Sellers Dorsey Summary:

CMS Final Medicaid Managed Care Rule (CMS-2439-F)

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EXECUTIVE SUMMARY

On April 22, 2024, the Centers for Medicare & Medicaid Services (CMS) released for public inspection a final rule, Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality. The final rule will be published in the Federal Register on May 10, 2024. In the unlikely event CMS makes changes to the final rule published on May 10, Sellers Dorsey will reissue this document with updates. 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 final rule adopts new standards for access to care for services delivered through a managed care model, and new and enhanced requirements related to program quality and finance. CMS largely adopted the rules as proposed, with key revisions to state directed payment and quality provisions based on its request for public comment. Effective dates vary, with some provisions applicable on the effective date of the rule (July 9, 2024), and other provisions with longer implementation periods.

The proposed rule was published in the Federal Register on May 3, 2023. CMS accepted public comment on the proposed rulemaking through July 3, 2023. CMS received a total of 415 timely comments, including comments from nineteen state Medicaid agencies and numerous managed care organizations, hospital systems, providers, and other stakeholders. In their comments, many stakeholders requested additional time, resources, and flexibility to comply with the rule.

Of note, CMS simultaneously released a companion final 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 is creating a separate summary of the access rule, coming soon.

KEY PROVISIONS IN THE FINAL RULE INCLUDE

ACCESS

PROPOSED	FINAL
Requires states to conduct annual enrollee experience surveys.	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.	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 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 to Medicare rates for the same services.	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 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.	Requires states to conduct an analysis comparing managed care plan payment rates for homemaker services, home health aide services, personal care services, and habilitation services to fee-for-service (FFS) rates for the same services.

STATE DIRECTED PAYMENTS (SDPs)

PROPOSED

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 and the use of ACR as upper limit for four service areas.

Requires states to submit SDP preprints for approval no later than 90 days before the end of the rating period.

FINAL

- Does NOT include a total expenditure limit for SDPs
- Requires that all SDPs be incorporated into Medicaid managed care capitation rates as adjustments to base capitation rates and prohibits use of separate payment terms.
- Prohibits plans from basing interim payments to a provider on historic utilization with a post-payment reconciliation to utilization during the rating period.
- Removes prior written approval requirement for SDPs that adopt a fee schedule of 100% Medicare rates.
- Requires states to submit SDP preprints and all required documentation no later than the start date specified in the preprint.

Sets an SDP total payment rate limit up to the ACR, for four services:

- Inpatient hospital services
- Outpatient hospital services
- Qualified practitioner services at an academic medical center
- Nursing facility services

Exempts states from submitting evaluation reports for SDPs with final cost percentage below 1.5 percent.

Requires providers to attest that they do not participate in any hold harmless arrangement for any health-related tax, and requires states to make written attestations available upon CMS request or provide satisfactory explanation for why providers are unable/unwilling to provide attestation.

Requires SDPs to have an evaluation plan that includes at least two metrics, including one performance metric.

Cannot be pay-for-reporting.

- Evaluation plan must include baseline statistics on all metrics and include performance targets, including one that is calculated as performance over a baseline.
- Initial evaluation report must include three most recent and complete years of annual metric results and be submitted no later than 2 years after the 3-year evaluation period (First submitted in year 5).

Approval in other years will be based on the evaluation plan and meeting the other SDP requirements in the rule.

Specifies that SDPs using population-based or condition-based payment (PMPMs) must use attribution methodology with data no more than 3 years old, accounts for member preference, and described when and how patients/panels are attributed.

MEDICAL LOSS RATIO (MLR) STANDARDS

PROPOSED

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.

FINAL

Requires Medicaid managed care plans to submit actual expenditures and revenues for SDPs as part of their MLR reports to states.

Requires managed care plans to report any identified or recovered overpayments to states within 30 calendar days.

Requires states to annually submit a summary MLR report for each MCO, PIHP and PAHP under contract that includes at a minimum: the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each plan for the MLR reporting year.

Provides additional flexibility to allow incentive payment contracts between plans and providers to be based on a percentage of a verifiable dollar amount or specific dollar amount.

IN LIEU OF SERVICES (ILOS)

PROPOSED

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.

FINAL

Formalizes CMS' previous ILOS guidance from State Medicaid Director Letter #23-001

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- 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%)

Removes language related to SDPs that are paid as separate terms from the projected and final ILOS cost percentage denominator calculations.

Revises the retrospective evaluation requirement to include language that the evaluation includes all ILOS in that managed care program.

Makes minor revisions to the completion date of the retrospective evaluations.

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

PROPOSED

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 three years.

Removes PCCM entities from the scope of mandatory EQR review.

Proposes changes to what data should be in EQRO reports.

FINAL

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 three years.

Removes PCCM entities from the scope of mandatory EQR review.

Specifies more meaningful data and information to be included in EQR reports.

Establishes consistent 12-month review periods for the annual EQR activities.

CMS is not finalizing changes proposed to the EQR report due date and will instead maintain the April 30 posting requirement.

CMS is not finalizing the proposed change to require states to notify CMS within 14 calendar days of posting their EQR reports.

QUALITY IMPROVEMENT-QUALITY RATING SYSTEM

PROPOSED

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.

FINAL

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Permits states to submit a request for a one-time, one-year extension for the methodology requirements if the State would be unable to fully implement the requirements
Finalizes 16 measures for the mandatory measure list after removing the MLTSS measures based on public comment.

Modifies the release date of the first complete technical resource manual from August 1, 2025 to CY 2027.

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ACCESS

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. Next, 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.

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 healthcare services across delivery systems.

Summary of Proposed to Final Rule and Effective Dates

Enrollee experience surveys

(§§ 438.66(b) and (c), 457.1230(b)) and 457.1207)

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
Revises § 438.66(c)(5) to require states to conduct an annual enrollee experience survey to assure necessary data is collected	Finalized as proposed with modification to	First rating period beginning on or after July 9, 2027.

for monitoring and improvement strategies. • States and managed care plans are encouraged to utilize provider surveys, but they are not currently mandated.	permit states to use a CAHPS survey as required for Medicare Advantage D-SNPs.	
Revises § 438.66(e)(3)(i) to specify states post the Managed Care Program Annual Report (MCPAR) to their website within 30 calendar days of submitting it to CMS.	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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 3 years after the effective date of the final rule. CMS proposed this applicability date in § 438.66(f).	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	CMS finalized the implementation date to provide states with adequate time to conduct the network adequacy analysis.	First rating period beginning on or after July 9, 2026.
Revises § 457.1207 to require states to post comparative summary	CMS finalized the implementation date to	First rating period beginning on or after July 9, 2026.

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.	provide states with adequate time to conduct the network adequacy analysis.	

Appointment Wait Time Standards

(§§ 438.68(e), 457.1218)

Proposed Language	Final Language	Effective Date
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	Finalized as proposed with minor revision at § 438.68(e)(1)(iv) to add "and covered in the MCO's, PIHP's, or PAHP's contract after "[…]other than those listed in paragraphs (e)(1)(i) through (iii) of this section." This is intended to clarify that states do not have to develop wait time standards or surveys for services other than mental health and SUD for behavioral health PIHPs and PAHPs.	First rating period beginning on or after July 9, 2027.

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.	Finalized as proposed with minor revision to add "as covered in the MCO's, PIHP's, or PAHP's contract."	First rating period beginning on or after July 9, 2027.
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	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

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).	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed noting in the preamble the importance for enrollees to be able to access routine appointments for the required services in a timely manner.	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed with a minor change to use "services" instead of "provider types".	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

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 4 years from the effective date of the final rule.	Finalized with a change from four years to three years, which is applicable for separate CHIPs through an existing cross reference at § 457.1230(a) and a proposed cross-reference at § 457.1200(d) as follows "...the first rating period that begins on or after three years after July 9, 2024..."	First rating period beginning on or after July 9, 2027.

Secret shopper surveys

(§§ 438.68(f), 457.1207, 457.1218)

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.

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).	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
New § 438.68(f)(1)(ii)(A) through (D) require 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).	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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).	Finalized as proposed.	First rating period beginning on or after July 9, 2028.

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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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 cannot be owned or controlled by any managed care plan subject to the surveys, and cannot own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.

Assurances of adequate capacity and services- Provider payment analysis

(§§ 438.207(b), 457.1230(b))

Proposed Language	Final Language	Effective Date

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
	Finalized as proposed except for a minor wording correction in § 438.207(b)(3)(i) and to add habilitation in § 438.207(b)(3)(ii).
	• At § 438.207(b)(3)(i), CMS is correcting the regulation to include the phrase "amount paid by the" to ensure that the analysis includes both the total amount paid and percentage to Medicare rates.
	• At § 438.207(b)(3)(ii), CMS is making edits to include habilitation services in the payment analysis. Clarifies that rates approved in 1915(c) waivers are CMS-approved FFS payment rates and can be used for the payment analysis.
		First rating period beginning on or after July 9, 2026.

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.		

Assurances of Adequate Capacity and Services Reporting

(§§ 438.207(d), 457.1230(b))

Proposed Language	Final Language	Effective Date
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	Finalized as proposed with minor revision to § 438.207(d)(3)(i) to clarify states will be required to submit their NAAAR before contract approvals.	§§ 438.207(d)(2), 438.207(b)(3): First rating period beginning on or after July 9, 2026. § 438.207(f): First rating period beginning on or after July 9, 2028.

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 two 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.	Finalized as proposed.	First rating period beginning on or after July 9, 2025.
States must post the report on their website within 30 calendar days of submission to CMS.	Finalized as proposed.	
States must submit their assurance of compliance and analyses using the published Network Adequacy and Access Assurances Report template.	Finalized as proposed.	
Separate CHIP will be required to align with Medicaid for the proposed network adequacy analysis submission timeframes.	Finalized as proposed.	

Remedy Plans to Improve Access

(§ 438.207(f))

Proposed Language	Final Language	Effective Date
Redesignates existing § 438.207(f) as § 438.207(g).	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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	Finalized as proposed.	First rating period beginning on or after July 9, 2028.

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)

Proposed Language	Final Language	Effective Date
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	Finalized as proposed.	First rating period beginning on or after July 9, 2026.

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.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.
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 two years from the effective date of the final rule.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.
Obligates states comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after three	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

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 four years from the effective date of the final rule.	Finalized as proposed.	First rating period beginning on or after July 9, 2028.
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	Finalized as proposed.	First rating period beginning on or after July 9, 2026.

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 do not apply and references to subpart K under part 438 should be read to	Finalized as proposed.	First rating period beginning on or after July 9, 2026.

refer to parity requirements at § 457.496.		

Terminology

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

Proposed Language	Final Language	Effective Date
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."	Finalized as proposed.	July 9, 2024
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."	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
Replaces the definition of PCCM entity at § 438.2 to slash between "health systems" and "providers" with "and" for grammatical accuracy.	Finalized as proposed.	July 9, 2024
Changes "psychiatric" to "mental health" in § 438.3(e)(2)(v) and § 438.6(e).	Finalized as proposed.	First rating period beginning on or after September 7, 2024.

STATE DIRECTED PAYMENTS

Regulatory Background

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

CMS has issued guidance to states regarding SDPs on multiple occasions. In November 2017, CMS published the initial preprint form and guidance for states on using 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 this final rule, CMS seeks to codify policy previously issued as sub-regulatory guidance and requirements incorporated into the 2021 preprint version as well as add new rules and requirements they believe achieve their policy goals. In the preamble to the proposed rule, CMS expressed 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.

Given concerns about oversight of separate payment terms and removal of risk from plans, the final rule requires that all SDPs be incorporated into managed care capitation rates. Notably, while CMS explored the potential for a total expenditure limit on SDPs using a percent of total costs between 10 to 25% in the proposed rule, CMS did not finalize a limit, given concern that alternative options for SDP expenditure limit could have unintended consequences to states' efforts to further their overall Medicaid program goals and objectives. Further, CMS establishes the total payment limit at the ACR for the four specific categories of services (listed below) as the reasonable and appropriate policy to ensure the fiscal integrity of SDP arrangements.

CMS is increasingly focused on demonstrable quality performance and outcomes in SDPs while providing some flexibility related to value-based payments and delivery system reform initiatives. CMS also makes clear that they reserve the right to disapprove programs that do not improve and remove the restriction that previously prohibited states from recouping unspent funds. The final rule will require greater emphasis on states' quality strategy goals and objectives.

Summary of Proposed to Final Rule and Effective Dates

Definitions

(§ 438.6(a))

Proposed Language	Final Language	Effective Date
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	The definition of "state directed payment" is aligned with how it is listed in § 438.2, not in 438.6 (was moved over in the final rule); state-directed payment also replaces the phrase "contract arrangement" throughout the rule. CMS finalized the following definitions as listed in the proposed rule: "Academic medical center," "Average commercial rate," "Final State directed payment cost percentage," "Inpatient hospital services," "Maximum fee schedule," "Minimum fee schedule," "Outpatient hospital services," "Nursing facility services," "Performance measure," "Population-based payment," "Qualified practitioner services at an academic medical center," "Total payment rate," "Total published Medicare payment rate," and "Uniform increase." • The definition for "Condition-based payment" was updated to include: "covered under the contract" to specify that prospective payment must be for services delivered to Medicaid managed care enrollees under the MCO contract. • CMS is *NOT finalizing* a definition for the term "separate payment term" or provisions regarding separate payment terms.	July 9, 2024.

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 an 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))

Proposed Language	Final Language	Effective Date
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).	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.

Non-Network Providers

(§ 438.6(c)(1)(iii))

Proposed Language	Final Language	Effective Date

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.	Finalized as proposed.	July 9, 2024.

SDP Submission Timeframes

(§ 438.6(c)(2)(viii) and (ix))

Proposed Language	Final Language	Effective Date
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.	§ 438.6(c)(2)(viii) is revised to specify "that States must complete and submit all required documentation for each SDP for which written approval is required before the specified start date of the SDP." CMS also specified the "required documentation to satisfy § 438.6(c)(2)(viii) does not include the Medicaid managed care contract amendment or rate amendment that accounts for the SDP."	First rating period beginning on or after July 9, 2026.
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.	This section is not finalized in the final rule language.	First rating period beginning on or after July 9, 2026.
New § 438.6(c)(2)(ix)(A) and (B) requires all amendments be submitted for written prior approval.	This section is not finalized in the final rule language.	First rating period beginning on or after July 9, 2026.

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))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed with minor revisions.	July 9, 2024
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.	Finalized as proposed.	July 9, 2024
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
§ 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	Finalized as proposed.	First rating period beginning on or after July 9, 2024.

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 three 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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
New § 438.6(c)(2)(iii)(B), CMS proposed to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State	Finalized as proposed.	First rating period beginning on or after July 9, 2024

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.	Finalized as proposed.	First rating period beginning on or after the Effective Date of the Final Rule July 9, 2024.

Financing

(§ 438.6(c)(2)(ii)(G) and (H))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	July 9, 2024.
New § 438.6(c)(2)(ii)(H) proposes providers receiving payment under an SDP attest that they do not participate in any hold harmless arrangement with respect to any healthcare-related tax.	Finalized with revisions "States must ensure that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations."	Applicable for the first rating period on or after January 1, 2028.

Tie to Utilization and Delivery of Services for Fee Schedule Arrangements

(§ 438.6(c)(2)(vii))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	Applicable for the first rating period beginning on or after July 9, 2027.
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	Finalized as proposed.	Applicable for the first rating period beginning on or after July 9, 2027.

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))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
Clarifies § 438.6(c)(2)(vi)(B) on how performance in these types of arrangements is measured.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
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.	Finalized as proposed with minor grammatical revisions.	First rating period beginning on or after July 9, 2024.

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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
New § 438.6(c)(2)(vi)(B)(4) and (5) stipulates performance-based payments include a baseline metric and use measurable performance targets relative to a baseline.	Finalized § 438.6(c)(2)(vi)(B)(5) as proposed but with revision to allow performance targets that demonstrate either maintenance or improvement over baseline.	First rating period beginning on or after July 9, 2024.
New § 438.6(c)(2)(vi)(B)(3) proposes states can use 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.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
Adds § 438.6(c)(2)(vi)(C)(1) that population-based payments must be conditioned on the actual delivery of covered services.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.
Adds § 438.6(c)(2)(vi)(C)(2) that condition-based payments require an attribution methodology that uses data no	Finalized as proposed.	First rating period beginning on or after July 9, 2024.

more than three 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.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.
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.	Finalized as proposed with a technical correction.	First rating period beginning on or after July 9, 2024.
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.	Finalized as proposed.	July 9, 2024.

Quality and Evaluation

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

Proposed Language	Final Language	Effective Date
New § 438.6(c)(2)(iv) requires that states must submit an evaluation plan for all SDPs which require written approval.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

New § 438.6(c)(2)(iv)(A) requires 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)).	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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."	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	Finalizing at § 438.6(c)(2)(vi)(B)(5) with a revision, which aligns with § 438.6(c)(2)(iv)(C), that performance targets must demonstrate either maintenance or improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment.	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
Revises § 438.6(c)(7)(i) for the final SDP cost percentage be calculated and recalculated annually to ensure consistent application across all states and managed care programs.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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).	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

• Must submit the three 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 two years after the conclusion of the three-year evaluation period. • Subsequent reports would be submitted to CMS every three years.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
New § 438.6(c)(2)(v)(A)(2) requires evaluation reports include the three most recent and complete years of annual results for each metric as approved under the evaluation plan approved as part of the preprint review.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	CMS is revising paragraph (c)(2)(ii)(F) to clarify that, at CMS' request, States must provide an evaluation report for each SDP demonstrating the achievement of the stated goals and objectives identified in the State's evaluation plan.	First rating period beginning on or after July 9, 2027.
In a concurrent proposal at § 438.358(c)(7), CMS added a new, optional EQR activity to support evaluation requirements.	Finalized as proposed.	July 9, 2024.

Contract Term Requirements

(§§438.6(c)(5), 438.7(c)(6))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.
New §438.6(c)(5)(iii) requires the state to include a description of each SDP arrangement in the managed care contract.	Finalized as proposed with minor grammatical revisions.	First rating period beginning on or after July 9, 2026.
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 to audit the SDP and report provider-level payment amounts to CMS.	Finalized as proposed.	First rating period beginning on or after July 9, 2026.
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.	CMS finalized "a requirement for submission of minimum contract documentation for an SDP to CMS no later than 120 days after the SDP start date but not the proposal for submission within 120 days of CMS' written prior approval if that is later than the start date of the SDP" (see pg. 327).	July 9, 2028.
§438.6(c)(5)(vi) requires that all SDPs must be specifically	This content is moved to 438.6(c)(5)(v).	Not Applicable.

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))

Proposed Language	Final Language	Effective Date
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 principles and practices" with a requirement to meet the standards in Sections 438.7 (rate certification submission) and 438.8 (MLR standards).	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
New § 438.6(c)(6)(ii) would prohibit states from using	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

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 SDP and to each managed care program to provide clarity to the managed care plan and to facilitate state and federal oversight.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.
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.	Finalized as proposed.	First rating period beginning on or after July 9, 2027.

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.	Finalized as proposed	First rating period beginning on or after July 9, 2027.
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.	This section is not finalized in the final rule.	Not Applicable.
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.	This section is not finalized in the final rule.	Not Applicable.
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.	This section is not finalized in the final rule.	Not Applicable.
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.	This section is not finalized in the final rule.	Not Applicable.
New § 438.7(f)(4) would require States to submit a rate certification incorporating the	This section is not finalized in the final rule.	Not Applicable.

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

(§ 438.6(c)(6), 438.7(c)(4) through (6))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	July 9, 2024.
New § 438.7(c)(4) requires states to 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.	Finalized as proposed.	July 9, 2024.

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.	Finalized as proposed with minor revisions.	First rating period beginning on or after July 9, 2028.

Appeals

(§ 430.3(e))

Proposed Language	Final Language	Effective Date
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	Finalized § 430.3(d) as proposed, but redesignated as § 430.3(e) to reflect new § 430.3(d) in the interim final rule Enforcement of State Compliance with Reporting and Federal Medicaid Renewal Requirements under the Social Security Act (88 FR 84733) published December 2023.	July 9, 2024.

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 6 to 9 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.		

Reporting Requirements to Support Oversight

(§438.6(c)(4), 438.8(e)(2)(iii)(C) and (f)(2)(vii))

Proposed Language	Final Language	Effective Date
Modifies § 438.8(k) to require that managed care plans include SDPs and associated revenue in	CMS is not finalizing §§ 438.8(k)(1)(xiv) and (xv) or 438.74(a)(3) through (4) to	July 9, 2024.

their MLR reports to the state and, as required under § 438.74, have states report this information to CMS.	require State and plan line-level reporting of SDPs CMS finalized §§ 438.8(k)(1)(vii) as proposed.	
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.	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	Applicable for the first rating period beginning on or after July 9, 2026.

MEDICAL LOSS RATIO (MLR) STANDARDS

Regulatory Background

Medical Loss Ratios (MLR) are a tool for CMS and states to use to assess that Medicaid managed care capitation funds are appropriately set and 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. Also of note, managed care MLR reporting requirements in § 438.8(k) codified in the 2016 final rule do not address inclusion of SDPs in MLR.

The final rule aims to address vulnerabilities CMS identified as part of their review of states' oversight of managed care plan MLR reporting. The final rule further aligns MLR requirements across markets in support of administrative efficiency for states and provides for a comparison of MLR data between the private market issuers and Medicaid and CHIP. The final rule included only minor changes from the proposed rules to further align provider bonus and incentive payment language with language in the July 1, 2022, private market regulations at 45 CFR 158.140(b)(2)(iii), to extend the compliance effective date to July 9, 2025, and to provide additional flexibility regarding the financial terms of incentive payments to include either a specific dollar amount or a percentage of a verifiable dollar amount.

Summary of Proposed to Final Rule and Effective Dates

Standards for Provider Incentives

(§§ 438.3(i), 438.8(e)(2), 457.1201, 457.1203)

Proposed Language	Final Language	Effective Date
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 be signed by all parties. • Include clearly defined, objectively measurable and well-document clinical or quality improvement/performance standards/metrics to receive bonus or incentive (required to be included in MLR numerator).	Finalized as proposed with slight modifications as follows: Modifies § 438.3(iii) to align the language with the private market regulations and § 438.8(e)(2) as follows: • Include **clearly** defined, **objectively measurable, and well-documented clinical or** quality improvement **standards** that the provider must meet to receive the incentive payment. Revised § 438.3(iv) to allow for a specific dollar amount **or a**	First rating period beginning on or after July 9, 2025.

• Specify a dollar amount clearly linked to successful completion of metrics and date of payment.	**percentage of a verifiable** dollar amount that can be linked to successful completion of metrics defined in the incentive payment contract including a date of payment. § 438.3(i)(3)(iii) and (iv) are equally applied to separate CHIP through cross-reference at § 457.1201(b).	
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 state routinely. • Prohibit the use of attestations as documentation.	Finalized as proposed.	First rating period beginning on or after July 9, 2024.

Prohibited Costs in Quality Improvement Activities

(§§ 438.8(e)(3)), 457.1203(c))

Proposed Language	Final Language	Effective Date
Amends § 438.8(e)(3)(i) and §457.1203(c) to prohibit the inclusion of indirect or overhead expenses that are not directly related to quality improvement.	Finalized as proposed.	

Additional Requirements for Expense Allocation Methodology

(§§438.8(k)(l)(vii)), 457.1203(f))

Proposed Language	Final Language	Effective Date
New § 438.8(k)(l) (vii) and § 457.1203(f) require that managed care plans include information that reflects the same documentation as required under Marketplace requirements, including that managed care plans include a description of their methodology for allocating expenses, including incurred claims, quality improvement expenses, Federal and State taxes, and licensing or regulatory fees and other non-claims costs.	Finalized as proposed.	July 9, 2024.

Credibility Factor Adjustment to Publication Frequency

(§§ 438.8(h)(4)), 457.1203(c))

Proposed Language	Final Language	Effective Date
Revises §§438.8(h)(4) and 457.1203(c) to remove requirements 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.	Finalized as proposed.	July 9, 2024.

MCO, PIHP, PAHP MLR Reporting Resubmission Requirements

(§§ 438.8(m)), 457.1203(f))

Proposed Language	Final Language	Effective Date
Amends §§ 438.8(m) and 457.1203(f) to specify that managed care plans would only be required to re-submit MLR reports to State when the State makes a retroactive change to capitation rates, not when there are changes made to capitation payments.	Provisions were removed and not finalized as proposed. CMS determined the proposed provisions at §§ 438.8(m) and 457.1203(f) restricting managed care plan MLR submissions to when States making capitation rate changes may not accurately reflect MLRs.	Not applicable

Level of MLR Data Aggregation

(§§ 438.74), 457.1203(e))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	September 7, 2024.
Adds language in § 438.74(a)(2) that the summary description submitted by the state to CMS be provided for each contracted plan.	Finalized as proposed.	September 7, 2024.

Contract Requirements for Overpayments

(§§ 438.608(a)(2) and (d)(3)), 457.1285)

Proposed Language	Final Language	Effective Date
Amends §§ 438.608(a)(2) and 457.1285 to define "prompt" as within 10 business days of identifying or recovering an overpayment.	Revises §§ 438.608(a)(2) and 457.1285 to define "prompt" as within 30 calendar days of	First rating period beginning on or after July 9, 2025.

	identifying or recovering an overpayment.	
Revises §§438.608(d)(3) and 457.1285 to specify that any overpayment (whether identified OR recovered) must be reported by plans to the State.	Modifies §§ 438.608(d)(3) and 457.1285 to specify that any overpayment (whether identified OR recovered) must be reported by plans **annually** to the state.	First rating period beginning on or after July 9, 2025.

Reporting of SDPs in the Medical Loss Ratio

(MLR) (§§ 438.8(e)(2)(iii) and (f)(2), § 438.74, 457.1203(e), 457.1203(f))

Proposed Language	Final Language	Effective Date
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 State in the MLR numerator. • In § 438.8(f)(2)(vii), require that State payments to plans for approved arrangements be included in 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. • Amend § 457.1203(f) to exclude references to state	Finalized §§ 438.8(e)(2)(iii) and 457.1203(f) as proposed. Revised § 438.8(f)(2)(vii) to require that state payments to plans for all state directed payments (including those that are currently paid as separate payment terms, until they are no longer permissible) be included in the denominator as revenue. Removed proposals at § 438.8(k)(l)(xiv) and (xv) requiring line item-level reporting.	September 7, 2024.

directed payments for CHIP plan MLR reporting		
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 number 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 State makes to plans for approved SDPs under § 438.6 (c). • Amends § 457.1203(e) to exclude any reference to state directed payment reporting for CHIP MLR reporting.	Removes § 438.74(a)(3)	Not applicable.

IN LIEU OF SERVICES AND SETTINGS (ILOS)

Regulatory Background

In-Lieu of Services (ILOS) can be an innovative option that states may consider employing in Medicaid and CHIP managed care to address social determinants of health (SDOH) and health-related social needs (HRSN). The use of ILOSs can also improve population health, reduce health inequities, and lower overall healthcare costs in Medicaid. ILOS 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 state's applicable contracts with its managed care plans and corresponding capitation rates and are subject to CMS review and approval in accordance with § 438.3(a) and § 438.7(a). 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 final rule is 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 Proposed to Final Rule and Effective Dates

Overview of ILOS Requirements

(§§ 438.2, 438.3(e), 438.16, 457.1201(e))

Proposed Language	Final Language	Effective Date
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).	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	July 9, 2024.

ILOS General Parameters

(§§ 438.16(a) through (d), 457.1201(c) and (e)), 457.1203(b))

Proposed Language	Final Language	Effective Date

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
	Finalized §§ 438.16(a-d) and 457.1201(c) and (e) and 457.1203(b) as proposed, with modifications to §§ 438.16(c)(2)(ii) and 438.16(c)(3)(ii) to remove the language related to SDPs that are paid as separate payment terms from the projected and final ILOS cost percentage denominator calculations as these will no longer be permitted.	The first rating period beginning on or after September 7, 2024.

capitation payments for *each* managed care program, including all SDP in effect and pass-through payments in effect, and the actual total SDP that are 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.	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.
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).	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.
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	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.

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), 438.10(g), 457.1201(e), 457.1207)

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed with grammatical modification.	July 9, 2024.
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	Finalized as proposed with grammatical modification.	July 9, 2024.

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))

Proposed Language	Final Language	Effective Date
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).	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.
Further specifies § 438.16(d)(1)(i) and (ii) to require that States provide 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.	Finalized as proposed, with grammatical modifications.	The first rating period beginning on or after September 7, 2024.

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).	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.
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).	Finalized as proposed	The first rating period beginning on or after September 7, 2024.

Payment and Rate Development

(§§ 438.3(c), 438.7(b), 457.1201(c))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed	July 9, 2024.
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.	Finalized as proposed	For § 438.7(b)(6), the first rating period beginning on or after September 7, 2024. For § 438.7(c)(4), July 9, 2024.
Note CMS intent to issue additional guidance: CMS intends to issue additional guidance in the Medicaid Managed Care Rate Development Guide, per §	CMS notes that they do not believe additional Federal guidelines are necessary, but they will continue to monitor this issue and may consider providing guidance within the	Not applicable

438.7(e), on the federal standards and documentation requirements for adequately addressing ILOSs in all rate certifications.	annual Medicaid Managed Care Rate Development Guide if deemed necessary.	

State Monitoring

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

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.
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).	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.

Retrospective Evaluation

(§§ 438.16(e), 457.1201(c))

Proposed Language	Final Language	Effective Date
New § 438.16(c)(1)(i) requires that the projected ILOS cost percentage cannot exceed 5 percent and the	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.

final ILOS cost percentage cannot exceed 5 percent.		
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.	Revised § 438.16(e)(1) to require states to submit at least one retrospective evaluation of all ILOSs to CMS when the final ILOS cost percentage exceeds 1.5 percent in any of the first 5 rating periods that each ILOS is authorized and identified in the managed care plan contracts. CMS revised § 438.16(e)(1)(i) to include language that the retrospective evaluation must be completed separately for each managed care program that includes an ILOS **and include all ILOSs in that managed care program.** Finalized with minor grammatical modifications.	The first rating period beginning on or after September 7, 2024.
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.	Revised § 438.16(e)(1)(ii) to require states' retrospective evaluations be completed using 5 years of accurate and validated data for the ILOS with the basis of the data being the first 5 rating periods that the ILOS is authorized and identified in the managed care plan contracts.	The first rating period beginning on or after September 7, 2024.
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.	Revised § 438.16(e)(1)(iv) to require the state to submit the retrospective evaluation to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that the ILOS is authorized and identified in the managed care plan contract or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent.	The first rating period beginning on or after September 7, 2024.
Minimum elements in evaluation include:	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.

• New § 438.16(e)(1)(iii)(A) requires 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. • New § 438.16(e)(1)(iii)(F) requires states 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))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed with grammatical modifications.	The first rating period beginning on or after September 7, 2024.
New § 438.16(e)(2)(ii) permits CMS to terminate the use of an ILOS, if determined to be noncompliant or receive State notification of noncompliance.	Finalized as proposed, with an edit to clarify that identified noncompliance relates to part 438, not just § 438.16.	The first rating period beginning on or after September 7, 2024.
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.	Revised to allow states to submit an ILOS transition plan within 30 calendar days of notice receipt as follows: "Within 30 calendar days of receipt of a notice described in paragraph(e)(2)(iii)(A), (B) or (C) of this section, the State must submit an ILOS transition plan to CMS for review and approval: (A) The notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS; (B) The notice an MCO, PIHP, or PAHP provides to the State of its decision to cease offering an ILOS to its enrollees; or (C) The notice CMS provides to the State of its decision to require the State to terminate an ILOS."	The first rating period beginning on or after September 7, 2024.

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.	Redesignated the requirements for an ILOS transition plan to § 438.16(e)(2)(iv)	The first rating period beginning on or after September 7, 2024.
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.	Finalized as proposed.	The first rating period beginning on or after September 7, 2024.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM, STATE QUALITY STRATEGIES AND EXTERNAL QUALITY REVIEW

Regulatory Background

Current regulation at § 438.330 establishes the Quality Assessment and Performance Improvement (QAPI) programs states must require of Medicaid managed care plans and further describes the performance improvement projects states must require of Medicaid managed care plans as part of the QAPI program. In Section 422.152, the quality improvement program requirements for Medicare Advantage (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 removed the QIP requirements. Through this final rule, QIPs are permitted as a substitute for performance improvement programs in plans serving dually eligible individuals.

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. Included in these enhanced requirements set forth in the rule is that state quality strategies must be both posted for public comment and submitted to CMS every 3 years, regardless of whether there is significant change. States are then obligated to evaluate the progress through a mandatory External Quality Review. The final rule defines that EQR technical reports must include any outcomes data and results from quantitative assessments and whether data has been validated AND require data from network adequacy validation. The full scope of 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 states that this final rule is intended to create more flexibility, enhance evaluation requirements, promote greater transparency, and reduce unnecessary administrative burdens, among other things.

Summary of Proposed to Final Rule and Effective Dates

Quality Assessment and Performance Improvement Program

(§ 438.330)

Proposed Language	Final Language	Effective Date
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	Finalized as proposed.	Proposed compliance no later than rating period for contracts beginning after July 9, 2024. However, because the change is optional, CMS is not finalizing applicability date.

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)

Proposed Language	Final Language	Effective Date
Revises § 438.340(c)(1) to require states 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)).	Finalized as proposed.	No later than July 9, 2025. Note: The applicability date is finalized at § 438.310(d)(1) rather than § 438.310(d)(2) as proposed.
Modifies §438.340(c)(3)(ii) to clarify that revised and renewed quality strategies must be submitted to CMS every 3 years, in addition to when significant changes are made.	Finalized as proposed.	No later than July 9, 2025. Note: The applicability date is finalized at § 438.310(d)(1) rather than § 438.310(d)(2) as proposed.

External Quality Review

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

Proposed Language	Final Language	Effective Date
Removes "primary care case management entity" from the managed care entities subject to EQR under § 438.350.	Finalized as proposed with two modifications: • Modifies § 438.358(b)(2) to more explicitly allow validation of performance measures and performance improvement projects conducted by PCCM entities	July 9, 2024.

	by modifying the word "must" and replacing with "may". • Modifies § 438.358(c)(3) and (4) to remove references to PCCM entities within the optional activities.	
New § 438.358(b)(1) defines the 12-month review period for all but one of the EQR-related activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c). • Exception is the activity that requires a review within the 3 previous years.	CMS removed the reference to review period from the optional activities at § 438.358(c).	December 31, 2025.
§ 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.	Finalized as proposed but removes reference to the optional activities in the new review period regulation at § 438.358(a)(3).	December 31, 2025.
Adds a new optional EQR activity at § 438.358(c)(7) to support current and proposed managed care evaluation requirements.	Finalized as proposed.	No later than July 9, 2025. Note: The applicability date is finalized at § 438.310(d)(2) rather than § 438.310(d)(3) as proposed.

Modifies § 438.360(a)(1) by eliminating requirements for provider accreditation organization to obtain MA deeming authority in order for states to utilize them for EQR activities.	Finalized as proposed.	July 9, 2024.
Revises § 438.364(a)(2)(iii) to require EQR technical reports include any outcomes data and results from quantitative assessments and whether data has been validated AND require data from network adequacy validation.	Finalized as proposed.	No later than one year from the issuance of the associated protocol.
Revises § 438.364(c) to 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.	This section is not finalized in the final rule.	July 9, 2024.
Revises § 438.364(c)(2)(i) to require states to notify CMS within 14 calendar days of posting their EQR reports on the web.	This section is not finalized in the final rule.	July 9, 2024.

QUALITY IMPROVEMENT-QUALITY RATING SYSTEM

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 represents the first time states would be held to a minimum federal standard for their rating systems and beneficiaries. Current regulations designate CMS 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. Through this final rule, States are permitted to request a one-time one-year extension to implement the QRS methodology requirements and related requirements.

CMS states that the final rule will aid beneficiaries' access to information about eligibility and managed care as well as allow the comparison of plans based on quality and other factors to support beneficiary decision making.

Summary of Proposed to Final Rule and Effective Dates

Provisions of the Proposed Rule

(§§ 438.334, 438 subpart G, 457.1240(d))

Proposed Language	Final Language	Effective Date
New subpart G in 42 part 438 implements the MAC Quality Rating System (QRS) framework under § 438.334, including mandatory measures, a rating methodology (either CMS-developed or approved alternative), and mandatory website display format.	Finalized as proposed. Specific modifications below.	July 9, 2028.
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.	CMS maintains the implementation timeline for the fourth calendar year following the effective date of the final rule. However, in new provisions at § 438.515(d) and § 438.520(b), CMS finalized that states may submit a request for a one-time, one-year extension for the methodology requirements if the state would be unable to	Must comply by December 31, 2028. States that request an extension will not be required to fully comply until December 31, 2029.

	fully implement the requirements in § 438.515(b) or § 438.520(a)(2)(v) and (a)(6).	
§ 438.520(a)(6), requires implementation of some website display requirements.	The website requirements will be implemented in a second phase. In § 438.520(a)(6), states will be required to implement interactive search tools and stratify quality ratings by certain additional factors identified by CMS. In new provisions at § 438.515(d) and § 438.520(b), allows states to submit a request for a one-time, one-year extension for the website display requirements if the state would be unable to fully implement the requirements in § 438.515(b) or § 438.520(a)(2)(v) and (a)(6).	By a date specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in 438.505 (July 9, 2028).
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.	Finalized as proposed with minor changes to improve readability.	By December 31, 2028.
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.	Finalized as proposed.	Not Applicable

Establishing and Modifying a Mandatory Measure Set for MAC QRS

(§§ 438.334(b), 438.510, 457.1240(d))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed with minor revisions: • Modifies (c)(1)(ii) to require alignment *to the extent appropriate* with other CMS programs. • Modifies the proposed feasibility measure selection criteria at § 438.510(c)(1)(v) to add "providers" to ensure burden of data reporting for providers is considered. CMS finalized a new (c)(4) at § 438.510 that permits CMS, when assessing whether a measure meets the measure standards in § 438.510(c)(2) and (3), to consider the measure set as a whole, each specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas. The finalized measure criteria are available in Appendix A.	July 9, 2024.

Mandatory Measure Set

(§§ 438.510(a) and 457.1240(d))

Proposed Language	Final Language	Effective Date
New § 438.510(a) specifies the quality rating system for managed care plans must include	Finalized as proposed with modifications to clarify that the mandatory minimum measure	July 9, 2024.

the measures in the mandatory measure set – which will be identified by CMS in the technical resource manual proposed at § 438.530.	set includes only measures calculated using the technical specifications identified and specified by CMS in the technical resource manual.	
CMS proposes 18 measures, many that overlap with other CMS programs and are commonly reported by states.	Finalized 16 of the 18 measures proposed and removed the MLTSS measures: • MLTSS-1 LTSS Comprehensive Assessment and Update ○ CMS – MLTSS-7: LTSS: Minimizing Institutional Length of Stay The finalized measure set is available in Appendix B.	July 9, 2024.
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.	CMS is finalizing as proposed §§ 438.510(b) and 457.1240(d) related to the sub-regulatory process. CMS is modifying § 438.510(b) to clarify CMS is required to engage in the sub-regulatory process at least every other year, however they are not required to update the mandatory measure set at least every other year after completing the sub-regulatory process.	July 9, 2024.
New § 438.510(f) requires CMS to publish the modifications to the mandatory measure set in the technical resource manual.	Finalized as proposed.	July 9, 2024.

Adding Mandatory Measures

(§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	July 9, 2024.
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)).	Finalized as proposed.	July 9, 2024.

Updating Mandatory Measure Technical Specifications

(§§ 438.510(b)(2), (d) and (e) and 457.1240(d))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed with a clarification revision in the last sentence of the introductory paragraph (e) to remove the phrase "but not limited to".	July 9, 2024.

• In the case of non-substantive changes, sub-regulatory processes would not be implemented.		
New § 438.510(e)(2) specifies updates to a mandatory measure with substantive changes can only occur after completing the sub-regulatory process.	Finalized as proposed with a clarification revision in the last sentence of the introductory paragraph (e) to remove the phrase "but not limited to".	July 9, 2024.

Finalization and Display of Mandatory Measures and Updates

(§§ 438.510(f) and 457.1240(d))

Proposed Language	Final Language	Effective Date
New § 438.510(f) requires CMS 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.	Finalized as proposed.	July 9, 2024.
No stipulation on a specific deadline for states to stop display of a measure that has been removed from the mandatory measure set.	Finalized as proposed.	July 9, 2024.

MAC QRS Methodology

(§§ 438.334(d), 438.515, 457.1240(d))

Proposed Language	Final Language	Effective Date
New § 438.525 establishes requirements for collecting and using data to calculate managed care quality ratings for mandatory measures.	Finalized new addition at § 438.515(c)(1).	July 9, 2024.
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)).	CMS finalized at § 438.515(a)(1)(i), as proposed, the enrollment threshold of 500 will be calculated as described by CMS in the technical resource manual. CMS is not finalizing the proposed requirement at § 438.515(a)(1)(i) that enrollment as of July 1 of the measurement year be used to determine which managed care plans are subject to the MAC QRS rating and will instead issue sub-regulatory guidance on how to determine if a plan has 500 or more enrollees. CMS is modifying § 438.515(a)(2) by adding language to require that the validation of data used to calculate performance rates for MAC QRS measures must not be performed by any entity with a conflict of interest, including managed care plans. New paragraph (d) provides the opportunity for States to request one-time one-year extension of the deadline by which the first quality ratings must be issued.	July 9, 2024.

New § 438.515(a)(1) requires States to issue quality ratings as measure performance rates.	Finalized as proposed. Note: Modifications finalized at § 438.510(a)(1) narrowed the scope of measures that must be included in the MAC QRS which subsequently narrows the scope of data that must be collected and validated.	July 9, 2024.
New § 438.515(c) requires CMS engage with States, beneficiaries, and other stakeholders before proposing to implement domain-level quality ratings for managed care plans.	Language is instead finalized as paragraph (e).	July 9, 2024.
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.	CMS finalized the requirement that MAC QRS quality ratings are inclusive of all plan enrollees. Removed reference to § 438.515(a)(1) in this section due to modifications in other areas.	No later than December 31, 2028. The flexibility for States to request a one-time, one-year implementation extension for the MAC QRS methodology requirements applies and if requested would require compliance by December 31, 2029.
New § 438.515(b)(2) stipulates quality ratings must be calculated at plan level by program (not contract level).	Finalized as proposed.	July 9, 2024.

MAC QRS Website Display

(§§ 438.334(e), 438.520(a) and (b), 457.1240(d))

Proposed Language	Final Language	Effective Date
Modifies § 438.344(e) by redesignating at § 438.520(a)(1)(i) which requires states to provide users information necessary to understand and navigate the	CMS revised 438.520(a) to include language establishing that the requirements described in § 438.520(a) must be both prominently displayed and accessible to the public on the	July 9, 2024.

MAC QRS display, including the purpose, dual eligibility and enrollment, and overview of use to the site to select plans.	website required under § 438.10(c)(3).	
Modifies § 438.520(a)(1)(ii) to require states to provide users information on accessing the beneficiary support system.	Finalized as proposed.	July 9, 2024.
Modifies § 438.520(a)(1)(iii) to require states to inform users of how information provided would be used.	CMS modified § 438.520(a)(1)(iii) to clarify if users are requested to input user-specific information the state must provide an explanation of why the information is requested, how it will be used, and whether it is optional or required to access a QRS feature or type of information	July 9, 2024.
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.	Finalized as proposed.	July 9, 2024.
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.	Finalized as proposed.	July 9, 2024.
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, that can be satisfied by providing hyperlinks. • § 438.520(a)(6)(i) and (ii) provides states two additional years after a state's implementation of	CMS finalized § 438.520(a)(6)(i) and (ii) with modifications to require these search tools only for managed care programs with more than one plan.	New § 438.520(a)(2)(ii) is effective July 9, 2024. At § 438.520(a)(6) the effective date will be specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in 438.505 (4 years after effective date).

their MAC QRS to display this information.		
New § 438.520(a)(2)(v) implements a first phase on implementation that requires states display quality ratings for mandatory measures stratified by factors (e.g., dual eligibility status, race and ethnicity, and sex).	Finalized as proposed.	July 9, 2024
Revises § 438.520(a)(3) requires states display standardize 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.	Finalized as proposed with modification at § 438.520(a)(3)(iv) to add discretion for CMS to require States to include on the MAC QRS website, in addition to displaying a summary of benefits including differences in benefits among available managed care plans within a single program, other similar information on benefits such as whether access to the benefit requires prior authorization from the plan.	July 9, 2024
Modifies § 438.520(a)(4)(i) obligates states to provide plain language descriptions of the importance and impact of each quality measure included.	Finalized as proposed.	July 9, 2024
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).	Finalized as proposed.	July 9, 2024
§ 438.520(b)(1) provides states the option to display additional measures that are not included	Finalized as proposed. CMS is also finalized at § 438.520(b)(1) that an extension request for	July 9, 2024.

in the mandatory measure set if the two requirements set forth in proposed § 438.520(b)(1) and (2) are met.	requirement under § 438.520 must also include the information described in § 438.515(d)(1) and will be assessed by CMS using the same standards and conditions finalized at § 438.515(d)(3).	
Requires states through § 438.520(b)(1) 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 and modifications made based on that input or rationale for not accepting the input.	Finalized as proposed.	July 9, 2024.
New § 438.535(a)(3) requires states to report the documented input as part of the MAC QRS annual report.	Finalized as proposed.	July 9, 2024.

Alternative Quality Rating System

(§§ 438.334(c), 438.525, 457.1240(d))

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed and addressed the following technical errors: • Corrected the citation that describes the MAC QRS methodology established in CMS. Note: In the final rule, § 438.525 is moved to § 438.515(c). • Conformed technical changes proposed at § 438.525(a)(2) by citing specifically to § 438.515(b)	July 9, 2024.

	describing the CMS methodology.	
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.	Finalized as proposed. Note: As finalized at § 438.510(a), all States must include the mandatory measures that are applicable to the State's managed care program in their QRS, regardless of whether the State uses the CMS or an alternative methodology.	July 9, 2024
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 demonstrates compliance with the substantial comparability standards.	Finalized as proposed.	July 9, 2024
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.	Finalized as proposed.	July 9, 2024

Annual Technical Resource Manual

(§§ 438.334, 438.530, 457.1240(d))

Proposed Language	Final Language	Effective Date
New § 438.530(a) obligates CMS to develop and update annually	CMS modified the release date of the first complete technical	July 9, 2024.

a Medicaid managed care quality rating system technical resource manual no later than August 1, 2025, that is then updated manually.	resource manual from August 1, 2025, to CY 2027. CMS finalized that they may publish the technical resource manual information identified in § 438.530(a) in installments throughout the year to give flexibility to publish the individual pieces of information identified in § 438.530(a) as they are available.	
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 year's list 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.	CMS modified to add a paragraph (c) that stipulates CMS to provide, no later than August 1, 2025, the initial list of mandatory measures, any measures removed from the set before August 2025, and subset of initial mandatory measures that must be stratified. The publishing of technical resource manual in installments throughout the year applies to the requirements at § 438.530(a)(3) to release an updated list of mandatory measures and summary of the sub-regulatory process used to identify the updated set.	July 9, 2024.
New § 438.530(b) requires CMS 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.	Finalized as proposed.	July 9, 2024.

Reporting

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

Proposed Language	Final Language	Effective Date
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.	Finalized as proposed.	July 9, 2024.
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.	CMS finalized § 438.535(a)(1) with modifications to add content to the required report to: • Identify mandatory measures that are not included in their MAC QRS because they are not appliable to the State's Medicaid managed care program. • identify measures as inapplicable to include a brief explanation of why the State determined that the measure is inapplicable. • identify measures as applicable to the managed care programs to which the measure is applicable. CMS added new paragraph (a)(8) to include additional reporting requirements related to Medicare and Medicaid data that is not included in MAC QRS quality ratings.	July 9, 2024.

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.	Finalized as proposed.	July 9, 2024.
New § 438.535(b) establishes states have a minimum of 90 days' notice to provide the report.	Finalized as proposed.	July 9, 2024.

APPENDIX A

As finalized in the rule, CMS defines three considerations that guide the selection of measures in the initial mandatory measure set. CMS will continue to evaluate measures based on those factors:

- Must meet five of six 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, CMS modified language to require alignment *to the extent appropriate* with other CMS programs and modified the proposed feasibility measure selection criteria to add "providers" to ensure burden of data reporting for providers is considered.

APPENDIX B

TABLE 2: Initial MAC QRS Mandatory Measure Set
https://public-inspection.federalregister.gov/2024-08085.pdf

CMIT #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
743	NCQA	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP)	The percentage of members who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment. Ages: 1 to 17	Administrative**
394	NCQA	Initiation and Engagement of Substance Use Disorder Treatment (IET)	The percentage of new substance use disorder (SUD) episodes that result in treatment initiation and engagement. Two rates are reported: • Initiation of SUD Treatment. The percentage of new SUD episodes that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive	Administrative or EHR

			outpatient encounter, partial hospitalization, telehealth, or medication treatment within 14 days. • Engagement of SUD Treatment. The percentage of new SUD episodes that have evidence of treatment engagement within 34 days of initiation. Ages: 13 and older	
672	CMS	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF)	The percentage of members screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of the qualifying encounter. Ages: 12 and older	Administrative or EHR
268	CMS	Follow-Up After Hospitalization for Mental Illness (FUH)	The percentage of discharges for members who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are reported: • The percentage of discharges for which the member received follow-up within 30 days after discharge. • The percentage of discharges for which the member received follow-up within 7 days after discharge. Ages: 6 and older	Administrative

761	NCQA	Well-Child Visits in the First 30 Months of Life (W30)	The percentage of members who had the following number of well-child visits with a primary care practitioner (PCP) during the last 15 months. The following rates are reported: • Well-Child Visits in the First 15 Months. Children who turned age 15 months during the measurement year: Six or more well-child visits. • Well-Child Visits for Age 15 Months to 30 Months. Children who turned age 30 months during the measurement year: Two or more well-child visits. Ages: 0 to 15 months | 15 to 30 months Administrative	Administrative

123	NCQA	Child and Adolescent Well-Care Visits (WCV)	The percentage of members who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement year. Ages: 3 to 21	Administrative
93	NCQA	Breast Cancer Screening (BCS-E)	The percentage of members who were recommended for routine breast cancer screening and had a mammogram to screen for breast cancer. Ages: 50 to 74	Electronic Clinical Data System (ECDS)
118	NCQA	Cervical Cancer Screening (CCS, CCS-E)	The percentage of members who were recommended for routine cervical cancer screening who were screened for cervical cancer using any of the following criteria: • Members 21 to 64 years of age who were recommended for routine cervical cancer screening and had cervical cytology performed within the last 3 years. • Members 30 to 64 years of age who were recommended for routine cervical cancer screening and had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years. • Members 30 to 64 years of age who were recommended for routine cervical cancer screening and had cervical cytology/high-risk human papillomavirus (hrHPV) co-testing within the last 5 years. Ages: 21 to 64	Administrative, hybrid, EHR, or ECDS
139	NCQA	Colorectal Cancer Screening (COL-E)	The percentage of members who had appropriate screening for colorectal cancer. Ages: 45 to 75	ECDS
897	DQA	Oral Evaluation, Dental Services (OEV)	The percentage of members who received a comprehensive or periodic oral evaluation within the reporting year. Ages: 0 to 20	Administrative
166	OPA	Contraceptive Care - Postpartum Women (CCP)	Among women who had a live birth, the percentage that: 1. Were provided a most effective or moderately effective method of contraception within 3 days of delivery and 90 days of delivery. 2. Were provided a long-acting reversible method of contraception (LARC) within 3 days of delivery and 90 days of delivery. Ages: 15 to 44	Administrative
581	NCQA	Prenatal and Postpartum Care (PPC)	Percentage of deliveries of live births on or between October 8 of the year prior to the measurement year and October 7 of the	Administrative or hybrid

			measurement year. For these members, the measure assesses the following facets of prenatal and postpartum care: 1. Timeliness of Prenatal Care. The percentage of deliveries that received a prenatal care visit in the first trimester, on or before the enrollment start date, or within 42 days of enrollment in the organization. 1. Postpartum Care Rate. The percentage of deliveries that had a postpartum visit on or between 7 and 84 days after delivery. Ages: All Ages	
148	NCQA	Glycemic Status Assessment for Patients with Diabetes (GSD)	The percentage of members with diabetes (types 1 and 2) whose most recent glycemic status (hemoglobin A1c [HbA1c] was at the following levels during the measurement year: • Glycemic Status <8.0%. • Glycemic Status >9.0%. Ages: 18 to 75	Administrative or hybrid
80	NCQA	Asthma Medication Ratio (AMR)	The percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. Ages: 5 to 64	Administrative
167	NCQA	Controlling High Blood Pressure (CBP)	The percentage of members who had a diagnosis of hypertension and whose blood pressure was adequately controlled (< 140/90 mm Hg) during the measurement year. Ages: 18 to 85	Administrative, hybrid, or EHR
151/152	AHRQ	CAHPS – How people rated their health plan	The percentage of members who rated their health plan a 9 or 10, where 0 is the worst health plan possible and 10 is the best health plan possible. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ	CAHPS – Getting care quickly	Composite of the following items: • The percentage of members who indicated that they always got care for illness, injury, or condition as soon as they needed, in the last six months. • The percentage of members who indicated they always got check-up or routine care as soon as they needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ	CAHPS – Getting needed care	Composite of the following items: • The percentage of members who indicated that it was always easy to get necessary care, tests, or treatment, in the last six months.	Consumer survey

			• The percentage of members who indicated that they always got an appointment with a specialist as soon as needed, in the last six months. Ages: 0 to 17 | 18 and older	
151/152	AHRQ	CAHPS – How well doctors communicate	Composite of the following items: • The percentage of members who indicated that their doctor always noted things in a way that was easy to understand. • The percentage of members who indicated that their doctor always listened carefully to enrollee. • The percentage of members who indicated that their doctor always showed respect for what enrollee had to say. • The percentage of members who indicated that their doctor always spent enough time with enrollee. Ages: 0 to 17 | 18 and older	Consumer survey
151/152	AHRQ	CAHPS – Health plan customer service	Composite of the following items: The percentage of members who indicated that customer service always gave necessary information or help, in the last six months. The percentage of members who indicated that customer service always was courteous and respectful, in the last six months. Ages: 0 to 17 | 18 and older	Consumer survey

*The CMS Measures Inventory Tool (CMIT) is the repository of record for information about the measures that CMS uses in various quality, reporting, and payment programs. More information is available at https://www.cms.gov/medicare/quality/measures/cms-measures-inventory. A public access quick start guide for CMIT is available at https://cmit.cms.gov/cmit/assets/CMIT-QuickStartPublicAccess.pdf.

**Examples of administrative data collection methods are claims, encounters, vital records, and registries. v AHRQ is the measure steward for the survey instrument (CMIT 151/152) and NCQA is the developer of the survey administration protocol.[1]