the burden on states, health plans, and providers, while others urged for accelerated implementation or further extensions. Several commenters suggested challenges in meeting the implementation dates, particularly in data collection for certain beneficiaries and requested phased implementation of mandatory measures. Additionally, commenters overwhelmingly supported alignment of the MAC QRS with existing CMS initiatives to reduce burdens, emphasizing the importance of consistency and coordination across quality measurement efforts. In response, CMS finalized the extension of the implementation timeline by an additional year and introduced provisions allowing states to request extensions for specific MAC QRS requirements. Furthermore, CMS affirmed its commitment to alignment with existing initiatives, clarifying flexibility for states and ensuring continued functionality of the MAC QRS even if specific provisions faced legal challenges.

Establishing and Modifying a Mandatory Measure Set for MAC QRS (§§ 438.334(b), 438.510 and 457.1240(d)) (pg. 593)

Finalized Changes

CMS finalized modifications to the feasibility criterion for measure selection to explicitly include consideration of provider burden, ensuring a comprehensive assessment process. They clarified the process for assessing administrative burden associated with potential measures, emphasizing stakeholder input and consideration of relevant information. Additionally, CMS declined to add suggested criteria, such as NQF endorsement and outcomes-based measures, as mandatory, citing the existing flexibility and comprehensive evaluation process. Furthermore, CMS affirmed their commitment

to gathering diverse viewpoints through the subregulatory process to inform decisions regarding measure inclusion in the mandatory set.

CMS finalized several changes regarding the implementation of new measures and the composition of the mandatory measure set for the MAC QRS. Firstly, they declined the suggestion to implement a 2-year pilot period for new measures, instead emphasizing the importance of established selection criteria and flexibility in determining implementation timelines. They also modified the alignment measure selection criteria to accommodate HCBS measures, recognizing their unique nature. Additionally, CMS finalized the initial set of 18 mandatory measures, which cover a wide range of preventive and chronic care measures. They provided detailed explanations for measures included and excluded from the initial set, considering factors such as feasibility, alignment with other programs, and stakeholder feedback. Finally, CMS clarified that the mandatory measure set will include only measures calculated using CMS-specified technical specifications to ensure uniformity and consistency in reporting across Medicaid programs.

In response to comments, CMS finalized the inclusion of specific measure topics in the MAC QRS mandatory measure set, emphasizing the relevance of measures addressing health outcomes, health equity, and EPSDT services. While acknowledging suggestions for additional measures, CMS opted not to add new measures at this time, citing the need for further input and adherence to selection criteria. Measures such as HIV Viral Load Suppression and Adherence to Antipsychotic Medications for Schizophrenia were declined due to feasibility and burden concerns, while others were excluded to maintain balance and alignment with existing measures. CMS also addressed requests for removal and replacement of certain measures, retaining those deemed appropriate based on alignment, feasibility, and burden considerations. Regarding MLTSS measures, CMS decided not to include proposed measures at this time, opting to evaluate them further through the subregulatory process. Additionally, CMS provided guidance on ECDS measures, affirming their inclusion while offering technical support to address implementation challenges.

CMS finalized changes including support for the inclusion of AHRQ CAHPS measures in the mandatory measure set, with suggestions to improve response rates through flexible surveying methods. CMS plans to work with AHRQ on long-term solutions for CAHPS. The alignment of patient experience survey questions between Medicaid and Medicare is acknowledged, and guidance will be provided on handling situations with fewer than 100 responses. States will have flexibility to include additional measures in their MAC QRS, with encouragement to limit the list to under 30 measures. CMS aims to preserve State flexibility while encouraging collaboration and monitoring the validity of measures. Sixteen measures are finalized for inclusion in the mandatory measure set, with flexibility for updates over time. The finalized measures table incorporates necessary updates and corrections.

CMS finalized changes to include the adoption of a subregulatory process for updating the mandatory measure set, with engagement from States and interested parties every other year. This process involves evaluating the current measures, gathering recommendations, and providing public notice and comment before finalizing any changes. The subregulatory process aims to ensure flexibility and responsiveness to changes in the quality field and user preferences. While most commenters supported the proposed biennial schedule for updates, some recommended more frequent updates. However, CMS decided to maintain the biennial timeframe but clarified that updates may not be necessary every two years. Consistent schedules for public notice and comment were emphasized to allow adequate time for health plans to respond to proposed changes. Overall, the finalized process aims to gather

diverse input and ensure that the mandatory measure set reflects important quality metrics in Medicaid and CHIP managed care programs.

CMS finalized further changes involving the subregulatory process for updating the mandatory measure set, particularly regarding engagement with States and interested parties. Commenters generally supported this process and suggested additional types of engagement, such as listening sessions with health plans or involving the existing Core Sets Annual Workgroup. However, CMS decided against establishing specific procedures, believing that the proposed subregulatory process allows for sufficient flexibility and input. The finalized provisions also include criteria and standards for adding mandatory measures, with CMS determining eligibility based on input gathered through the subregulatory process. Specifically, CMS illustrated this process with the example of adding measures related to follow-up care for mental illness, demonstrating how the proposed criteria were applied. Since there were no comments received regarding adding mandatory measures, these provisions were finalized as proposed.

CMS finalized provisions for removing existing mandatory measures from the Medicaid and CHIP Quality Rating System (MAC QRS) based on specified reasons. These provisions include criteria for determining when a measure should be removed, such as if the measure steward retires or stops maintaining a measure, if clinical guidelines associated with the measure change in a way that no longer aligns with positive health outcomes, or if the measure shows low statistical reliability. Additionally, CMS clarified that CBE endorsement is not required for MAC QRS mandatory measures and outlined how information from the CBE process could be considered in determining whether a measure should be removed. Furthermore, CMS addressed comments regarding reliability standards, indicating an intention to align with existing CMS policy while considering recommendations for assessing statistical reliability. Overall, CMS finalized these provisions to ensure the integrity and effectiveness of the MAC QRS.

CMS finalized rules for updating mandatory measures in the MAC QRS, which include both adding and removing measures as well as handling updates to existing measures' technical specifications. They proposed different processes for handling non-substantive and substantive updates to measure specifications. Non-substantive changes, such as clarifications or updates to clinical codes, would be incorporated without additional review. However, substantive updates would undergo a subregulatory process involving consultation with States, interested parties, and the public. Despite not receiving comments on these proposals, CMS finalized them as proposed. Additionally, they clarified that CMS being the measure steward is not a consideration for updates to existing measures.

CMS finalized rules regarding the communication and implementation timeline for modifications to the mandatory measure set in the MAC QRS. They proposed using the technical resource manual to communicate changes and giving States at least 2 calendar years from the start of the measurement year to implement these modifications. This timeline applies to both new measures and substantive updates to existing measures. CMS believes this timeframe allows States sufficient time for operational adjustments. They also proposed releasing the technical resource manual annually, regardless of modifications to the mandatory measure set, to address non-substantive changes or removals. Despite not receiving comments on these proposals, CMS finalized them as proposed.

Background/Rationale
CMS received numerous comments regarding the standards for measure selection, with overall support for the proposed measure selection criteria. However, some commenters suggested revisions to ensure consideration of provider burden and the feasibility of data collection, particularly in chart review

abstraction. In response, CMS agreed to modify the feasibility criterion to explicitly include provider burden considerations, ensuring a comprehensive assessment of feasibility that encompasses states, plans, and providers. Additionally, CMS clarified the process for assessing administrative burden associated with potential measures, emphasizing the importance of stakeholder input through a subregulatory process and the consideration of relevant information in decision-making. CMS also addressed suggestions for additional criteria, such as requirements for NQF endorsement, outcomes-based measures, and validation, auditing, and public reporting. While CMS acknowledged the importance of these considerations, it declined to add them as additional selection criteria, emphasizing the existing flexibility and comprehensive evaluation process outlined in the final rule. Lastly, CMS declined suggestions to make certain criteria mandatory, highlighting the need for flexibility in measure selection and the lack of consensus among commenters. Instead, CMS affirmed its commitment to gathering diverse viewpoints through the subregulatory process to inform decisions regarding measure inclusion in the mandatory set.

MAC QRS Methodology (§§ 438.334(d), 438.515 and 457.1240(d)) (pg. 654)

Finalized Changes
CMS finalized the proposal regarding the communication of modifications to the mandatory measure set and the timeline for implementation, stipulating that States would have at least 2 calendar years from the start of the measurement year following the technical resource manual to display measurement results and ratings using new or updated measures. They also finalized the regulations regarding the finalization and display of mandatory measure updates as proposed.

CMS finalized the requirement for states to calculate and report quality ratings for Medicaid managed care plans based on specific mandatory measures, addressing concerns about the inclusion of Medicaid Fee-For-Service (FFS) requirements. They emphasized that their rule does not mandate FFS reporting but rather ensures comprehensive quality measurement by allowing data coordination between managed care plans and FFS providers where necessary. The finalized rule specifies limited FFS data needed for certain measures, aiming for inclusivity of all managed care beneficiaries. Moreover, CMS highlighted the flexibility for states to provide explanatory information in their reporting and website displays, encouraging additional clarity for users. They acknowledged comments regarding the undue burden standard for data collection and affirmed their commitment to providing technical assistance to address challenges faced by states. Additionally, CMS adjusted the minimum enrollment threshold policy to align with other CMS quality rating programs and emphasized the importance of privacy and validity standards when reporting measures with low denominator sizes. They also addressed concerns about data exchange confidentiality, indicating plans to provide technical assistance tailored to each state's unique circumstances.

CMS finalized several changes in response to comments regarding the validation of data for Medicaid managed care quality ratings. Commenters supported the proposal to validate data prior to displaying quality ratings, seeking clarification on the role of External Quality Review Organizations (EQROs) and whether states could allow plans to calculate and report their own ratings for certain measures. CMS agreed that data validation is crucial for trust in quality ratings, allowing states flexibility in data collection and validation methods, including utilizing EQROs or plans themselves. The finalized rule modified language to remove mandates for states to directly perform data collection and calculation, enabling plans or EQROs to undertake these tasks. However, plans are barred from validating their own data due to potential bias. States are tasked with issuing quality ratings based on plans' contractual

responsibilities, ensuring fairness. Moreover, CMS acknowledged support for percentage quality ratings and domain level ratings in the future, promising consideration of beneficiaries' preferences. Regarding dually eligible individuals, CMS clarified that states should include them in ratings when the assessed service aligns with Medicaid coverage, providing flexibility while aiming for inclusivity. Additionally, CMS addressed concerns about the timeframe for including dually eligible individuals, offering a one-year implementation extension upon state request. CMS affirmed assigning ratings at the plan level by managed care program, without providing an expanded definition for "managed care program" beyond existing regulatory language, with intentions to offer guidance aligning with current practices.

CMS finalized the requirement for states to ensure the inclusion of all enrollees in Medicaid managed care plan ratings issued for each plan and to issue ratings at the plan level by managed care program. Responding to concerns raised by commenters regarding compliance challenges, CMS introduced the option for states to request a one-time, one-year extension for meeting the MAC QRS methodology requirements. The extension request process includes specific criteria for submission, including identifying the requirement for extension, steps taken to meet it, barriers faced, and a detailed plan for implementation. The deadline for extension requests is set for September 1 of the fourth calendar year following the effective date of the final rule. Additionally, CMS made modifications to § 438.515(a) to clarify delegation practices, specifying that quality ratings are issued by the state for each managed care plan. Other modifications include clarifications on undue burden standards for excluding data and requirements for validation of performance rate data. A new paragraph (d) was added to provide states with an opportunity to request an extension of the deadline for issuing the first quality ratings. Finally, provisions on State alternative methodologies and domain level ratings were finalized.

Background/Rationale
Several commenters supported the use of additional data sources, including Medicaid FFS and Medicare data, to calculate mandatory measures, while others expressed concerns about the feasibility and validity of such an approach. CMS acknowledged the support for the proposal and emphasized its intent to ensure comprehensive quality measurement. They addressed concerns about undue burden by affirming the gradual implementation of data collection requirements and clarifying that the standard of "to the extent feasible without undue burden" would apply. Additionally, CMS clarified that only measures applicable to a state's managed care program would be included in the MAC QRS, addressing concerns about the inclusion of irrelevant measures.

CMS received comments addressing various concerns and suggestions regarding the finalized measures for Medicaid managed care quality reporting. One commenter questioned the appropriateness of including requirements for Medicaid Fee-For-Service (FFS) in a Medicaid managed care final rule, prompting CMS to clarify that their rule does not mandate FFS reporting but rather ensures comprehensive quality measurement through data coordination between managed care plans and FFS providers where necessary. Another commenter requested flexibility for states to provide explanatory information in their reporting and website displays, which CMS acknowledged and encouraged. Several commenters expressed appreciation for the undue burden standard proposed to limit data collection requirements, with CMS agreeing to consider factors such as Medicaid agency administrative capacity and system burden when determining undue burden. Moreover, comments were made regarding the minimum enrollment threshold, leading CMS to modify the policy to align with other CMS quality rating programs. Additional concerns raised included the impact of low denominator sizes on rating validity and privacy, to which CMS assured adherence to data suppression policies. Comments also highlighted challenges related to data exchange confidentiality, prompting CMS to

emphasize their commitment to providing technical assistance tailored to each state's unique circumstances.

Commenters expressed support for the proposal to validate data prior to displaying quality ratings, emphasizing the importance of trust in the ratings' integrity. They sought clarification on the role of External Quality Review Organizations (EQROs) and whether states could allow plans to calculate and report their own ratings for certain measures. Additionally, commenters raised concerns about how states would validate Medicare Advantage data and recommended the provision of a standard data set and technical assistance. Some commenters expressed concerns about potential confusion arising from duplication between the Medicaid managed care quality rating system (MAC QRS) and the Medicare and Part C quality rating system. Many commenters requested additional guidance and technical assistance related to the inclusion of dually eligible beneficiaries in MAC QRS ratings, including clarification on how dually eligible individuals would be included in MAC QRS measures and the timeframe for implementation. Several commenters supported assigning MAC QRS ratings at the plan level by managed care program, noting its potential benefits for beneficiaries and effective management of Medicaid programs.

Several commenters expressed concerns about the ability of states and managed care plans to meet the MAC QRS methodology requirements by the implementation deadline, citing challenges in data collection and integration. Some suggested a voluntary performance year before mandating MAC QRS implementation to allow for issue identification and resolution. In response, CMS clarified the extension request process, allowing states to request a one-time, one-year extension to meet the requirements. This extension request involves specific criteria, including identifying the requirement, steps taken, barriers faced, and a detailed implementation plan. The deadline for extension requests is set for September 1 of the fourth calendar year following the effective date of the final rule. Additionally, CMS made modifications to clarify delegation practices and ensure quality ratings are issued by the state for each managed care plan. Other adjustments were made to address concerns about undue burden standards for excluding data and validation requirements.

MAC QRS Website Display (§§ 438.334(e), 438.520(a), 428.520(b), 457.1240(d)) (pg. 699)

Finalized Changes
CMS finalized MAC QRS website requirements in § 438.520 as part of FFP available for the State's Medicaid Enterprise System (MES).

CMS finalized, with modifications, § 438.520(a)(6)(i) and (ii) to require these search tools only for managed care programs with greater than one plan. CMS finalized, with revisions, the proposal at 438.520(a) to incorporate language about the requirements described in § 438.520(a) that must be both prominently displayed and accessible to the public on the website required under § 438.10(c)(3).

CMS finalized, as proposed, § 438.520(a)(1)(i) that States must provide users with information necessary to navigate the MAC QRS display.

CMS also finalized, with revisions, § 438.520(a)(1)(iii) to avoid implying that States may require users to provide log-in credentials before utilizing or accessing a State's QRS. CMS finalized § 438.520(a)(1)(iii) that when individuals are prompted to input user-specific information, the State must provide a rationale regarding why the information is needed, how it will be used, and whether it is optional or

mandatory to access a QRS feature or particular information type. CMS described that it intends to offer technical guidance and assistance to States on how to create such a site or adjust an existing one, minimizing redundancy.

CMS finalized § 438.520(d), to regularly consult with stakeholders to assess website display requirements and to ensure that there is continued alignment with beneficiary preferences. CMS also finalized 438.520(b), that States can submit a request for a one-time, one-year extension for the website display requirements specified at § 438.520(a)(2)(v) and (a)(6).

CMS finalized that an extension request for a requirement under § 438.520 should incorporate information described in § 438.515(d)(1) and that CMS will evaluate the request using the same standards and conditions finalized at § 438.515(d)(3). CMS finalized the deadlines by which a State must submit an extension request for a website display requirement, depending on if the requirement was implemented in phase 1 or phase 2 of the website display implementation.

CMS finalized, as proposed, § 438.520(a)(5) that States would be required to provide users with information or hyperlinks that direct users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan.

CMS finalized, with modifications, § 438.520(a)(6) to limit the scope of the requirements proposed in § 438.520(a)(6)(i) and (ii) that States would be required to display a search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user and a search tool that enables users to identify available managed care plans that include a specific provider in the plan's network. CMS noted that in the final rule, it is applying these requirements only to managed care plans that participate in managed care programs with two or more participating plans.

CMS finalized, with modifications, § 438.520(a)(3)(iv) that CMS will require States to include on the MAC QRS website, in addition to presenting a summary of benefits that contains differences in benefits among the managed care plan options within a single program, other similar information on benefits including information as to whether access to the benefit requires prior authorization from the plan.

CMS finalized, with modifications, provisions at § 438.520(c)(2) to address the addition of new paragraph § 438.520(b) finalizing an implementation extension for certain website requirements. CMS is also modifying paragraph (c) to clarify that States may implement additional website features not described in § 438.520(a) in their MAC QRS, including the display of additional measures not included in the mandatory measure set.

Background/Rationale
Many commenters supported the CMS decision to incorporate a website display with clearly defined components in the framework for the MAC QRS.

CMS addressed concerns raised by commentators regarding the inclusion of State or national benchmarks and how they could help users understand displayed quality ratings. CMS indicated it would consider requiring benchmarking of the quality ratings in future rulemaking.

Several commenters supported the CMS requirement to display quality ratings for mandatory measures that are stratified by factors identified by CMS. Commenters noted current challenges related to reporting high-quality, reliable data to stratify quality measures and requested CMS collaborate with

States and other stakeholders to improve data collection. CMS responded that it would provide guidance to support States in collecting data necessary to implement CMS required stratification factors.

Commenters recommended adding plan comparison information about the accessibility of covered benefits, such as an indication of the services and drugs that require prior authorization by the plan and appointment wait times. CMS agreed, and modified the proposal to add discretion for CMS to specify information on benefits to be included on the website such as whether access to the benefit requires prior authorization from the plan.

Alternative Quality Rating System (§§ 438.334(c), 438.525 and 457.1240(d)) (pg. 727)

Finalized Changes
CMS finalized, with modifications, how the alternative QRS requirements are articulated and organized in the rule. CMS finalized, with modifications, the QRS provision in § 438.525 by removing references to "alternative MAC QRS" and using the term "alternative QRS methodology" instead in the regulation text. CMS finalized the requirements in § 438.515(c) to receive approval to apply an alternative QRS methodology in part 438.

CMS finalized a modification at § 438.505(a)(1)(i) to reflect the updated placement of the provisions regarding the alternative QRS methodology.

CMS finalized a new provision at § 438.515(c)(3), to enhance clarity regarding the extent of flexibility in implementing an alternative methodology and reduce burdens on States to help them ensure that they do not design a MAC QRS that does not comply with the general rule in § 438.505(a). CMS finalized that it will not review or approve requests to implement a MAC QRS if states do not comply with the requirements to include mandatory measures established in § 438.510(a)(1), the general requirements for calculating quality ratings established in § 438.515(a)(1) through (4), or the requirement to include the website features identified in § 438.520(a)(1) through (6). CMS finalized that it will not review or approve requests to implement additional measures or website features as these are permitted, without CMS review or approval, as established in § 438.520(c) and requests to include plans that do not meet the threshold established in 483.515(a)(1)(i).

CMS stated that it did not finalize the proposed § 438.525(a)(1) because it is duplicative of the finalized § 438.510(a)(1).

To address technical errors in the proposed rule, CMS finalized, with modifications, § 438.525(a) (moved to § 438.515(c)(1) in the final rule), which allows States to implement a MAC QRS that applies an alternative methodology from that described in § 438.510(a)(3).

Background/Rationale
CMS responded to a comment about renaming MCAC (Medical Care Advisory Committee) by removing reference to MCAC in the final rule.

Commenters expressed confusion about the scope of the alternative methodology and CMS made modifications to the final rule for clarification.

Annual Technical Resource Manual (§§ 438.334, 438.530 and 457.1240(d)) (pg. 736)

Finalized Changes
CMS finalized, with modifications, that CMS may publish the technical resource manual information identified in § 438.530(a) in installments during the year to allow CMS flexibility to publish individual pieces of information identified in § 438.530(a) as these pieces become available. CMS finalized, with modifications, § 438.530(a) and changed the release date of the first complete technical resource manual from August 1, 2025, to CY 2027.

CMS finalized, with modifications, the requirement for CMS to publish the information specified in paragraph § 438.530(a)(1) no later than August 1, 2025.

CMS finalized, with technical changes, § 438.530(a)(4) to indicate that a summary of public feedback would be integrated in the technical resource manual during the years when the engagement with stakeholders takes place.

Background/Rationale
Many commenters requested that the technical resource manual information be released earlier than 5 months prior to the measurement year. CMS agreed and modified how the technical resource manual information will be released.

Commenters also requested that CMS release information as soon as possible and CMS agreed and modified the release of technical specifications.

CMS noted that it will continue to consider recommendations from commenters when deciding on future release dates for the technical resource manual and to ensure alignment with the Annual Core Set technical specifications publication.

Reporting (§§ 438.334, 438.535 and 457.1240(d)) (pg. 744)

Finalized Changes
CMS finalized, § 438.535(a)(1) with modifications, which will also apply to separate CHIP, that the required report must include: identification of mandatory measures not included in the MAC QRS because they do not relate to the State's Medicaid managed care program; brief explanations for measures that are inapplicable to the State's managed care program; specification of managed care programs to which applicable measures apply.

Background/Rationale
CMS indicated that it would consider comments regarding timing as it finalizes guidance pertaining to annual reporting.

Technical Changes (§§ 438.334, 438 Subpart G, 438.358 and 457.1240(d)) (pg. 747)

Finalized Changes
CMS finalized technical changes related to redesignating the regulations under current § 438.334(a) to part 438, subpart G, § 438.505, incorporating policy changes and modifications to accommodate new

subpart G provisions. CMS modified § 438.358(c)(6) by changing the reference for this EQR optional activity from § 438.334 to part 438, subpart G to align with the proposed redesignation of § 438.334.