Sellers Dorsey Summary

CMS-2439 Proposed Medicaid Managed Care Rules

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CONTENTS

Executive Summary

On April 27, 2023, the Centers for Medicare & Medicaid Services (CMS) released for public inspection a notice of proposed rulemaking, "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality." The proposed rule was published in the *Federal Register* on May 3, 2023. Building on the access and quality standards established in the 2016 and 2020 managed care final rules and informed by the results of a 2022 request for information related to access, the proposed rules adopt new standards for access to care for services delivered through a managed care model, as well as new and enhanced requirements related to program quality and finance. Of note, CMS simultaneously released a companion proposed rule, "Medicaid Program; Ensuring Access to Medicaid Services," addressing broader topics related to access in Medicaid, including new requirements around home and community-based services (HCBS) and rate transparency; Sellers Dorsey will issue a summary of the companion proposed rule in the coming days.

Key provisions in the proposed rule include:

Access	• Requires states to conduct annual enrollee experience surveys • Sets appointment time standards for certain services, including outpatient mental health and substance use disorder services, adult and pediatric primary care, adult and pediatric obstetrics and gynecology, and one additional service to be defined by the State • Requires States to use independent "secret shoppers" to validate provider networks • Requires States to conduct an analysis comparing managed care plan payment rates for outpatient mental health and substance use disorder services, adult and pediatric primary care, adult and pediatric obstetrics and gynecology, and one additional service (to be defined by the State) to Medicare rates for the same services • Requires States to conduct an analysis comparing managed care plan payment rates for homemaker services, home health aide services, and personal care services to fee-for-service (FFS) rates for the same services
State Directed Payments (SDPs)	• Proposes limits on total SDP program payments and seeks comment on the level of this cap and how it would be calculated. • Codifies guidance related to provider taxes and hold harmless arrangements from CMS' February 2023 informational bulletin • Requires new reporting and evaluation plans for SDPs • Proposes states require an average commercial rate (ACR) demonstration specific to the type of service, but not specific to the provider class. Requires states to submit SDP preprints for approval no later than 90 days from the end of the rating period

Medical Loss Ratio (MLR) Standards	• Requires Medicaid managed care plans to submit actual expenditures and revenues for SDPs as part of their MLR reports to States, and requires States to submit these amounts as separate line items in their annual MLR summary reports to CMS • Specifies when managed care plans are required to resubmit reports to States • Requires managed care plans to report any identified or recovered overpayments to States within 10 business days • Requires states to provide MLRs for each plan

In Lieu Of Services (ILOS)	• Formalizes CMS' previous ILOS guidance from State Medicaid Director Letter #23-001
	• Defines and provides key principles around ILOS. ILOS must:
	  ○ Meet general parameters, including appropriately documented in managed care plan contracts and considered in the development of capitation rates;
	  ○ Be provided in a manner that preserves enrollee rights and protections;
	  ○ Be medically appropriate and cost-effective substitutes for State Plan services and settings;
	  ○ Be subject to monitoring and oversight; and
	  ○ Undergo a retrospective evaluation, when applicable (i.e., if the final ILOS cost percentage exceeds 1.5%)
	• Requires State actuary to calculate both a projected ILOS cost percentage and a final ILOS cost percentage
	• Requires States to identify specific codes and modifiers for each ILOS and provide them to managed care plans

Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review	• Allows managed care plans exclusively serving duals to use a Medicare-Advantage Chronic Care improvement program in place of Quality Improvement Program (QIP) • Requires States to solicit public comment on their managed care quality strategy every three years, and to submit their quality strategy to CMS every 3 years • Removes PCCM entities from the scope of mandatory EQRO review • Proposes changes to what data should be in EQRO reports
Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review	• Establishes the framework of a Medicaid Quality Rating System (QRS), including mandatory quality measures and a defined process to add or change measures, as well as requirements for states to publicly post QRS data to allow beneficiaries to compare plans

CMS will accept public comment on the proposed rulemaking through July 3, 2023. Note that throughout this analysis, the term "managed care plans" will be used to refer to "MCOs, PIHPs, and PAHPs."

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

Regulatory Background

The 2016 final rule aligned many of the regulations governing Medicaid and CHIP managed care with those of other major sources of coverage, implemented applicable statutory provisions, strengthened efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries, and enhanced policies related to program integrity. Additionally, the 2020 final rule streamlined the Medicaid and CHIP managed care regulatory framework to relieve regulatory burdens, support state flexibility and local leadership, and promoted transparency, flexibility, and innovation in the delivery of care. The 2023 proposed rule aims to continue and/or expand provisions included in the 2016 and 2020 final rules.

In 2022, CMS released a request for information (RFI) to collect feedback on a broad range of questions including: challenges with eligibility and enrollment; ways to use data available to measure, monitor, and support improvement efforts related to access to services; strategies for implementation to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and CHIP payments are sufficient to enlist enough providers. Most of the feedback CMS received through the RFI related to promoting cultural competency in access to and the quality of services for beneficiaries across all dimensions of health care and using payment rates as a driver to increase provider participation in Medicaid and CHIP. There was also interest in opportunities to align approaches for payment regulation and compliance across Medicaid and CHIP delivery systems and services. In addition to CMS' three proposed rules to address these comments (the Streamlining Eligibility and Enrollment proposed rule, the Ensuring Access to Medicaid Services proposed rule, and this proposed rule on managed care) CMS is engaged in non-regulatory activities to improve access to health care services across delivery systems.

Summary of New or Amended Provisions

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

- Revises § 438.66(b)(4) to explicitly include "enrollee experience" to ensure state's managed care program monitoring systems required at § 438.66(a) appropriately capture the enrollee experience.
- Revises § 438.66(c)(5) to require states to conduct an annual enrollee experience survey to assure necessary data is collected for monitoring and improvement strategies.
    - States and managed care plans are encouraged to utilize provider surveys, but they are not currently mandated.
    - ***Note on request for public comment:*** CMS does invite comments on whether to mandate the use of a specific enrollee experience survey, define characteristics of acceptable survey instruments, and the operational considerations of enrollee experience surveys states use currently.
- Revises § 438.66(e)(3)(i) to specify that states post the Managed Care Program Annual Report (MCPAR) to their website within 30 calendar days of submitting it to CMS.

- Adds enrollee experience surveys as a document subject to the requirements in § 438.10(d)(2) to ensure enrollees that receive a state's enrollee experience survey would be fully notified that oral interpretation in any language and written translation in the state's prevalent languages would be readily available, and how to request auxiliary aids and services, if needed.
- Proposes that states comply with § 438.66(b) and (c) no later than the first managed care plan rating period that begins on or after three years after the effective date of the final rule. CMS proposed this applicability date in § 438.66(f).
- Amends § 457.1230(b) to require states to evaluate annual CAHPS survey results as part of the state's annual analysis of network adequacy as described in § 438.207(d). CMS proposes § 457.1230(b) to be applicable 60 days after the effective date of the final rule.
    - ***Note on request for public comment:*** CMS is open to a later applicability date such as one, two, or three years after the effective date of the final rule and invites comment on the appropriate applicability date for this provision.
- Revises § 457.1207 to require states to post comparative summary results of CAHPS surveys by CHIP plans annually on state websites as described at § 438.10(c)(3). The posted summary results must be updated annually and allow for easy comparison between the managed care plans.

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

- Redesignates existing § 438.68(e) regarding publication of network adequacy standards to § 438.68(g) and creates a new § 438.68(e) titled "Appointment wait time standards:"
    - New § 438.68(e)(1)(i) through (iv) proposes that states develop and enforce wait time standards for routine appointments for four types of services:
        - Outpatient mental health and substance use disorder (SUD)- adult and pediatric;
        - Primary care- adult and pediatric;
        - Obstetrics and gynecology (OB/GYN);
        - An additional type of service determined by the state (in addition to the three listed) in an evidence-based manner for Medicaid
    - For the first three types of services listed, standards only need to be developed and enforced if the service is covered by the managed care plan's contract, but the fourth service must be one that is covered by the plan's contract.
- New § 438.68(e)(1)(iv) proposes states select a provider type in an evidence-based manner to give states the opportunity to use an appointment wait time standard to address an access challenge in their local market.
    - States would identify the provider type(s) they choose in existing MCPAR reporting, per § 438.66(e), and the Network Adequacy and Access Assurances Report, per § 438.207(d).
    - CMS clarifies that setting appointment wait time standards for routine appointments as proposed at § 438.68(e)(1) would be a minimum; states are encouraged to set additional appointment wait time standards for other types of appointments.
- New § 438.68(e)(1)(i)-(iii) proposes maximum wait times:
    - State-developed appointment wait times must be no longer than 10 business days for routine outpatient mental health and SUD appointments in § 438.68(e)(1)(i) and no longer than 15 business days for routine primary care in § 438.68(e)(1)(ii) and OB/GYN appointments in § 438.68(e)(1)(iii). CMS does not propose a maximum appointment wait time standard for the state-selected provider type.

- Revises § 438.206(c)(1)(i) to include appointment wait time standards as a required provision in managed care contracts for Medicaid (applicable to separate CHIP programs through an existing cross-reference).
- New § 438.68(e)(2) (applicable to separate CHIP through an existing cross-reference) would deem managed care plans compliant with the standards established in paragraph (e)(1) when secret shopper results, described in section I.B.1.c. of this rule, reflect a rate of appointment availability that meets state-established standards at least 90 percent of the time.
- New § 438.68(e)(3) (applicable to separate CHIP through an existing cross-reference) allows CMS to select additional types of appointments to be added to § 438.68(e)(1) after consulting with states and other interested parties and providing public notice and opportunity to comment.
- Adds a new standard at § 438.68(d)(1)(iii) for Medicaid (applicable to separate CHIP through an existing cross-reference) for reviews of exception requests, which would require states to consider the payment rates offered by the MCO, PIHP, or PAHP to providers included in the provider group subject to the exception.
- Revises the existing applicability date in § 438.206(d) for Medicaid (applicable to separate CHIP through an existing cross-reference) to reflect that states would have to comply with § 438.206(c)(1)(i) no later than the first managed care plan rating period that begins on or after four years from the effective date of the final rule.

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

- New § 438.68(f) requires states use independent entities to conduct annual secret shopper surveys of managed care plan compliance with appointment wait time standards proposed at § 438.68(e) and the accuracy of certain data in all managed care plans' electronic provider directories required at § 438.10(h)(1).
    - These proposed changes apply equally to separate CHIP through existing cross-references.
- New § 438.68(f)(1)(i) requires states use secret shopper surveys to determine the accuracy of certain provider directory information in managed care plan's most current electronic provider directories.
- New § 438.68(f)(1)(i)(A) through (C) require surveys of electronic provider directory data for primary care providers, OB/GYN providers, and outpatient mental health and SUD providers if they are included in the managed care plan's provider directories.
- New § 438.68(f)(1)(i)(D) requires secret shopper surveys for provider directory data for the provider type selected by the state for its appointment wait time standards in § 438.68(e)(1)(iv).
- New § 438.68(f)(1)(ii)(A) through (D) require that states use independent entities to conduct annual secret shopper surveys to verify the accuracy of four pieces of data in each managed care plan electronic provider directory required at § 438.10(h)(1):
    - The active network status with the managed care plan.
    - The street address as required at § 438.10(h)(1)(ii).
    - The telephone number as required at § 438.10(h)(1)(iii).
    - Whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi).
- New § 438.68(f)(1)(iii) and (iv) require states to receive information on all provider directory data errors identified in secret shopper surveys no later than three business days from identification by the entity conducting the secret shopper survey and that states must then send that data to the applicable managed care plan within three business days of receipt.

    - The information sent to the state must be "sufficient to facilitate correction" to ensure enough detail to enable the managed care plans to quickly investigate the accuracy of the data and make necessary corrections.
- New § 438.10(h)(3)(iii) requires managed care plans to use the information from secret shopper surveys required at § 438.68(f)(1) to obtain corrected information and update provider directories no later than the timeframes specified in § 438.10(h)(3)(i) and (ii) and included in separate CHIP regulations through an existing cross-reference.
- New § 438.68(f)(2) requires states to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards proposed in § 438.68(e)(1).
- New § 438.68(f)(2)(i) allows CMS to select additional provider types to be added to secret shopper surveys of appointment wait time standards after consulting with states and other interested parties and providing public notice and opportunity to comment.
- New § 438.68(f)(2)(ii) proposes that appointments offered via telehealth only be counted towards compliance with appointment wait time standards if the provider also offers in-person appointments and that telehealth visits offered during the secret shopper survey be separately identified in the survey results.
- New § 438.68(f)(3) proposes that any entity that conducts secret shopper surveys must be independent of the State Medicaid agency and its managed care plans subject to a secret shopper survey.
- New § 438.68(f)(3)(i) and (ii) define the criteria for an entity to be considered independent:
    - The entity cannot be a part of any state governmental agency to be independent of a State Medicaid agency; and,
    - The entity must be independent of the managed care plans subject to the survey, an entity would not be a Managed care plan, would not be owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and would not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.
- New § 438.68(f)(4) requires secret shopper surveys be completed for a statistically valid sample of providers and: (1) use a random sample; and, (2) include all areas of the state covered by the MCO's, PIHP's, or PAHP's contract. Secret shopper surveys to determine plan compliance with appointment wait time standards must be completed for a statistically valid sample of providers.
- New § 438.68(f)(5) requires the results of these surveys to be reported to CMS and posted on the state's website within 30 calendar days of the state submitting them to CMS.

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

- Amends § 438.207(b) to require managed care plans to submit annual documentation to the state that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract.
    - The analysis must use paid claims data from the immediate prior rating period to ensure that all payments are captured, including those that are negotiated differently than a plan's usual fee schedule.
    - Managed care plans would use paid claims data from the immediate prior rating period to determine the total amount paid for evaluation and management current procedural terminology (CPT) codes for primary care, OB/GYN, mental health, and SUD services.
        - Plans must include separate total amounts paid and separate comparison percentages to Medicare for ease of analysis and clarity.

        - Percentages must be reported separately if they differ between adult and pediatric services.
    - The analysis must provide the percentage that results from dividing the total amount the managed care plan paid by the published Medicare payment rate for the same codes on the same claims.
    - The analysis must also provide the total amount paid for homemaker services, home health aide services, and personal care services, and the percentage that results from dividing the total amount paid by the amount the state's Medicaid or CHIP FFS program would have paid for the same claims.
    - FQHCs and rural health clinics are excluded from the analysis.
    - Claims for the services in which the managed care plan is not the primary payer are excluded from the analysis.
- States must comply no later than the first rating period that begins on or after two years from the effective date of the final rule.

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

- Revises § 438.207(d) to explicitly require states to include the results from the secret shopper surveys proposed in § 438.68(f) and the payment analysis proposed in § 438.207(b)(3) in their assurances and analyses reporting.
    - States are required to include the data submitted by each plan and use the data from its plans' reported payment analysis percentages and weight them using the member months associated with the applicable rating period to produce a statewide payment percentage for each service type.
    - States would have to comply no later than the first managed care plan rating period that begins on or after 2 years from the effective date of the final rule.
- Requires states submit their assurance and analysis: (1) at the time it submits a completed readiness review, as specified at § 438.66(d)(1)(iii); (2) on an annual basis and no later than 180 calendar days after the end of each contract year; and, (3) any time there has been a significant change as specified in § 438.207(c)(3) and with the submission of the associated contract.
    - States would have to comply no later than the first managed care plan rating period that begins on or after 1 year from the effective date of the final rule.
- States must post the report on their website within 30 calendar days of submission to CMS.
- States must submit their assurance of compliance and analyses using the published Network Adequacy and Access Assurances Report template.
- Separate CHIP will be required to align with Medicaid for the proposed network adequacy analysis submission timeframes.

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

- Redesignates existing § 438.207(f) as § 438.207(g).
- New § 438.207(f) requires the state to submit a plan to remedy access issues identified by the State, managed care plan, or CMS, including any access issues with the standards specified in §§ 438.68 and 438.206. The State must develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties. If a State identifies an issue with a managed care plan's performance regarding any state standard for access to care, the State must follow the following four proposed steps:
    - States must submit to CMS for approval a remedy plan no later than 90 calendar days following the date the state becomes aware of a managed care plan's access issue.
    - States must develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties.
    - States must ensure that improvements in access are both measurable and sustainable.
    - States must submit quarterly progress updates to CMS on implementation of the remedy plan so CMS can determine if the state was making reasonable progress toward completion and if the actions in the plan are effective.

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

- Revises § 438.10(c)(3) to add new webpage requirements:
    - Require all information, or links to the information, required in this part to be posted on the state's website, be available from one page.
    - Require states' websites use clear and easy to understand labels on documents and links so users can easily identify the information contained in them.
    - Require states check their websites at least quarterly to verify they are functioning as expected and the information is the most currently available.
    - Require states' websites explain that assistance in accessing the information is available at no cost, including information on the availability of oral interpretation in all languages and written translation in each prevalent non-English language, alternate formats, auxiliary aids and services, and a toll-free TTY/TDY telephone number.
- Revises § 438.602(g) to require States to post additional information to their websites:
    - Enrollee handbooks, provider directories, and formularies,
    - Information on rate ranges,
    - Reports required at §§ 438.66(e) and 438.207(d),
    - Network adequacy standards,
    - Secret shopper survey results,
    - SDP evaluation reports,
    - Links to all required Application Programming Interfaces,
    - Quality related information, and
    - Documentation of compliance with requirements in subpart K - Parity in Mental Health and Substance Use Disorder Benefits.
- Proposes to review § 438.10(j) to reflect that states would have to comply with § 438.10(c)(3) no later than the first managed care plan rating period that begins on or after 2 years from the effective date of the final rule.

- Obligates states comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after 3 years from the effective date of the final rule.
- Obligates states comply with § 438.10(h)(3)(iii) no later than the first managed care plan rating period that begins on or after 4 years from the effective date of the final rule.
- For separate CHIP managed care, states are currently required to comply with the transparency requirements at § 438.602(g) through an existing cross-reference. CMS proposes to align with Medicaid by adopting most of the consolidated requirements for posting on a state's website proposed at § 438.602(g)(5) through (13) for separate CHIP.
    - Adopts § 438.602(g)(5) because requirements at § 438.10(g) through (i) are currently required for separate CHIP through an existing cross-reference.
    - Adopts § 438.602(g)(7) since the proposed network adequacy reporting at § 438.207(d) would apply to separate CHIP through an existing cross-reference. Since CMS did not adopt the managed care program annual reporting requirements at § 438.66(e) for separate CHIP, it proposes to exclude this reporting requirement.
    - Adopts § 438.602(g)(8) for separate CHIP because it proposes to adopt the new appointment wait time reporting requirements through an existing cross-reference, though CMS proposes to exclude references to LTSS as not applicable to separate CHIP.
    - Adopts § 438.602(g)(9) for separate CHIP network access reporting to align with the proposed adoption of secret shopper reporting at § 438.68(f) through an existing cross-reference.
    - Adopts the provision at § 438.602(g)(11) given the existing requirements at § 457.1233(d).
    - Adopts the provision at § 438.602(g)(12) for separate CHIP as required through cross-references, as well as the applicable EQR report through an additional cross-reference. However, CMS proposes to exclude the reference to § 438.362(c) since managed care plan EQR exclusion is not applicable to separate CHIP.
    - Adopts § 438.602(g)(13) for separate CHIP through the existing cross-reference. However, CMS proposes to replace the reference to subpart K of part 438 with CHIP parity requirements at § 457.496 in alignment with contract requirements at § 457.1201(l).
- Amends § 457.1285 to require state compliance with the program integrity safeguards in accordance with the terms of subpart H of part 438, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2) and 438.608(d)(4) and references to LTSS ido not apply and references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

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

- Replaces the definition of PCCM entity at § 438.2 and for the provider types that must be included in provider directories at § 438.10(h)(2)(iv), "behavioral health" with "mental health and substance use disorder".
- For the provider types for which network adequacy standards must be developed in § 438.68(b)(1)(iii), CMS proposes to remove "behavioral health"; and for the provider types addressed in credentialing policies at § 438.214(b), CMS proposes to replace "behavioral" with "mental health."
- Replaces the definition of PCCM entity at § 438.2 to slash between "health systems" and "providers" with "and" for grammatical accuracy.
- Changes "psychiatric" to "mental health" in § 438.3(e)(2)(v) and § 438.6(e).

Effective Date

For appointment wait time standards, CMS proposes states would have to comply with § 438.68(b)(1), (e), and (g) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule; comply with § 438.68(f) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule; and comply with § 438 (d)(1)(iii) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule.

For secret shopper surveys, CMS proposes that states would have to comply with § 438.68(f) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule.

The state must develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties.

States must comply with § 438.10(c)(3) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule.

States must comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule.

States must comply with § 438.10(h)(3)(iii) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule.

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

Regulatory Background

While States are generally not permitted under Medicaid rules to direct the expenditures of a Medicaid managed care plan to make payments to providers for services covered under the contract, CMS acknowledges that there are circumstances in which a state may require such directed payments. Therefore, in their 2016 final rule, CMS established specific exceptions to the general rule prohibiting states from directing the expenditures of managed care plan at § 438.6(c)(1)(i) through (iii). These exceptions came to be known as state directed payments (SDPs).

CMS has issued guidance to states regarding SDPs on multiple occasions. In November 2017, CMS published the initial preprint form along with guidance for states on the use of SDPs. In May 2020, CMS published guidance on managed care flexibility to respond to the COVID-19 public health emergency (PHE), including how states could use SDPs in support of their COVID-19 response efforts. In January 2021, CMS published additional guidance for states to clarify existing policy, and issued a revised preprint form that states must use for rating periods beginning on or after July 1, 2021.

In the preamble to the proposed rule, CMS expresses concern that the risk-based nature of capitation rates for managed care plans has diminished as more of the Medicaid capitation payments are financed through SDPs. They cite similar concerns raised by the Medicaid and CHIP Payment and Access

Commission (MACPAC) and the Government Accounting Office (GAO) about the growth of SDPs in managed care programs.

In this proposed rule, CMS seeks to codify policy that has previously been issued as sub-regulatory guidance and requirements that were incorporated into the 2021 version of the preprint as well as add new rules and requirements that they believe achieve their policy goals.

Summary of New or Amended Provisions

Definitions (§ 438.6(a))

- Amends § 438.6(a) by adding the following definitions:
  - *Academic medical center* means a facility that includes a health professional school with an affiliated teaching hospital.
  - *Average commercial rate* means the average rate paid for services by the highest claiming third-party payers for specific services as measured by claims volume.
  - *Condition-based payment* means a prospective payment for a defined set of Medicaid-covered service(s) that are tied to a specific condition and delivered to Medicaid managed care enrollees.
  - *Final SDP cost percentage* means the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each SDP for which written prior approval is required under paragraph (c)(2)(i) of this section and for each managed care program.
  - *Maximum fee schedule* means any SDP where the State requires an MCO, PIHP, or PAHP to pay no more than a certain amount for a covered service(s).
  - *Minimum fee schedule* means any SDP where the State requires an MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s).
  - *Population-based payment* means a prospective payment for a defined set of Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group.
  - *Qualified practitioner services at an academic medical center* means professional services provided by both physicians and non-physician practitioners affiliated with or employed by an academic medical center.
  - *Separate payment term* means a pre-determined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a SDP for which the State has received written prior approval under § 438.6(c)(2)(i). Payments made from this funding pool are made by the State to the MCOs, PIHPs or PAHPs exclusively for SDP for which the State has received written prior approval under §
  - *SDP* means a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section.
  - *Total payment rate* means the aggregate for each managed care program of:
    - (i) The average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the SDP;
    - (ii) The effect of the SDP on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under § 438.6(c)(2)(i);
    - (iii) The effect of any and all other SDP on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph § 438.6(c)(2)(i); and

    - (iv) The effect of any and all allowable pass-through payments, as defined in paragraph (a) of this section, paid to any and all providers included in the provider class specified in the SDP for which the State is seeking prior approval under paragraph § 438.6(c)(2)(i) on the average payment rate to providers in the specified provider class.
  - *Total published Medicare payment rate* means amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B.
  - *Uniform increase* means any SDP that directs the MCO, PIHP, or PAHP to pay the same amount (the same dollar amount or the same percentage increase) per Medicaid-covered service(s) in addition to the rates the MCO, PIHP or PAHP negotiated with the providers included in the specified provider class for the service(s) identified in the SDP.

Medicare Exemption, SDP Standards and Prior Approval (§ 438.6(c))

- New § 438.6(c)(1)(iii)(B) would allow for an SDP that adopts a minimum fee schedule for providers using a published Medicare rate no older than three years. (Note that adding this subparagraph then renumbers current B, C, and D as C, D, and E).
- New § 438.6(c)(2)(i) would outline which SDPs require written prior approval. Those under §§ 438.6(c)(1)(iii)(A) or (B), using either state plan approved rates or 100% of the published Medicare rate, would not need written prior approval.
- New paragraph § 438.6(c)(5)(iii)(A)(5) would require the managed care plan contracts 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.

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

- Modifies § 438.6(c)(1)(iii)(A through D) to delete "network" before "providers" such that non-network providers could also be eligible to receive payments under an approved SDP.

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

- New § 438.6(c)(2)(viii)(A) requires that all SDPs that require written approval must be submitted no later than 90 days in advance of the end of the rating period to which the SDP applies.
- New § 438.6(c)(2)(viii)(B) allows states the flexibility to use shorter-term SDPs in response to infrequent events, such as PHEs and natural disasters. For these SDPs, the deadline would be before the end of the rating period in which the SDP would be effective.
- New § 438.6(c)(2)(ix)(A) and (B) requires all amendments be submitted for written prior approval.

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

- Redesignates § 438.6(c)(2)(i) as § 438.6(c)(2)(ii)(I) and (J) to allow total payment rates in an SDP up to the ACR.
- New § 438.6(c)(2)(ii)(I) codifies current policy that each SDP ensure the total payment rate for each service, and each provider class included in the SDP must be reasonable, appropriate, and attainable and, upon request from CMS, the state must provide documentation demonstrating the total payment rate for each service and provider class.

- New § 438.6(c)(2)(iii) proposes that states provide two pieces of documentation in their SDP submissions: (1) an ACR demonstration; and, (2) a total payment rate comparison to the ACR.
- § 438.6(c)(2)(iii) further specifies the standards and documentation requirements for determining the total payment rate.
    - ***Note on request for public comment:*** CMS seeks input on 1. The viability and reasonableness of imposing a limit on SDPs; and, 2. The specific methodologies outlined in the preamble to calculate such a limit.
- New § 438.6(c)(2)(iii)(A) specifies 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 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.
- New § 438.6(c)(2)(iii)(B), we propose to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services.
    - Under this proposal, the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which written prior approval is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as defined in § 438.6(a) as a percentage of the average commercial rate, demonstrated pursuant to § 438.6(c)(2)(iii)(A), for each of the four categories of services.
- New § 438.6(c)(2)(iii)(C) requires 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.
- ***Note on request for public comment:*** CMS seeks comment on whether a limit on SDP expenditures should be adopted. CMS also seeks input on both the overall approach of using a percent of total costs as well as on the appropriateness of 10% to 25% or what a reasonable percentage limit for SDP expenditures could be.
- CMS is considering the following alternatives that the limit on total SDP expenditures could be based on:
    - A portion of the total costs for each Medicaid managed care program.
    - A portion of the total costs for each Medicaid managed care program, but only focus on the costs related to inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at academic medical centers.

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

- Revises §438.6(c)(2)(ii)(G) to require that an SDP comply with all Federal legal requirements for the financing of the non-Federal share, including by not limited to
- New § 438.6(c)(2)(ii)(H) proposes each SDP would need to ensure that each provider receiving payment under an SDP attests it does not participate in any hold harmless arrangement with respect to any health care related tax and ensure such attestations be available upon CMS request

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

- New § 438.6(c)(2)(vii)(A) stipulates SDPs that are minimum fee schedules, maximum fee schedules, and uniform increases are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only.
- New § 438.6(c)(2)(vii)(B) 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.

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

- Modifies § 438.6(c)(2)(iii)(C) to remove requirements that prohibit states from setting the amount or frequency of the managed care plan's expenditures.
- Modifies § 438.6(c)(2)(iii)(D) to remove requirements that prohibit States from recouping unspent funds allocated for SDPs to enable states to reinvest these unspent funds to further promote VBP/delivery system innovation.
    - Possible use of funds – data collection and sharing for performance improvement.
- Clarifies § 438.6(c)(2)(vi)(B) on how performance in these types of arrangements is measured.
- New § 438.6(c)(2)(vi)(C) establishes requirements for use of population-based and condition-based payments in VBP arrangements, in addition to existing performance-based payments.
- Codifies interpretation at § 438.6(c)(2)(vi)(B)(1) that performance-based payments cannot be used for administrative tasks, including "pay for reporting" arrangements.
- New § 438.6(c)(2)(vi)(B)(1) and (3) through (5) clarifies or extends current requirements that SDPs use a common set of metrics.
- New § 438.6(c)(2)(vi)(B)(4) and (5) stipulate performance-based payments include a baseline metric and use measurable performance targets relative to a baseline.
- New § 438.6(c)(2)(vi)(B)(3) proposes states can use a performance period that precedes the start of the rating period up to 12 months, must not exceed the length of the rating period, and requires all payments are documented in the rate certification for the rating period in which payment is delivered – no retrospective payments.
    - ***Note on request for public comment:*** CMS seeks input on whether 12 months is an appropriate time period to allow for claims runout and data analysis, or if the time period that precedes the rating period should be limited to six months or extended to 18 or 24 months, or if the performance period should remain consistent with the rating period.
- Adds § 438.6(c)(2)(vi)(C)(1) that population-based payments must be conditioned on the actual delivery of covered services.

- Adds § 438.6(c)(2)(vi)(C)(2) that condition-based payments require an attribution methodology that uses data no more than 3 years old, preserves doctor-patient relationships, accounts for enrollee choice, and describes when patient panels are attributed.
- Adds § 438.6(c)(2)(vi)(C)(3) that population-based and condition-based payments are required to replace the negotiated rate between managed care plans and providers to prevent duplicate payments.
- Adds § 438.6(c)(2)(vi)(C)(2) to establish a requirement that prevents payments from being made in addition to other payments made to the same provider for the same services.
- Modifies § 438.6(c)(3)(i) to codify existing policy that multi-year approval may be for up to three rating periods for SDPs with VBP pay-for-performance arrangements, Multi-payer or Medicaid-specific delivery reform, or performance improvement initiative.

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

- New § 438.6(c)(2)(iv) that states must submit an evaluation plan for all SDPs which require written approval.
- New § 438.6(c)(2)(iv)(A) that each evaluation plan must include at least two metrics, with one being a performance metric (noted in § 438.6(c)(2)(iv)(A)(2)).
- New §438.6(c)(2)(iv)(A)(1) details that for VBP programs, one of the metrics must be reported at the provider-class level for the SDP "when practical and relevant".
- ***Note on forthcoming guidance:*** CMS will issue more sub-regulatory guidance to provide best practices and recommendations for choosing appropriate performance measures when not using existing measure sets.
- New § 438.6(c)(2)(iv)(B) requires states include a baseline statistic used in the evaluation, and subsequently § 438.6(c)(2)(iv)(C) requires states include performance targets relative to the baseline statistic.
- New § 438.6(c)(2)(iv) makes clear CMS has the authority to disapprove proposed SDPs if states fail to provide in writing evaluation plans for their SDPs that meet new requirements.
- § 438.6(c)(7)(i) proposes the final SDP cost percentage be calculated and recalculated annually to ensure consistent application across all states and managed care programs.
- New § 438.6(c)(2)(v)(A) adopts three new requirements for state evaluation reports.
    - Must include all elements of the evaluation plan required in § 438.6(c)(2)(iv).
    - Must submit the 3 most recent and complete years of annual results for each measure in § 438.6(c)(2)(v)(A)(2).
    - Must publish evaluation reports on their public facing websites under § 438.10(c)(3).
- New § 438.6(c)(2)(v)(B) requires states submit their first evaluation report no later than 2 years after the conclusion of the 3-year evaluation period.
    - Subsequent reports would be submitted to CMS every 3 years.
- New § 438.6(c)(2)(v)(A)(2) requires evaluation reports include the 3 most recent and complete years of annual results for each metric as approved under the evaluation plan approved as part of the preprint review.
- New standard at § 438.6(c)(2)(ii)(F) requires all SDPs must result in achievement of the stated goals and objectives in alignment with the state's evaluation plan.
- In a concurrent proposal at § 438.358(c)(7), CMS has added a new, optional EQR activity to support evaluation requirements.

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

- *New §438.6(c)(5)(i) requires the state to identify the start date and, if applicable the end date within the managed care contract for the applicable rating period.*
- *New §438.6(c)(5)(ii) requires the managed care contract to describe the provider class eligible for the SDP arrangement and all eligibility requirements.*
- *New §438.6(c)(5)(iii) requires the state to include a description of each SDP arrangement in the managed care contract.*
- *New §438.6(c)(5)(iv) requires that the state include in the managed care contract any encounter reporting and separate reporting requirements that the state needs in order to audit the SDP and report provider-level payment amounts to CMS.*
- *New §438.6(c)(5)(v) requires the state indicate in the managed care contract whether the state would be using a separate payment term to implement the SDP.*
- *§438.6(c)(5)(vi) requires that all SDPs must be specifically described and documented in the MC plan contracts no later than 120days after the start of the SDP or approval of the SDP, whichever is later.*

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

- Redesignates part of the provision in § 438.6(c)(2)(i) to become 438.6(c)(2)(ii)(J) and would continue to require that directed payments be developed in accordance with actuarial soundness and rate development standards but replaces the reference to "generally accepted actuarial principals and practices" with a requirement to meet the standards in Sections 438.7 (rate certification submission) and 438.8 (MLR standards).
- New § 438.6(c)(6)(i) would require states to indicate when a separate payment term is being used on the preprint form, codifying current practice. While CMS does not prohibit the use of separate payment terms in these proposed rules, they have proposed new regulations to put up guardrails in instances where states may use them.
- New § 438.6(c)(6)(ii) would prohibit states from using separate payment terms for SDPs that are exempted from the CMS written approval process (such as minimum fee schedules). States would be required to incorporate these changes into the capitation payments.
- New § 438.6(c)(6)(iii) would require each separate payment term to be specific to both an individual approved SPD and to each managed care program to provide clarity to the managed care plan and to facilitate state and federal oversight.
- New § 438.6(c)(6)(iv) would limit payments made through a separate payment term to the total amount documented in the approved preprint. CMS notes the current amendment process causes significant delays and increases State and federal administrative burdens.
- New § 438.6(c)(6)(v) would require States to document the separate payment term in the State's managed care contract no later than 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later.

- New § 438.6(c)(6)(v)(A) would prohibit States from amending the separate payment term after CMS approval except to account for an amendment to the payment methodology.
    - ***Note on request for public comment:*** CMS is considering a proposal to permit amendments to the separate payment term to account for a change in the total aggregate dollars to be paid where there is no change to the non-federal portion and is seeking comments on this idea.
- New § 438.7(f) would require State actuaries to certify the total dollar amount of each separate payment term and that all separate payment terms be included in the rate certification.
- New § 438.7(f)(1) would codify existing practice that allows States to pay individual plans different amounts as long as the total amount paid does not exceed the total amount in the separate payment term.
- New § 438.7(f)(2) would codify existing practice that requires the State's actuary to provide an estimate at the rate cell level of the impact of the separate payment term.
- New § 438.7(f)(3) would require States to submit a final certification that includes the separate payment term by rate cell no later than 12 months after the close of the rating period.
- New § 438.7(f)(4) would require States to submit a rate certification incorporating the separate payment term within 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later.

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

- New § 438.7(c)(5) specifies 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 minimum fee schedule SDP 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.
- New § 438.7(c)(4) requires states 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.
- New § 438.7(c)(6) requires states submit the required rate certification documentation for SDPs incorporated through adjustments to base rates (either the initial rate certification or a revised rate certification) no later than 120 days after either the start date of the SDP approved under § 438.6(c)(2)(i) (redesignated from § 438.6(c)(2)(ii)) or 120 days after the date CMS issued written prior approval of the SDP, whichever is later.

Appeals (§430.3(d))

- New § 430.3(d) would explicitly permit disputes that pertain to written disapprovals of SDPs under § 438.6(c) to be heard by the Health and Human Services (HHS) Department Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16, as set forth, in part, below.
    - The State would have 30 days to appeal to the Board after an appellant receives a final written decision from CMS communicating a disapproval of an SDP.
    - The case would then be assigned a presiding Board member who would preside over procedural matters and conduct record development in the case.

- Within 10 days of receiving the notice of appeal, the Board would assess the filing for completeness and jurisdiction. If it is appropriately filed, the Board would acknowledge the notice and outline the next steps in the case.
- The State would then have 30 days to file its appeal brief, which would contain its argument for why the final decision of CMS was in error, and its appeal file, which would include the documents on which its arguments are based.
- CMS would then have 30 days to submit its brief in response to the State's brief as well as any additional supporting documentation not already contained in the record.
- The State would be given 15 days to submit its optional reply.
- Parties are encouraged to work cooperatively to develop a joint appeal file and stipulate facts alleviating the need to submit documentation.
- The Board may request additional documentation or information, request additional briefings, hold conferences, set schedules, issue orders to show cause, and take other steps as appropriate to "develop a prompt, sound decision" at any time.
- States appealing a CMS disapproval of a proposed SDP could request a hearing or oral argument, or the Board may call for one *sua sponte* should it determine, its decision-making would be enhanced by such proceedings.
- The Board's proceedings are held in Washington, DC, but may be held in an HHS Regional Office or "other convenient facility near the appellant."
- The Board has established general goals for its consideration of cases within six to nine months; however, the top concern of the Board is to take the time needed to review a record fairly and adequately to produce a sound decision.
- Mediation may be used as an alternative or preliminary process to resolve the issues between the parties.

Note on request for public comment: *CMS seeks comment on a potential alternative to the Board. They are also* considering permitting appeals of SDP written disapprovals to be heard by the CMS Offices of Hearings and Inquiries (OHI) and the CMS Administrator for final agency action.

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

- Modifies § 438.8(k) to require that managed care plans include SDPs and associated revenue in their MLR reports to the state and, as required under § 438.74, have states report this information to CMS.
- New § 438.6(c)(4) requires States annually submit data, no later than 180 days after each rating period to CMS's Transformed Medicaid Statistical Information System (T-MSIS), specifying the total dollars expended by each managed care plan for SDPs that were in effect for the rating period, including amounts paid to individual providers.
- New § 438.6(c)(4) outlines the minimum data fields to include: provider identifiers, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, and allowed, billed, and paid amounts.
- CMS also proposes a conforming requirement at § 438.6(c)(5)(iv) – a requirement that states document any reporting requirements necessary to comply with § 438.6(c)(4) in their managed care contracts.

Effective Date

CMS acknowledges that some of these proposed changes will be administratively and technically challenging, thereby providing for transition periods, and effective dates, of varying length. The general effective dates for many of the changes in this section would be - no later than the first rating period for contracts with managed care plans beginning on or after two years after the effective date of the final rule.

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

Regulatory Background

Medical Loss Ratio (MLR) is used as a tool for CMS to ensure that Medicaid managed care funds are spent on claims and quality improvement activities rather than administrative expenses. Current regulations require Medicaid managed care plans to report their MLR to states on an annual basis. States are also required to submit a summary of MLR reports to CMS; however, current regulations lack details on several parameters including lack of explicit requirements around provider incentive payments being contingent on providers meeting quantitative clinical or quality improvement standards. Note also that Managed care MLR reporting requirements in § 438.8(k) codified in 2016 final rule do no address inclusion of SDPs in MLR.

The proposed rules aim to further standardize MLR requirements across markets in support of administrative efficiency for states. Proposed revisions align Medicaid provisions with QHP MLR reporting standards as noted below.

Summary of New or Amended Provisions

Standards for Provider Incentives – (§ 438.3(i), § 438.8(e)(2))

- New § 438.3(i)(3)(i-iv) and 438.8(e) (2)(iii)(A) require that provider incentive payment contracts:
    - Have defined performance period and must be signed by all parties.
    - Include clearly defined, objectively measurable and well-documented clinical or quality improvement/performance standards/metrics to receive bonus or incentive (required to be included in MLR numerator).
    - Specify a dollar amount clearly linked to successful completion of metrics and date of payment.
- New § 438.3(i)(4)(i-iv) requires that:
    - State's contracts must define documentation required to support provider incentive arrangements that plans make available to the state routinely.
    - Prohibit the use of attestations as documentation.

Prohibited Costs in Quality Improvement Activities (§ 438.8(e)(3))

- Amends § 438.8(e)(3)(i) prohibit the inclusion of indirect or overhead expenses that are not directly related to quality improvement.

Additional Requirements for Expense Allocation Methodology (§ 438.8(k)(l)(vii))

- New § 438.8(k)(l) (vii) requires that managed care plans include information that reflects same documentation as required under Marketplace requirements, including that managed care plans include a description of their methodology for allocating expenses, including incurred claims, taxes, and licensing fees.

Credibility Factor Adjustment to Publication Frequency (§ 438.8(h)(4))

- Revises § 438.8(h)(4) to remove the requirement and related language for CMS to update factors "on an annual basis" since it is no longer deemed necessary as these factors are not expected to change annually.

MCO, PIHP, PAHP MLR Reporting Resubmission Requirements (§ 438.8(m))

- Amends § 438.8(m) to specify that managed care plans would only be required to re-submit MLR reports to State when the State makes a change to capitation rates, not when there are changes made to capitation payments.

Level of MLR Data Aggregation (§ 438.74)

- Amends § 438.74(a) to specify that State MLR summary reports must include the required elements for *each* managed care plan contracted with the State.
- Adds language in 438.74(a)(2) that the summary description submitted by the State to CMS be provided for each contracted plan.

Contract Requirements for Overpayments (§§ 438.608(a)(2) and (d)(3))

- Amend § 438.608(a)(2) to define "prompt" as within 10 business days of identifying or recovering an overpayment.
- Revise 438.608(d)(3) to specify that any overpayment (whether identified OR recovered) must be reported by plans to State.

Reporting of SDPs in the Medical Loss Ratio (MLR) (§§ 438.8(e)(2)(iii) and (f)(2), § 438.74)

- Amend § 438.8(k) to require plans to identify and include SDPs and associated revenue as separate lines in annual MLR reports. Specifically:
    - In § 438.8(e)(2)(iii)(c), require inclusion of managed care plan expenditures to providers that are directed by the State in the MLR numerator.
    - In § 438.8(f)(2)(vii), require that State payments to plans for approved arrangements be included in the denominator as premium revenue.
    - In § 438.8(k)(l)(xiv), require reporting of Medicaid managed care expenditures to providers that are directed by the State.
    - In § 438.8(k)(l)(xv), require reporting of Medicaid managed care plan revenue from the State.
- Require two additional line items to support plan-level SDP expenditure reporting in States' annual summary MLR reports to CMS.
    - In § 438.74(a)(3)(i), require State reporting of the amount of payments made to providers that direct plan expenditures under § 438.6 (c)

- In § 438.74(a)(3)(ii), requires State reporting of the payment amounts, including amounts included in capitation payments that the State makes to plans for approved SDPs under § 438.6 (c).

Effective Date

No later than the rating period for contracts beginning on or after 60 days following the effective date of the final rule.

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

Regulatory Background

In-Lieu of Services (or ILOSs) can be an innovative option that states may consider employing in Medicaid and CHIP managed care to address social determinants of health (SDOHs) and health-related social needs (HRSNs). The use of ILOSs can also improve population health, reduce health inequities, and lower overall health care costs in Medicaid. ILOSs may also offset potential future acute and institutional care when offered as immediate or longer-term substitutes for State Plan-covered services and settings.

In the 2016 final rule, CMS specified in § 438.3(e)(2) that managed care plans have flexibility under risk contracts to provide a substitute service or setting for a service or setting covered under the State Plan, when medically appropriate and cost-effective, to enrollees at the managed care plan and enrollee option. ILOSs are incorporated into the applicable states' contracts with its managed care plans and associated capitation rates and are subject to CMS review and approval in accordance with § 438.3(a) and § 438.7(a) respectively. On January 4, 2023, CMS released a State Medicaid Director letter, SMD# 23-001, to provide additional guidance on the ILOS option for states to use in Medicaid managed care programs.

CMS states that the proposed rules are necessary to ensure adequate assessment of these substitute services and settings prior to approval, support ongoing monitoring for appropriate utilization of ILOSs and beneficiary protections, and provide appropriate fiscal protections and accountability of expenditures.

Summary of New or Amended Provisions

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

- Revises § 438.2 to establish a new definition for "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).
- Specifies in § 438.6(e) the exclusion of applicability of § 438.16 for short term stays for inpatient mental health or SUD treatment in an IMD.

ILOS General Parameters (§§ 438.16(a) through (d), 457.1201(c) and (e))

- New § 438.16(c)(2) provides ILOS cost percentage calculations are required by each managed care program.
    - *Projected ILOS cost percentage* is calculated by dividing:
        - Numerator: Total capitation payments attributable to all ILOSs, excluding short-term stays in an IMD for each managed care program
        - Denominator: Projected total capitation payments for *each* managed care program, including all SDPs and the projected total SDP that are paid as a separate payment term.
    - *Final ILOS cost percentage* is calculated by dividing:
        - Numerator: Total capitation payments attributable to all ILOSs, excluding a short term stay in an IMD for each managed care program
        - Denominator: Actual total capitation payments for *each* managed care program, including all SDP in effect and pass-through payments in effect, and the actual total SDP that is paid as a separate payment term.
- New § 438.16(c)(1)(ii-iii) requires the projected ILOS cost percentage and the final ILOS cost percentages be calculated and certified on an *annual basis* by the same actuary who develops and certifies the associated Medicaid capitation rates and the SDP paid as a separate payment term.
- New § 438.16(c)(5)(ii) requires states annually submit documentation to CMS to review the projected and final ILOS cost percentage for each managed care program as part of the Medicaid rate certification required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that included an ILOS(s).
    - ***Note on request for comment:*** CMS requests comment on the timeline.
- New § 438.16(c)(4) requires states provide to CMS a summary report of the actual managed care plan costs for delivering ILOSs based on claims and encounter data.
    - Documentation requirements for states with a projected ILOS cost percentage that is less than or equal to 1.5 percent would be streamlined relative to states with a higher projected ILOS cost percentage. States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS.

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

- Adds § 438.3(e)(2)(ii)(A), to allow enrollees who are offered or utilize an ILOS to retain all rights and protections afforded under Part 438, and if an enrollee chooses not to receive an ILOS, they retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option.
- Adds § 438.3(e)(2)(ii)(B) to ensure 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.

Medically Appropriate and Cost-Effective (§§ 438.16(d), 457.1201(e))

- Revises § 438.16(d)(1) to specify documentation requirements that must be included in any managed care plan contract that includes ILOS(s) to obtain CMS approval consistent with § 438.3(a).
- Further specifies § 438.16(d)(1)(i) and (ii) to require that States would include within each managed care plan contract that includes ILOS(s):
    - The name and definition for each ILOS and clearly identify the State Plan-covered service or setting for which each ILOS has been determined to be a medically appropriate and cost-effective substitute by the state.
    - The clinically defined target population(s) for which each ILOS has been determined to be a medically appropriate and cost-effective substitute.
    - Documented process by which a licensed network or managed care plan staff provider would have to determine that an ILOS is medically appropriate for a specific enrollee.
- Describes in § 438.16(d)(2)(i) the process and supporting evidence the state used to determine each ILOS would be a medically appropriate service or setting for the clinically defined target population(s), consistent with proposed § 438.16(d)(1)(iii).
- Describes in § 438.16(d)(2)(ii) the process and supporting data the State used to determine each ILOS is a cost-effective substitute for a state plan-covered service or setting for the defined target population(s).

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

- Revises § 438.3(c)(1)(ii) to include "ILOS" even though it is not a managed care plan requirement, but rather offered at the option of the managed care plan.
- Revises § 438.7(b)(6) and the proposed § 438.7(c)(4) to add "ILOS in § 438.3(e)(2)" to ensure any contract provision related to ILOSs must be documented in all rate certifications submitted to CMS for review and approval.
- ***Note on Forthcoming guidance:*** CMS intends to issue additional guidance in the Medicaid Managed Care Rate Development Guide, in accordance with § 438.7(e), on the federal standards and documentation requirements for adequately addressing ILOSs in all rate certifications

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

- New § 438.16(d)(1)(vi) requires states include a contractual requirement that managed care plans utilize the specific codes established by the State to identify each ILOS in enrollee encounter data, including the use of specific Healthcare Common Procedure Coding System (HCPCS) or CPT codes and modifiers, if needed, that identify each ILOS.
- Revises § 438.66(e)(2)(vi) to add the phrase "including any ILOS" to provide an explicit reference in the annual performance report to CMS for each Medicaid managed care program (MCPAR).

Retrospective Evaluation (§§ 438.16(d) and (e), 438.66(e), 457.1201(c))

- New § 438.16(e)(1) requires states to submit a retrospective evaluation to CMS of ILOS, if the final ILOS cost percentage exceeds 1.5 percent and that an evaluation be completed separately for each managed care program that includes an ILOS.
    - ***Note on request for public comment:*** CMS seeks input on whether the evaluation should be completed for each managed care program, across multiple managed care programs, each managed care plan contract, or at a level selected by the state.
- New § 438.16(e)(1)(ii) requires a state's retrospective evaluation would have to use the 5 most recent years of accurate and validated data for the ILOSs and that it be retroactive to the first complete rating period following the effective date of this provision in which the ILOS was included in the managed care plan contracts and capitation rates.
- New § 438.16(e)(1)(iv) requires states submit a retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included the ILOS following the effective date of this provision.
- Minimum elements in evaluation include:
    - New § 438.16(e)(1)(iii)(A) requires an assessment of impact on utilization of state plan-covered services and settings, including any associated savings.
    - New § 438.16(e)(1)(iii)(B) requires assessment of utilization trends in managed care plan and enrollee use of each ILOS.
    - New § 438.16(e)(1)(iii)(C) requires assessment to evaluate if each ILOS is a cost-effective and medically appropriate substitute for the identified covered service or setting under the State plan or a cost-effective measure to reduce or prevent the future need to utilize the identified covered service or setting under the State plan.
    - New § 438.16(e)(1)(iii)(D) requires assessment of impact on quality of care.
    - ***Note on request for public comment:*** CMS is soliciting comments on whether states should be required to use an independent evaluator for ILOS evaluations.
    - New § 438.16(c)(1)(i) requires the final ILOS cost percentage for each year in their retrospective evaluation, with a declaration of compliance with the allowable 5 percent threshold proposed.
    - New § 438.16(e)(1)(iii)(F) requires states to evaluate appeals, grievances, and State fair hearings data, reported separately for each ILOS, including volume, reason, resolution status, and trends.
    - New § 438.16(e)(1)(iii)(G) requires states evaluate the impact of each ILOS on health equity efforts undertaken by the State to mitigate health disparities, using data on sex (including sexual orientation and gender identity), race, ethnicity, disability status, rurality and language spoken.

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

- New § 438.16(e)(2)(i)(A) and (B), require states notify CMS within 30 calendar days if the state determines 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.
- New § 438.16(e)(2)(i) permits CMS to terminate the use of an ILOS, if determined to be noncompliant or receive State notification of noncompliance.

- New § 438.16(e)(2)(iii) requires states submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision by the State to terminate an ILOS, a managed care plan notifying the State it will no longer offer an ILOS, or receipt of notice from CMS to terminate.
- New § 438.16(e)(2)(iii)(A) requires states establish a process to notify enrollees that the ILOS will be terminated 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.
- Permits 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.

Effective Date

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)) no later than the effective date of the final rule. States and managed care plans would have to comply with §§ 438.3(e)(2)(v), 438.16, 438.7(b)(6) no later than the rating period for contracts with Managed care plans beginning on or after 60 days following the effective date of the final rule.

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

Regulatory Background

Current regulation at § 438.330 establishes the Quality Assessment and Performance Improvement (QAPI) programs that states must require of Medicaid managed care plans and further describes the performance improvement projects that states must require of Medicaid managed care plans as part of the QAPI program. In Section 422.152, the quality improvement program requirements for MA organizations are described, including a Chronic Care Improvement Program (CCIP). CMS also required MA organizations to develop and implement Quality Improvement Projects (QIP). However, due to the burden and complexity of those requirements, the 2019 Final Rule (83 FR 16440) removed the QIP requirements.

Further regulations at § 438.340 define requirements for states to draft and implement a quality strategy for assessing and improving the quality of care and services provided by managed care plans. States are then obligated to evaluate the progress through a mandatory External Quality Review. The requirements for the annual External Quality Review on quality, timeliness, and access are noted in §§ 438.350, 438.354, 438.358, 438.360, 438.364, and 457.1250.

CMS proposes these additions and revisions with the intent of creating more flexibility, enhancing evaluation requirements, promoting greater transparency, and reducing unnecessary administrative burdens, among others.

Summary of New or Amended Provisions

Quality Assessment and Performance Improvement Program (§ 438.330)

- Modifies § 438.330 to update regulations that still reference QIP, which was removed in the 2019 Final Rule, as a substitute for performance improvement program in plans serving duals
    - With updates to § 438.330(d)(4) to §422.152(d), CMS will allow states to permit managed care plans exclusively serving duals to use a Medicare-Advantage Chronic Care improvement program in place of QIP.

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

- Revises §438.340(c)(1) to require states to make their quality strategy open for public comment every 3 years regardless of whether changes are made as well as posting evaluation results (proposed at §438.340(c)(2)(ii)).
- Modifies §438.340(c)(3)(ii) to clarify revised and renewed quality strategies must be submitted to CMS every 3 years, in addition to when significant changes are made.

Effective Date

States are required to comply with these updates in § 438.340 no later than one year from the effective date of the final rule and are proposing to codify this applicability date at § 438.310(d)(2) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP.

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

- Propose to remove “primary care case management entity” from the managed care entities subject to EQR under §438.350.
- New §438.358(b)(1) defines the 12-month review period for all but one of the EQR-relate activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c).
    - Exception is the activity that requires a review within the three previous years.
- § 438.358(a)(3) stipulates the 12-month review period for the applicable EQR activities begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity.
    - 12-month review period for EQR activities does not have to be the same as the performance measures time period.
    - Modifies § 438.358(b)(1) and (c) to clarify the EQR-related activities must be performed in the 12 months preceding the finalization and publication of the annual report.
- Propose to add a new optional EQR activity at in § 438.358(c)(7) to support current and proposed managed care evaluation requirements.
- Modifies § 438.360(a)(1) by eliminating requirements for provider accreditation organizations to obtain MA deeming authority in order for states to utilize them for EQR activities.
- Revises § 438.364(a)(2)(iii) to require EQR technical reports include any outcomes data and results from quantitative assessments and whether or not data has been validated AND require data from network adequacy validation.

- Revisions in § 438.364(c) change the date annual EQR technical reports must be finalized and posted from April 30th to December 31st of each year to allow for HEDIS reporting.
- Revisions to § 438.364(c)(2)(i) require states to notify CMS within 14 calendar days of posting their EQR reports on the web, though the manner of notification is not yet specified.

Effective Date

States must comply with these updates to § 438.358 no later than December 31, 2025. CMS plans to codify this applicability date at § 438.310(d)(3) for Medicaid, and through a proposed amendment at § 457.1200(d) to include a cross-reference to § 438.310(d) for separate CHIP. This applicability date aligns with the new annual due date for EQR technical reports as proposed at § 438.364(c)(2)(i).6. Quality Improvement-Quality Rating System (§§ 438.334 and 457.1240)

6. Quality Improvement-Quality Rating System (§§ 438.334 and 457.1240)

Regulatory Background

In the 2016 final rule, § 438.334 established CMS' authority to obligate states to operate a Medicaid managed care quality rating system (QRS). The MAC QRS presents the first time states would be held to a minimum federal standard for their rating systems and beneficiaries. Current regulations also designate CMS to work with states to develop a MAC QRS framework that includes quality measures and a methodology for calculating quality ratings and a minimum set of mandatory quality measures. CMS engaged in several forums to understand state quality measure collecting and reporting efforts in addition to beneficiary challenges and needed resources.

CMS makes these additions and modifications to aid beneficiaries' access to information about eligibility and managed care as well as compare plans based on quality and other factors to support beneficiary decision-making.

Summary of New or Amended Provisions

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

- New subpart G in 42 part 438 implements the MAC Quality Rating System (QRS) framework under § 438.33, including mandatory measures, a rating methodology (either CMS-developed or approved alternative), and mandatory website display format.
- Modifies § 438.505(a)(2) to require states to implement MAC QRS by the end of the fourth calendar year following the effective date of the final rule.
- In § 438.520(a)(6), requires implementation of some website display requirements.
- ***Note on request for public comment:*** CMS requests comment on whether these proposed policies give states sufficient time to implement their MAC QRS or alternative QRS on a timeline that meets their operational needs.
- New § 438.505(a)(3) requires states use the beneficiary support system implemented under current § 438.71 to provide choice counseling to all beneficiaries, and assistance for enrollees on understanding how to use the managed care quality rating system to select a managed care plan, including the receipt of LTSS.

- Redesignates § 438.334(b)(1) to its own provision at § 438.505(c) that requires the MAC QRS to align with the Qualified Health Plan QRS, the MA and Part D QRS, and other related CMS quality rating approaches.

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

- New § 438.510(c)(1)-(3) defines three considerations guiding the selection of measures to establish initial mandatory measure set and to make future updates:
    - Must meet 5 of 6 measure inclusion criteria, that consider if the measure:
        - Is meaningful and useful.
        - Aligns with other CMS rating programs.
        - Assesses health plan performance in at least one of the following areas: customer service, access, health outcomes, quality of care, health plan administration, and health equity.
        - Provides opportunity for plans to influence their performance.
        - Based on data that is available and feasible to report
        - Demonstrate scientific acceptability.
    - Contributes to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas with the measure set.
    - Burdens associated with including the measure do not outweigh the benefits to the overall QRS framework of including the measure.
- ***Note on request for public comment:*** CMS requests comment on the proposed initial mandatory measure set and the criteria to evaluate prospective measures and whether there are additional criteria to use, requiring measures to meet five of six criteria and if that produces a sufficient number of measures, as well reasons and/or data for why the proposed measures meet or do not meet the criteria.

Mandatory Measure Set

- New § 438.510(a) specifies the quality rating system for managed care plans must include the measures in the mandatory measure set – which will be identified by CMS in the technical resource manual proposed at § 438.530.
- CMS is proposing 18 measures, many which overlap with other CMS programs and are commonly reported by states:

Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP-CH)	Prenatal and Postpartum Care (PPC)
Initiation and Engagement of Substance Use Disorder (SUD) Treatment	Hemoglobin A1c Control for Patient with Diabetes (HBD)
Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF)	Asthma Medication Ratio (AMR)
Follow-Up After Hospitalization for Mental Illness (FUH)	Controlling High Blood Pressure (CBP)
Well-Child Visits in the First 30 Months of Life (W30)	CAHPS – How people rated their health plan
Child and Adolescent Well-Care visits (WCV)	CAHPS – Getting care quickly

Breast Cancer Screening (BCS)	CAHPS – Getting needed care
Cervical Cancer Screening (CCS)	CAHPS – How well doctors communication
Colorectal Cancer Screening (COS)	CAHPS – Health plan customer service
Oral Evaluation, Dental Services (OEV)	CMS – MLTSS-1 LTSS Comprehensive Assessment and Update
Contraceptive Care – Postpartum Women (CCP)	CMS – MLTSS-7: LTSS: Minimizing Institutional Length of Stay

- If the proposed rule is approved in 2024, the timeline for adoption of MAC QRS is 12/31/2028.
    - Defines the first measurement year would be 2026.
- Revises § 438.334(b)(1) and (2), redesignated at new proposed § 438.510(b) for Medicaid, to undergo a two-step sub-regulatory process to engage with states and other interested parties, to obtain expert and public input and recommendations prior to modifying the mandatory measure.
- § 438.510(f) requires CMS to publish the modifications to the mandatory measure set in the technical resource manual.
- ***Note on request for public comment:*** CMS requests comment if the agency should initiate the sub-regulatory process to update the mandatory measure list for the third display year, types of engagements important to this sub-regulatory process, types of experts to include, and the medium (e.g., call letter) to obtain public input.

Adding Mandatory Measures (§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

- New § 438.510(b) permits CMS to use the sub-regulatory process to gather input that would be used to determine if a measure meets the proposed standards, at least biennially.
- New § 438.510(d)(1) allows CMS to remove measures outside the sub-regulatory process in three circumstances:
    - When a measure steward (other than CMS) retires or stops maintaining a measure (noted in § 438.510(d)(2))
    - If CMS determines the clinical guidelines of the measure no longer align with positive health outcomes (noted in § 438.510(d)(3))
    - If CMS determines that the measure shows a low statistical reliability (noted in § 438.510(d)(4))
- ***Note on request for public comment:*** CMS requests comment on whether there are additional circumstances to prompt removal without engaging in the sub-regulatory process.

Updating Mandatory Measure Technical Specifications (§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

- New § 438.510(e)(1) obligates CMS to update the technical resource manual to revise descriptions of existing mandatory measures that undergo non-substantive measure technical changes.
    - In the case of non-substantive changes, sub-regulatory processes would not be implemented.
    - New § 438.510(e)(1)(i)-(iv) codifies examples of non-substantive changes.
- New § 438.510(e)(2) specifies updates to a mandatory measure with substantive changes can only occur after completing the sub-regulatory process.

- ***Note on request for public comment:*** CMS requests comment on incorporating substantive measure-specific updates to the existing mandatory measure set only after consultation with states, other interested parties, and the public, or whether CMS should consider a separate process for these types of updates.

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

- New § 438.510(f) requires CMS to communicate changes to mandatory measure sets and the timeline states would be given to implement in the annual technical resource manual.
    - Proposes states have 2 years from the start of the measurement year following the technical resource manual release.
- ***Note on request for public comment:*** CMS requests comment on whether states need the flexibility to update their quality ratings by the end of the second year.
- No stipulation on a specific deadline for states to stop display of a measure that has been removed from the mandatory measure set.
- ***Note on request for public comment:*** CMS requests comment on if the timeframes are appropriate for updates to the mandatory measure set and rationale for why or why not. Further comment is sought on whether CMS should engage in this process more frequently.

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

- New § 438.525 establishes requirements for collecting and using data to calculate managed care quality ratings for mandatory measures.
- New § 438.515(a)(1) requires states must collect data necessary to calculate quality ratings for mandatory measures from plans, and when possible, the FFS program and Medicare.
    - Data must be collected from plans with 500 or more enrollees on July 1 of the measurement year.
    - Further stipulates at § 438.515(a)(2) that states are required to ensure all data collected are validated if used to calculate performance rates for managed care plans (noted in § 438.515(a)(3)).
- ***Note on request for public comment:*** CMS requests comment on the requirement that states collect available data from multiple sources on the mandatory measures and the type of technical assistance that would be most beneficial to States.
- New § 438.515(a)(1) requires States to issue quality ratings as measure performance rates.
- ***Note on request for public comment:*** CMS requests comment on the requirement to issue individual performance rates and additional input on not requiring percentage ratings to reflect a national baseline for each mandatory measure.
- New § 438.515(c) requires CMS to engage with States, beneficiaries, and other stakeholders before proposing to implement domain-level quality ratings for managed care plans.
- ***Note on forthcoming rulemaking*:** CMS intends to issue a future rule on the care domains, methodology, and website display requirements for a MAC QRS.
- New § 438.515(b)(1) specifies states must ensure that the quality ratings include data for all beneficiaries who receive coverage from an MC plan for a service or action for which data are required to calculate the quality rating – including dual eligibles.
- ***Note on forthcoming guidance:*** CMS intends to issue guidance on which beneficiaries must be included in the quality ratings for each MAC QRS mandatory measure in the technical resource manual alongside technical specifications from measure stewards.

- New § 438.515(b)(2) stipulates quality ratings must be calculated at plan level (not contract level).

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

- Modifies § 438.344(e) by redesignating at § 438.520(a)(1)(i) which requires states to provide users the information necessary to understand and navigate the MAC QRS display, including the purpose, dual eligibility and enrollment, and overview of use to the site to select plans.
- Modifies § 438.520(a)(1)(ii) to require states to provide users information on accessing the beneficiary support system.
- Modifies § 438.520(a)(1)(iii) to require states to inform users of how the information provided would be used.
- New § 438.520(a)(5) requires states to provide users information or hyperlinks to direct users to resources and how and where to apply for and enroll in Medicaid or CHIP.
- New § 438.520(a)(2)(i) requires states to enable users to view available plans that a person may be eligible for based on age, location, dual status, and other demographic data.
- ***Note on forthcoming guidance:*** CMS intends to release a MAC QRS design guide that provides an overview of the user testing that states may reference in the website design.
- New § 438.520(a)(2)(ii) and (iii) require states to display each plan's provider directory and drug coverage information as phase one of the display requirements, which can be satisfied by providing hyperlinks.
    - § 438.520(a)(6)(i) and (ii) provides states two additional years after a state's implementation of their MAC QRS to display this information.
- New § 438.520(a)(2)(v) implements a first phase on implementation that requires states to display quality ratings for mandatory measures stratified by factors (e.g., dual eligibility status, race and ethnicity, and sex).
- Amends § 438.520(a)(3) requires states display standardized information defined by CMS to enable users to compare managed care plans and programs (e.g., name, website, phone number, premium, and cost sharing information, covered benefits, certain performance metrics, dual plan offerings).
    - § 438.520(a)(3)(v) authorizes CMS to specify the metrics that are required to be displayed.
- Modifies § 438.520(a)(4)(i) obligates states to provide plain language descriptions of the importance and impact of each quality measure included.
- Requires states through § 438.520(a)(4)(ii) to include the measurement period data that was calculated and further stipulates states provide when, how, and by whom quality ratings have been validated (noted in § 438.520(a)(4)(iii).
- ***Note on request for public comment:*** CMS requests comments on the phased in approach, timeline, display requirements, and technical assistance needed.
- § 438.520(b)(1) provides states the option to display additional measures that are not included in the mandatory measure set if the two requirements set forth in proposed § 438.520(b)(1) and (2) are met.
- Requires states through § 438.520(b)(1) requires states to obtain input from prospective MAC QRS users (e.g., beneficiaries and their caregivers) and, as noted in § 438.520(b)(2), must document the input, modifications made based on that input or rationale for not accepting the input.
- New § 438.535(a)(3) requires states to report the documented input as part of the MAC QRS annual report.

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

- Redesignates § 438.334(c) at § 438.525 and modifies the policy to narrow the changes that would require CMS approval when states implement an alternative QRS.
- Removes language in § 438.334(c)(1) that includes the use of "different performance measures" being subject to review and approval as part of an alternative QRS to provide states flexibility to add measures outside the mandatory measures without CMS approval.
- Eliminates § 438.334(c)(4) and redesignates as § 438.525(c)(2)(i) through (iii) to specify that states are responsible for submitting documents and evidence to demonstrate compliance with the substantial comparability standards.
- ***Note on forthcoming guidance:*** CMS intends to provide instructions on the procedures and dates by which states must submit an alternative QRS request to meet the implementation dates and specifies that implementation must be by the end of the fourth calendar year following the effective date of the final rule.
- Redesignates § 438.334(c)(2), with revisions at § 438.525(c)(2)(iv) to allow states to provide additional supporting documents and evidence that they believe demonstrates the alternative would provide information of managed care plan performance that is comparable to the MAC QRS methodology.
- ***Note on request for public comment:*** CMS requires comment on the process and documentation requirements and the timeline states need to receive approval for implementation by the specified date.

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

- New § 438.530(a) obligates CMS to develop and update annually a Medicaid managed care quality rating system technical resource manual no later than August 1, 2025, that is then updated manually.
- New § 438.530(a)(1) through (3) identify the components of the technical resource manual to be issued by CMS including:
    - The mandatory measure set to inform states what they are required to report, technical specifications, and the subset of measures that must be stratified by demographic factors.
    - Which MAC QRS measures are added or removed from the prior years and the stakeholder engagement that informed those changes.
    - How to use the methodology described in § 438.515 to calculate quality ratings for managed care plans.
- New § 438.530(b) requires CMS to consider stratification guidance issued by measure stewards and other CMS reporting programs when deciding which measures states must stratify. The proposal also describes the agency's intent to align the stratification schedule defined in the Mandatory Medicaid and CHIP Core Set Reporting Proposed Rule.
- The agency is considering releasing an updated technical resource manual at least five months prior to the measurement period the manual will apply.
- ***Note on request for public comment:*** CMS requests comments on which topics states and health plans would like technical assistance or additional guidance, as well as if the manual release timing of at least five months prior to the measurement period is sufficient to make changes.

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

- New § 438.535 requires states to submit to CMS, upon request, information on their MAC QRS to support oversight of Medicaid and CHIP and compliance with MAC QRS requirements. Such requests would be no more than annually.
- The report obligations noted in § 438.535(a)(1) through (7) include:
    - A list of all measures included in the state's MAC QRS, including a list of the mandatory measures reported and, if a state chooses to display additional measures, what they are and a description.
    - The date on which the state publishes or updates its quality ratings for the state's managed care plan.
    - The link to the state's MAC QRS website to enable CMS to ensure the MAC QRS ratings are current.
    - The use of any technical specification adjustments to MAC QRS mandatory measures, which are outside the measure steward's allowable adjustment for the mandatory measure, but that the measure steward has approved for use by the state.
- New § 438.535(a) specifies the report will be "in a form and manner determined by CMS" to allow states to submit information via an online portal.
- New § 438.535(b) establishes states have a minimum of 90 days' notice to provide the report.
- ***Note on request for public comment:*** CMS requests whether states prefer one annual reporting date or a date that is relative to their MAC QRS updates.

Effective Date

These requirements will be effective in accordance with the specified measurement collection period and related requirements.