| **Summary** |
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| This proposed rule would advance CMS’ efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid and Children’s Health Insurance Program (CHIP) managed care enrollees. The proposed rule would specifically address standards for timely access to care and States’ monitoring and enforcement efforts, reduce burden for some State Directed Payments and certain quality reporting requirements, add new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and specify the scope and nature of ILOS, specify medical loss ratio (MLR) requirements, and establish a quality rating system for Medicaid and CHIP managed care plans. This rule also proposes new standards to help States improve their monitoring of access to care by requiring establishment of new standards for **appointment wait times, use of secret shopper surveys, use of enrollee experience surveys, and requiring States to submit a managed care plan analysis of payments made by plans to providers**, for specific services, to more closely monitor plans’ network adequacy.  **DATES:** To be assured consideration, comments must be received by July 3, 2023.  **Final Rule Published May 10, 2024** |

| **Proposed Changes/Notes—As Finalized** | | | |
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| **Proposed Changes Related to Terminology and Definitions** | | | |
| **Proposed Citation/Proposed Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **Terminology: §438.2, §438.3(e), §438.10(h), §438.68(b), §438.214(b)**  ***Applicability date*:**  No later than the effective date of the final rule (July 9, 2024). | * In the definition of PCCM entity at §438.2 and for the provider types that must be included in provider directories at §438.10(h)(2)(iv), we propose to replace ‘‘behavioral health’’ with ‘‘mental health and substance use disorder;’’ * For the provider types for which network adequacy standards must be developed in §438.68(b)(1)(iii), we propose to remove ‘‘behavioral health’’ and the parentheses; and for the provider types addressed in credentialing policies at §438.214(b), we propose to replace ‘‘behavioral’’ with ‘‘mental health.’’ * We also propose in the definition of PCCM entity at §438.2 to replace the slash between ‘‘health systems’’ and ‘‘providers’’ with ‘‘and’’ for grammatical accuracy. * Similarly, we also propose to change ‘‘psychiatric’’ to ‘‘mental health’’ in §438.3(e)(2)(v) and §438.6(e). We believe that ‘‘psychiatric’’ does not capture the full array of services that can be provided by IMDs. | **Terminology**: Throughout 42 CFR Part 438, [in the current rule] we use ‘‘behavioral health’’ to mean mental  health and SUD. However, it is an imprecise term that does not capture the full array of conditions that are intended to be included, and some in the SUD  treatment community have raised concerns with its use. It is important to use clear, unambiguous terms in  regulatory text. Therefore, we[[1]](#footnote-1) **propose** to  change ‘‘behavioral health’’ throughout  42 CFR Part 438. | Yes--Throughout |
| **Final Rule: Publish date 5/10/24**   * Finalizing “mental health” and “SUD” in §438.2, §438.3(e), §438.10(h), **§**438.68(b), and **§**438.214(b) to ensure that these provisions are clear and unambiguous. | | | |
| **§438.2**  ***Adding Definitions***  ***Applicability date*:** No later than the effective date of the final rule (July 9, 2024). | **§438.2—*Definitions***  **Add definition of *In Lieu of Services (ILOS):***  A service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with §438.3(e)(2). An ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan,  or when the ILOS can be expected to reduce or prevent the future need to utilize the covered service or setting under the State plan.  **Revise the definition of primary care case management entity (PCCM entity):** Revise element (9) ***From***: Coordination with *behavioral health systems/providers*.  ***To***: Coordination with *mental and*  *substance use disorder health systems*  *and providers*. | To ensure clarity on the use of the term ‘‘in lieu of service or setting’’ and the associated acronym ‘‘ILOS,’’ we  propose to add a definition in §438.2 for Medicaid to define an ‘‘in lieu of service or setting (ILOS)’’. | Yes  **§457.10** |
| **Final Rule: Publish date 5/10/24**   * Finalizing the definition of ILOS at §438.2 as proposed. | | | |

| **Proposed Changes/Notes** | | | |
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| **Proposed Changes Related to Payment and Rates** | | | |
| **Proposed Citation/Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **§438.3**  ***Revising****:* §438.3(c)(1)(ii) and  §438.3(e)(2)  ***Adding***: §438.3(i)(3) and (4)  ***Applicability* *date*:**  (e)(2)(v), (i)(3), and (i)(4)—the first rating period beginning on or after 60 days following the effective date of the final rule. | **§438.3—*Standard Contract Requirements* (c)(1)(ii)** The final capitation rates must be based only upon services covered under the State plan, ILOS, and additional services deemed by the State to be necessary to comply with the requirements of Subpart K of this Part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid eligible individuals in a manner compliant with contractual requirements.  **§438.3(e)(2)** An MCO, PIHP or PAHP may  cover, for enrollees, an ILOS as follows:  (ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the ILOS, **and the MCO, PIHP or PAHP must comply with the following requirements:**  (A) An enrollee who is offered or utilizes an ILOS offered as a substitute for a covered service or setting under the State plan retains all rights and protections afforded under Part 438, and if an enrollee chooses not to receive an ILOS, they retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option; and  (B) An ILOS may not be used to reduce, discourage, or jeopardize an enrollee’s access to services and settings covered under the State plan, and an MCO, PIHP or PAHP may not deny access to a service or setting covered under the State plan, on the basis that the enrollee has been offered an ILOS as an optional substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past;  (v) With the exception of a short term stay as specified in §438.6(e) in an Institution for Mental Diseases (IMD), as defined in §435.1010 of this chapter, for inpatient mental health or substance use disorder treatment, an ILOS must also comply with the requirements in §438.16 (new).  **§438.3(i)(3)** The State, through its contracts with an MCO, PIHP, and PAHP must require that incentive payment contracts between the MCO, PIHP, and PAHP and network providers:  (i) Have a defined performance period that can be tied to the applicable MLR reporting periods.  (ii) Be signed and dated by all appropriate parties before the commencement of the applicable performance period.  (iii) Include well-defined quality improvement or performance metrics that the provider must meet to receive the incentive payment.  (iv) Specify a dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a date of payment.  **§438.3(i)(4)** The State through its contracts  with an MCO, PIHP, and PAHP must:  (i) Define the documentation that must be maintained by the MCO, PIHP, and PAHP to support the provider incentive payments.  (ii) Prohibit the use of attestations as supporting documentation for data that factor into the MLR calculation.  (iii) Require the MCO, PIHP, and PAHP to make incentive payment contracts, and any documentation in paragraph (e)(4)(i), available to the State upon request and at any routine frequency established in the State’s contract with the MCO, PIHP, and PAHP. | **§438.3(c)(1)(ii)** As an ILOS is not a managed care plan requirement, but rather offered at the option of the managed care plan, it would not be included within the requirement in §438.3(c)(2)(ii) related to contractual requirements. We propose to revise §438.3(c)(1)(ii) to include ‘‘ILOS’’ to ensure clarity on this matter. We consider this a technical correction to §438.3(c)(1)(ii) as §438.3(e)(2)(iv)  and §438.4(b)(6) clearly denote the inclusion of ILOSs in rate development and we believe this was inadvertently  excluded from the final regulatory text in the 2016 final rule.  **§438.3(e)(2):** Conforming changes to replace “alternative service or setting” and “in lieu of service” with ILOS.  Add new provisions at §438.3(e)(2)(ii)(A) and (B) to ensure enrollee rights and protections and a new  §438.3(e)(2)(v):A short term stay in an IMD as an ILOS is excluded from the calculation for an ILOS cost percentage and must not be used in rate development given the statutory limitations. Instead, States must use the unit costs of providers delivering the same services  included in the State plan as required in §438.6(e). Additionally, as described in §438.6(e), States may only make a monthly capitation payment to an MCO  or PIHP for an enrollee aged 21 to 64 receiving inpatient treatment in an IMD when the length of stay in an IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. Therefore, we propose to add **§438.3(e)(2)(v)** to explicitly provide an **exception from the applicability of §438.16 for short term stays, as specified in §438.6(e), for inpatient mental health or substance use disorder treatment in an IMD.** This proposal does not replace or alter existing Federal requirements and limitations regarding the use of short term IMD stays as an ILOS, or the availability of FFP for capitation payments to MCOs and PIHPs for enrollees who utilize an IMD.  In a new §438.3(i)(3) and (4)for Medicaid, we propose to require that the State, through its contract(s) with a managed care plan, must include specific provisions related to provider incentive contracts. Specifically, the proposed changes would require that incentive payment contracts between managed care plans and network providers have a defined performance period that can be tied to the applicable MLR reporting period(s), and such contracts must be signed and dated by all appropriate parties before the commencement of the applicable performance period. We also propose, in §438.3(i)(3)(iii), that all incentive payment contracts must include well defined quality improvement or performance metrics that the provider must meet to receive the incentive payment. In addition, in §438.3(i)(3)(iv), we propose that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of these metrics as well as a date of payment.  In §438.3(i)(4)(iii), we propose that the State’s contracts require that managed care plans must make the incentive  payment contracts and supporting documentation available to the State both upon request and at any routine frequency that the State establishes. | Yes  **§457.1200(d).§457.1201** (except No for §438.3(e)(2)  (v)as NA) |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.3(e) and §457.1201(c) and (e) with minor modifications. * **Finalizing an effective date for these new contract requirements for provider incentive arrangements as the first rating period beginning on or after 1 year after the effective date of this final rule for the provider incentive changes in §438.3(i) and §438.608(e), and applicable to separate CHIP through the existing cross references at §457.1200(d).** * Revised the proposed language at §438.3(i)(3)(iii) to include the following language, “clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards,” * **Revising §438.3(i)(3)(iv) to also allow for the incentive payment contracts between managed care plans and network providers to specify either a dollar amount or a percentage of a verifiable dollar amount that can be clearly linked to successful completion of the metrics. Revising §438.3(v) to make these provisions effective on or after 60 days following the effective date of this final rule. We are instead finalizing that these provisions are effective for the rating period beginning on or after 1 year following the effective date of this final rule, based on public comments that 60 days may not be long enough to engage with the contracted providers and complete the legal review necessary to implement new provider incentive arrangements.** * Modifying §438.3(i)(3)(iii) describing the performance metrics, based on public comment that consistency is needed between the private market regulations and Medicaid managed care regulations. Therefore, we are finalizing revised text at §438.3(i)(3)(iii) to mirror the text in the private market regulations at 45 CFR §158.140(b)(2)(iii). * Modifying §438.3(i)(3)(iv) that incentive payment contracts must specify a dollar amount that can be clearly linked to successful completion of performance metrics to provide additional flexibility that would better align with current incentive payment practices. As such, we are finalizing the proposal at §438.3(i)(3)(iv) to also allow a percentage of a verifiable dollar amount in the contract, as an alternative to a specific dollar amount, that can be clearly linked to successful completion of the metrics. **We are finalizing the effective date for this provision as the first rating period beginning on or after 1 year after the effective date for the provider incentive changes in §438.3(i) and §438.608(e).** | | | |
| **§438.6**  ***Expand and Restructure* §438.6(c)**  ***Applicability dates*** (§438.6(c)(4) and §438.6(c)(8),  upon the effective date of the final rule. | **§438.6—*Special Contract Provisions Related to Payment***  ***Outline of Changes for §438.6(c):***   * Contract Requirements Considered to be SDPs (Grey Area Payments) * Medicare Exemption, SDP Standards and Prior Approval (§438.6(c)(1)(iii)(B), (c)(2), and (c)(5)(iii)(A)(5)) * Non-Network Providers (§438.6(c)(1)(iii)) * SDP Submission Timeframes (§38.6(c)(2)(viii) and (ix)) * Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for certain SDPs and Expenditure Limit for All SDPs (§38.6(c)(2)(ii)(I) and (c)(2)(iii)) * Financing (§438.6(c)(2)(ii)(G) and (H)) * Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (§438.6(c)(2)(vii)) * Value-Based Payments and Delivery System Reform Initiatives (§438.6(c)(2)(vi)) * Quality and Evaluation (§438.6(c)(2)(ii)(D) and (F), (c)(2)(iv) and (v), and (c)(7)) * Contract Term Requirements (§438.6(c)(5)) * Including SDPs in Rate Certifications and Separate Payment Terms (§438.6(c)(2)(ii)(J), (c)(6), and §438.7(f)) * SDPs included through Adjustments to Base Capitation Rates (§438.7(c)(4) through (6)) * Appeals (§430.3(d)) * Reporting Requirements to Support Oversight (§438.6(c)(4)) | Proposing to define State Directed Payments (SDPs) as a contract arrangement that directs an MCO’s, PIHP’s, or PAHP’s expenditures.  There are circumstances in which a State may believe that requiring managed care plans to make specified payments to health care providers is an important tool in furthering the State’s overall Medicaid program goals and objectives;  for example, funding to ensure certain minimum payments are made to safety net providers to ensure access to care, funding to enhance behavioral health care providers as mandated by State legislative directives, or funding for quality payments to ensure providers are appropriately rewarded for meeting certain program goals. Because this type of State direction reduces the plan’s ability to effectively manage costs, CMS, in the 2016 final rule, established specific exceptions to the general rule prohibiting States from directing the expenditures of MCOs, PIHPs and PAHPs at §438.6(c)(1)(i) through (iii). These exceptions came to be known as State Directed Payments (SDPs).  Permissible SDPs include directives that certain providers of the managed care plan participate in value based purchasing (VBP) models, that certain providers participate in multipayer or Medicaid-specific delivery system reform or performance improvement initiatives, or that the managed care organization adhere to certain fee schedule requirements (for example, minimum fee schedules, maximum fee schedules, and uniform dollar or percentage increases).  The proposed changes in this notice of proposed rulemaking are intended to ensure the following policy goals:  (1) Medicaid managed care enrollees receive access to high-quality care under SDP payment arrangements;  (2) SDPs are appropriately linked to Medicaid quality goals and objectives for the providers participating in the  SDP payment arrangements; and (3) CMS and States have the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and transparency of SDP payment arrangements. | Yes **§457.1203** (except §438.6(c) does not apply |
| **Final Rule: Publish date 5/10/24**   * Finalizing the following definitions in §438.6(a) as proposed:   + “Academic medical center,”   + “Average commercial rate,”   + “Final State directed payment cost percentage,”   + “Inpatient hospital services,”   + “Maximum fee schedule,”   + “Minimum fee schedule,”   + “Outpatient hospital services,”   + “Nursing facility services,”   + “Performance measure,”   + “Population-based payment,”   + “Qualified practitioner services at an academic medical center,”   + “Total payment rate,”   + “Total published Medicare payment rate,” and   + “Uniform increase.” * We are not finalizing a definition for the term “separate payment term” or the provisions regarding separate payment terms (see section I.B.2.l. of this final rule for discussion). * The definition for the term “State directed payment” is finalized as proposed but has been moved from §438.6(a) to §438.2 because it is used in multiple provisions in Part 438. * Finalizing revisions throughout §438.6 and **§**438.7 to use the term “State directed payment” in place of “contract arrangement” or similar terms that are used in the current regulations to refer to State Directed Payments. * The definition for “Condition-based payment” is finalized with the phrase “covered under the contract” at the end to specify that such prospective payment must be for services delivered to Medicaid managed care enrollees covered under the managed care contract. * Finalizing the definition of “Total payment rate” at §438.6(a) as proposed, * Amending §438.6(c)(1) to add the phrase “in any way” after “…The State may not…” to make the regulation more explicit that any State direction of an MCO’s, PIHP’s or PAHP’s expenditures is impermissible unless it meets the requirements set forth in §438.6(c). * Finalizing revisions to §438.6 (c)(2)(i), and (c)(5)(iii)(A)(5) as proposed. * Finalizing §438.6(c)(2)(ii)(D), (c)(2)(iv) and (v) as proposed. * Finalizing the revision to remove “network” from the descriptions of the SDPs in §438.6(c)(1)(iii) as proposed. * **Updating the effective date for §438.6(c)(2)(ii)(H) to no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after January 1, 2028.** * Finalizing §438.6(c)(2)(ii)(F) with a revision to clarify that, at CMS’s request, States must provide an evaluation report to demonstrate that an SDP resulted in achievement of the stated goals and objectives in alignment with the State’s evaluation plan. * Finalizing **§**438.6(c)(2)(ii)(G) as proposed and §438.6(c)(2)(ii)(I) with minor revisions. * Modifying the regulatory text at §438.6(c)(ii)(H) to include language saying States must “ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations.” * Finalizing the following changes to the financing attestation provision in §438.6(c)(2)(ii)(H):   + Updating the proposed language, “ensure that providers receiving payment under a State directed payment attest that providers do not participate in any hold harmless arrangement” to read, in paragraph (H)(1), “ensure that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement.”   + Updating the proposed language, “directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount” to read, in paragraph (H)(1), “directly or indirectly guarantees to hold the taxpayer harmless for all or any portion of the tax amount.”   + Updating §438.6(c)(2)(ii)(H) with an organizational change to divide the provision into paragraphs (H)(1) and (H)(2).   + Updating the proposed language, “ensure that such attestations are available upon CMS request” to read, in paragraph (H)(2), “ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations.” * Finalizing §438.6(c)(2)(ii)(J) as proposed. **Clarification**: although we are only finalizing the total payment rate limit at ACR for four provider types and services (inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center) at §438.6(c)(2)(iii), in practice we intend to use ACR as the fiscal benchmark by which we will evaluate whether all SDP total payment rates are reasonable, appropriate, and attainable. (States are not required to implement SDPs.) * Finalizing §438.6(c)(2)(iii) as proposed, with one modification in paragraph (c)(2)(iii)(B)(*3*) to clarify that the prior approval referenced is “prior approval of the State directed payment…”. * Finalizing §438.6(c)(2)(vi)(B)(5) as proposed but with revisions to allow performance targets that demonstrate either maintenance of or improvement over baseline. * Finalizing all other provisions at paragraphs (c)(2)(vi)(B) and (C) as proposed but with minor grammatical revisions in paragraphs (c)(2)(vi)(C)(1) and (2) and with a technical correction in (c)(2)(vi)(C)(*2*). * Finalizing the removal of certain requirements currently codified at §438.6(c)(2)(iii)(C) and (D) (related to directing the timing and amount of expenditures and recouping unspent funds) and the redesignation of the current provision at §438.6(c)(2)(iii)(A) to §438.6(c)(2)(vi)(A). * Finalizing **§**438.6(c)(2)(vii)(A) and (B) as proposed. * **Modifying the applicability date for §438.6(c)(2)(vii) to no later than 3 years after the effective date of the final rule to align with the applicability date for the prohibition on separate payment terms in §438.6(c)(6).** * Finalizing §438.6(c)(2)(viii) to specify that States must complete and submit all required documentation for all SDPs and associated amendments for which written approval is required before the specified start date. * Proposed §438.6(c)(2)(viii)(A) through (C) and proposed §438.6(c)(2)(ix) are **not** being finalized. * Finalizing the minimum contract documentation requirements proposed in §438.6(c)(5)(i) through (iv). * Finalizing §438.6(c)(4) with revisions to modify the 180-day timeframe to “1 year” and add “, as applicable” At the end of the introductory text in §438.6(c)(4). * Finalizing **§**438.6(c)(4)(v) with a technical edit to remove “the amount for any pass-through payments under paragraph (d) of this section,” in acknowledgement that pass-through payments are separate financial transactions not tied to the delivery of services to Medicaid managed care enrollees and therefore, are not identifiable within encounter-level data. * Due to the separate payment term prohibition being finalized in §438.6(c)(6), we are not finalizing §438.6(c)(5)(v) as proposed. Finalizing §438.6(c)(5)(v) (originally proposed at §438.6(c)(5)(vi)) to require all SDPs to be specifically described and documented in the managed care contracts. * Finalizing §438.6(c)(5)(vi), with modifications, as paragraph (c)(5)(v). * **Not** finalizing §438.6(c)(6) as proposed and will instead, adopt a new provision at paragraph (c)(6) requiring that all SDPs be incorporated into Medicaid managed care capitation rates as adjustments to base capitation rates and finalizing a prohibition on the use of separate payment terms. * Finalizing the proposed applicability dates for §438.6(c)(5). * **Revising the applicability date for §438.6(c)(6) to the first rating period that begins on or after 3 years following the effective date of the final rule.** * Finalizing §438.6(c)(7) with modifications to be consistent with policy decisions. * Redesignating paragraph (d) as paragraph (e) and finalizing as proposed. | | | |
| **§438.7**  ***Revising***  §438.7(c)  ***Adding***  §438.7(f)  ***Applicability dates:***  §438.7 (b)(6) the rating period beginning on or after 60 days following the effective date of the final rule.  §438.7 (c)(4), (c)(5), (f)(1), (f)(2) and (f)(3) — beginning on the effective date of the final rule.  §438.7 (c)(6) and (f)(4) — no later than the first rating period beginning on or after 4 years after the effective date of the final rule.  §438.7(g)(2) and (3)) —upon the effective date of the final rule. | **§438.7—*Rate Certification Submission***  **(b) (6) Special contract provisions.** A  description of any of the special  contract provisions related to payment  in §438.6 and ILOS in §438.3(e)(2) that  are applied in the contract.  **(c)(4)—**The State must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under paragraph (a) of this section for any special contract provisions related to payment described in §438.6 and ILOS in §438.3(e)(2) not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.  **§438.7(c)(5)—**Retroactive adjustments to the capitation rates, as outlined in paragraph (c)(2), resulting from a State directed payment described in §438.6(c) must be a result of adding or amending any State directed payment consistent with the requirements in §438.6(c), or a material error in the data, assumptions or methodologies used to develop the initial capitation rate adjustment such that modifications are necessary to correct the error.  **§438.7(c)(6)—**The rate certification or retroactive adjustment to capitation rates resulting from any State Directed Payments for  which the State has obtained written prior approval under §438.6(c)(2)(i) must be submitted no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under §438.6(c)(2)(i) of this section or 120 days after the date CMS issued written prior approval of the State directed payment under §438.6(c)(2)(i) of this section, whichever is later.  **§438.7(f)—*State certification.*** The State, through its actuary, must certify the total dollar amount for each separate payment term included in the State’s MCO, PIHP or PAHP contracts in alignment with the requirements of  §438.6(c)(6).  **(1)** The State may pay each MCO, PIHP or PAHP a different amount under the separate payment term that is different than the amount paid to another MCO, PIHP or PAHP, so long as the aggregate total dollars paid to all MCOs, PIHPs and PAHPs does not exceed the total dollars of the separate payment term for each respective Medicaid managed care program  included in the Medicaid managed care contract.  **(2)** As part of the State’s rate certification documentation for a separate payment term, the State, through its actuary, must provide an  estimate of the impact of the separate payment term on a rate cell basis, as paid per the State directed payment approved by CMS under §438.6(c)(2)(i).  **(3)** No later than 12 months following the end of the rating period, the State must submit documentation to CMS that demonstrates the impact of the separate payment term by rate cell for which the State has obtained written prior approval under §438.6(c)(2)(i) consistent with the distribution methodology described in the State directed payment for which the State  obtained written prior approval under §438.6(c)(2)(i) in the manner and form required by CMS.  **(4)** Once CMS has issued written prior approval under §438.6(c)(2)(i), the State must submit a rate certification or a rate certification amendment incorporating the separate payment term no later than 120 days after the start date of the State directed payment for which the State has obtained written prior approval under §438.6(c)(2)(i) or 120 days after the date CMS issued written prior approval of the State directed payment under §438.6(c)(2)(i), whichever is later. | We also propose additional changes to §438.7(b)(6) and §438.7(c) to address adjustments to managed care capitation rates that are used for SDPs and ensure that the projected ILOS cost percentage documented in the rate certification would not exceed the proposed 5 percent limit.  To reflect our proposals that would require States to document separate payment terms in their managed care rate certifications, we propose changes to §438.7. Specifically, we propose to add a new §438.7(f) that would require the State, through its actuary, to certify the total dollar amount for each separate payment term as detailed in the State’s Medicaid managed care contract. | Yes **§457.1203** except  §438.7(b)(6)  since rate certifications are not applicable to separate CHIP. |
| **Final Rule: Publish date 5/10/24**   * Clarification: Provider incentive payments that a plan and provider negotiate without State direction or involvement are not SDPs. * Finalizing §438.7(b)(6) and §457.1201(c) as proposed. * Finalizing §438.7(c)(4) and (5) as proposed. * Finalizing §438.7(c)(6) with revisions to require submission of rate certifications that includes an SDP no later than 120 days after the start date of the SDP. * **Not** Finalizing proposed §438.7(f). * Finalizing as proposed (but redesignated to §438.7(f)(2)) that §438.7(c)(6) as revised here is applicable **no later than the first rating period for managed care plans beginning on or after 4 years of the effective date of this final rule.** | | | |
| **§438.8**  ***Revising*** (e)(2)(iii)(A);  (e)(3)(i); (h)(4)  introductory text; (k)(1)(vii); and (m)  ***Adding*** (e)(2)(iii)(C);  (f)(2)(vii); and (k)(1)(xiv) through (xv)  ***Applicability dates:***  §438.8(e)(2)(iii)(C) and (f)(2)(vii) 60  days after the effective date of the final  rule.  §438.8(k)(xvi),  and (xv) no later  than the first rating period beginning on or after the effective date  of the final rule. | **§438.8—*Medical Loss Ratio (MLR) Standards***  (e) *Numerator*—(1) *Required elements.*  The numerator of an MCO’s, PIHP’s, or PAHP’s MLR for a MLR reporting year is the sum of the MCO’s, PIHP’s, or PAHP’s incurred claims (as defined in (e)(2) of this section); the MCO’s, PIHP’s, or PAHP’s expenditures for activities that improve health care quality (as defined in paragraph (e)(3) of this section); and fraud reduction activities (as defined in paragraph (e)(4) of this section).  (2) *Incurred claims.* (iii) Expenditures that must be included in incurred claims include the following:  **§438.8(e)(2)(iii)(A)—** The amount of incentive and bonus payments made, or expected to be made, to network providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.  **§438.8(e)(2)(iii)(C)—** The amount of payments made under all contract arrangements that direct the MCO’s, PIHP’s, or PAHP’s expenditures as specified in §438.6(c)(1)(i) through (iii).  **§438.8(e)(3)** *Activities that improve health care quality.* Activities that improve health care quality must be in one of the following categories:  **§438.8(e)(3)(i)—** An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(a) and (b) and is not excluded under 45 CFR 158.150(c).  **§438.8(f)** *Denominator*—(1) *Required elements.* The denominator of an MCO’s, PIHP’s, or PAHP’s MLR for a MLR reporting year must equal the adjusted premium revenue. The adjusted premium revenue is the MCO’s, PIHP’s, or PAHP’s premium revenue (as defined in paragraph (f)(2) of this section) minus the MCO’s, PIHP’s, or PAHP’s Federal, State, and local taxes and licensing and regulatory fees (as defined in paragraph (f)(3) of this section) and is aggregated in accordance with paragraph (i) of this section.  **(2) *Premium revenue****.* Premium  revenue includes the following for the  MLR reporting year:  **§438.8(f)(2)(vii)—** Payments to the MCO, PIHP, or PAHP for expenditures approved under §438.6(c)(1)(i) through (iii).  **§438.8(h)(4)—** CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the  following methodology:  **§438.8(k)** *Reporting requirements.* (1) The State, through its contracts, must require each MCO, PIHP, or PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:  **§438.8(k)(1)(vii)—** Methodology(ies) for allocation of expenditures, which must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described in 45  CFR 158.170(b).  **(xiv)** The amount of payments made to providers under all contract arrangements that direct the MCO’s, PIHP’s, or PAHP’s expenditures as described in §438.6(c)(1)(i) through (iii).  **(xv)** Payments to the MCO, PIHP, or PAHP from the State for expenditures approved under §438.6(c)(1)(i) through (iii).  **§438.8(m)** *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation rates for an MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re- calculate the MLR for all MLR reporting years affected by the retroactive rate change and submit a new report meeting the requirements in paragraph (k) of this section. | As part of our Medicaid managed care program integrity oversight efforts, CMS recently conducted several in-depth reviews of States’ oversight of managed care plan MLR reporting. These reviews included examinations of the contract language for provider incentive arrangements between managed care plans and network providers. As part of these reviews, CMS identified several examples of managed care plan practices that could make an incentive  payment inappropriate to include in the numerator.  Examination of these contracts between managed care plans and their network providers revealed that some managed care plans did not require a provider to improve their performance in any way to receive an incentive payment.  To address these concerns, we are proposing additional requirements on provider incentive arrangements. | Yes **§457.1203**  (except **§438.8(k)(1)**  (xiv) and  (xv) because SDPs are not applicable to  separate CHIP)  Amend **§457.1203 except** to exclude any  references to SDPs in State MLR  reporting. |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.8(e)(2)(iii)(C) with technical clarifications to require States and managed care plans to report State Directed Payments made by managed care plans to providers under §438.6(c) as incurred claims within the MLR numerator and to refer to the newly defined term “State directed payment-” in §438.2. * Finalizing provisions at §438.8(e)(2)(iii)(C) and §438.8(f)(2)(vii) to require that all SDPs be included in plan-level and State summary MLR reports. * Finalizing §438.8(e)(3) and §457.1203(c) as proposed. * Finalizing §438.8(f)(2)(vii) to require States and managed care plans to report all State payments made to Medicaid managed care plans for arrangements under §438.6(c) be included in the MLR denominator as premium revenue and to refer to the newly defined term “State directed payment.” * Finalizing the regulation text in §438.8(f)(2)(vii) to remove the word “approved” as we require the MLR denominator to include all State Directed Payments, including those that are exempted from written prior approval as well as those that require written prior approval from CMS under §438.6(c)(2)(i). * Modifying our applicability date for §438.6(c)(4) in proposed §438.6(c)(8)(vi) from the first rating period beginning on or after the release of T-MSIS reporting instructions by CMS to the applicability date set forth in the T-MSIS reporting instructions released by CMS. Our method of releasing new reporting instructions includes preparation time for States and managed care plans as we are aware that any changes to data systems require substantial programming and testing before implementation. * Finalizing §438.8(e)(2)(iii)(C) and (f)(2)(vii) with technical clarifications and modifications to use the newly defined term “State directed payment” and to clarify the scope of the provisions, (Finalizing cross-referenced §457.1203(e), as proposed.) * Finalizing §438.8(h)(4) as proposed. * Finalizing §438.8(k)(1)(vii) and §457.1203(f) as proposed. * **Not** finalizing §438.8(k)(1)(xiv) and (xv) or §438.74(a)(3) through (4) to require State and plan line-level reporting of SDPs. Because we are not finalizing the line item-level reporting provisions in §438.8(k)(1)(xiv) and (xv) or §438.74(a)(3) nor the respective compliance dates, States will likely not be required to make as many modifications to systems and MLR reporting templates. * **Not** finalizing proposed §438.8(m). | | | |
| **Add §438.16**  ***Applicability date***  The rating period beginning on or after 60 days following the  effective date of the final rule. | **§438.16—*In lieu of services and settings***  ***(ILOS) requirements***  (a) *Definitions*   * *Final ILOS cost percentage* is the   annual amount calculated, in accordance with paragraph (c)(3) of this section, specific to each managed care program that includes ILOS.   * *Projected ILOS cost percentage* is the annual amount calculated, in accordance with paragraph (c)(2) of this section, specific to each managed care program that includes ILOS. * *Summary report of actual MCO, PIHP, and PAHP ILOS costs* is the report calculated, in accordance with paragraph (c)(4) of this section, specific to each managed care program that includes ILOS.   **(b)** ***General rule.***An ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i), or 1915(k) of the Act. | Because we are making numerous proposals related to ILOSs, we believe adding a cross reference in §438.3(e)(2)(v) to a new section would make it easier for readers to locate all of the provisions in one place and the designation flexibility of a new section would enable us to better organize the provisions for readability. To do this, we propose to create a new §438.16 titled *ILOS requirements* for Medicaid.  Our proposals would be based on several key principles.  These principles include that ILOSs would have to:  (1) meet general parameters;  (2) be provided in a manner that preserves  enrollee rights and protections;  (3) be medically appropriate and cost effective  substitutes for State plan services and settings,  (4) be subject to monitoring and oversight; and  (5) undergo a retrospective evaluation, when applicable.  We also propose parameters and limitations for ILOSs, including our proposed requirements for ILOSs to be appropriately documented in managed care plan contracts and considered in the development of capitation rates. | Yes  **§457.1201(c)**  and **(e) and §457.1203(b)**  **(except** §438.16(c)(5)  (ii) and exclude all references to pass-through and State Directed Payments at §457.1201(c).) |
|  | **(c) *ILOS Cost Percentage and summary report of actual MCO, PIHP, and PAHP ILOS costs.***  *(1) General rule.* (i) The projected ILOS cost percentage calculated as required in paragraph (c)(2) of this section may not exceed 5 percent and the final ILOS cost percentage calculated as required in paragraph (c)(3) of this section may not exceed 5 percent.  (ii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be calculated on an annual basis and recalculated annually.  (iii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.  (2) *Calculation of the projected ILOS cost percentage.* The projected ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(2)(i) of this section by the amount determined in paragraph (c)(2)(ii) of this section.  (i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in §438.6(e), for each managed care program.  (ii) The projected total capitation payments for each managed care program, including all State Directed Payments in effect under §438.6(c) and pass-through payments in effect under §438.6(d), and the projected total State Directed Payments in effect under §438.6(c) that are paid as a separate payment term as described in §438.6(c)(6).  (3) *Calculation of the final ILOS cost percentage.* The final ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(3)(i) of this section by the amount determined in paragraph (c)(3)(ii) of this section.  (i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in §438.6(e), for each managed care program.  (ii) The actual total capitation payments, defined at §438.2, for each managed care program, including all State Directed Payments in effect under §438.6(c) and pass-through payments in effect under §438.6(d), and the actual total State Directed Payments in effect under §438.6(c) that are paid as a separate payment term as described in §438.6(c)(6).  (4) *Summary report of actual MCO, PIHP, and PAHP ILOS costs.* The State must submit to CMS a summary report of the actual MCO, PIHP and PAHP costs for delivering ILOSs based on the claims and encounter data provided by the MCO(s), PIHP(s) and PAHP(s).  (5) *CMS review of the projected ILOS cost percentage, the final ILOS cost percentage and the summary report of actual MCO, PIHP and PAHP ILOS costs.*  (i) The State must annually submit the projected ILOS cost percentage to CMS for review as part of the rate certification required in §438.7(a).  (ii) The State must submit the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs annually to CMS for review as a separate report concurrent with the rate certification submission required in §438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes an ILOS.  **(d)** ***Documentation requirements***—(1) *State requirements.* All States that include an ILOS in an MCO, PIHP, or PAHP contract are required to include, at minimum, the following:  (i) The name and definition of each ILOS;  (ii) The covered service or setting under the State plan for which each ILOS is a medically appropriate and cost-effective substitute;  (iii) The clinically defined target populations for which each ILOS is determined to be medically appropriate and cost effective;  (iv) The process by which a licensed network or MCO, PIHP, or PAHP staff provider, determines and documents in the enrollee’s records that each identified ILOS is medically appropriate for the specific enrollee;  (v) The enrollee rights and protections, as defined in §438.3(e)(2)(ii); and  (vi) A requirement that the MCO, PIHP, or PAHP will utilize specific codes established by the State that identify each ILOS in encounter data, as required under §438.242.  (2) *Additional documentation requirements.* A State with a projected ILOS cost percentage that exceeds 1.5 percent is also required to provide the following documentation concurrent with the contract submission for review and approval by CMS under §438.3(a).  (i) A description of the process and supporting evidence the State used to determine that each ILOS is a medically appropriate service or setting for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.  (ii) A description of the process and supporting data the State used to determine that each ILOS is a cost effective substitute for the clinically  defined target population(s), consistent with paragraph (d)(1)(iii) of this section.  (3) *Provision of additional information.* At the request of CMS, the State must provide additional information, whether part of the MCO, PIHP or PAHP contract, rate certification or supplemental materials, if CMS determines that the requested information is pertinent to the review and approval of a contract that includes ILOS.  **(e)** ***Monitoring, evaluation and oversight****.* (1) *Retrospective evaluation.* A State with a final ILOS cost percentage that exceeds 1.5 percent, is required to submit at least one retrospective evaluation of ILOS to CMS. The retrospective evaluation must:  (i) Be completed separately for each managed care program that includes an ILOS.  (ii) Be completed using the 5 most recent years of accurate and validated data for the ILOS. The State must utilize these data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS.  (iii) Evaluate at least: (A) The impact each ILOS had on utilization of State plan approved services or settings, including any associated cost savings;  (B) Trends in MCO, PIHP, or PAHP and enrollee use of each ILOS;  (C) Whether encounter data supports the State’s determination that each ILOS is a medically appropriate and cost effective substitute for the identified covered service and setting under the State plan or a cost-effective measure to reduce or prevent the future need to utilize the covered service and setting under the State plan;  (D) The impact of each ILOS on quality of care;  (E) The final ILOS cost percentage for each year consistent with the report in paragraph (c)(5)(ii) of this section with a declaration of compliance with the allowable threshold in paragraph (c)(1)(i) of this section;  (F) Appeals, grievances, and State fair hearings data, reported separately, related to each ILOS, including volume, reason, resolution status, and trends; and  (G) The impact each ILOS had on health equity efforts undertaken by the State to mitigate health disparities.  (iv) The State must submit the retrospective evaluation to CMS no later than 2 years after the completion of the first 5 rating periods that included ILOS.  (v) CMS reserves the right to require the State to submit additional retrospective evaluations to CMS.  (2) *Oversight.* Oversight for each ILOS must include the following:  (i) *State notification requirement.* The State must notify CMS within 30 calendar days if:  (A) The State determines that an ILOS is no longer a medically appropriate or cost effective substitute for the covered service or setting under the State plan identified in the contract as required in paragraph (d)(1)(ii) of this section; or  (B) The State identifies noncompliance with requirements in this section.  (ii) *CMS oversight process.* If CMS determines that a State is out of compliance with any requirement in this part or receives a State notification in paragraph (e)(2)(i) of this section, CMS may require the State to terminate the use of an ILOS.  (iii) *Process for termination of ILOS.* When a State decides to terminate an ILOS, an MCO, PIHP or PAHP decides to cease offering an ILOS to its enrollees, or CMS makes the decision to require the State to terminate an ILOS, the State must submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision. The transition plan must include at least the following:  (A) A process to notify enrollees of the termination of an ILOS that they are currently receiving as expeditiously as the enrollee’s health condition requires.  (B) A transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to care to any enrollee who is currently receiving the ILOS that will be terminated. The State must make the transition of care policy publicly available.  (C) An assurance the State will submit the modification of the MCO, PIHP, or PAHP contract to remove the ILOS and submission of the modified contracts to CMS as required in §438.3(a), and a reasonable timeline for submitting the contract amendment.  (D) An assurance the State and its actuary will submit an adjustment to the actuarially sound capitation rate, as needed, to remove utilization and cost of the ILOS from capitation rates as required in §438.4, §438.7(a) and §438.7(c)(2), and a reasonable timeline for submitting the revised rate certification. | |  |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.16(a) through (d), §457.1201(c) and (e) and §457.1203(b) as proposed with minor modifications. * Finalizing §438.16(d)(1)(iii) with a modification to add language after “medically appropriate and cost effective” to add “substitute by the State”. * Otherwise finalizing §438.16(d) as proposed. * Finalizing §438.16(e) with minor changes. In addition, finalizing the requirement to submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision, to submission within 30 calendar days. * Finalizing applicability dates as proposed. | | | |
| **§438.74**  ***Revising***  §438.74(a)  ***Applicability date:***  The rating period  beginning on or after 60 days following  the effective date of the final rule. | **§438.74**—***State oversight of the minimum***  ***MLR requirement***  (a) *State reporting requirement.* (1)  The State must annually submit to CMS  a summary description of each report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to §438.8(k), with the rate certification required in §438.7.  (2) The summary description must be provided for each MCO, PIHP, or PAHP under contract with the State and must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.  (3) The summary description must also include line items for:  (i) The amount of payments made under all contract arrangements that direct the CO’s, PIHP’s, or PAHP’s expenditures as specified in §438.6(c)(1)(i) through (iii); and  (ii) Payments to the MCO, PIHP, or PAHP for expenditures approved under §438.6(c)(1)(i) through (iii). | Medicaid and CHIP managed care plans are required to submit detailed MLR reports to States, and States must submit a summary description of those reports to CMS. In the preamble to the 2015 managed care proposed rule we described the term ‘‘summary’’ as  meaning an abbreviated version of the more detailed reports required from managed care plans in §438.8(k), but did not refer to a Statewide aggregation of data across managed care plans. The  proposed regulatory text for §438.74 did not include the words ‘‘for each’’ and was finalized as proposed. In our compliance reviews of State summary MLR reports, several States provided MLR data aggregated over the entire State and neglected to provide the  abbreviated MLR report for each plan. These submissions of MLR summary reports that omitted information by plan indicate States’ confusion with what is required for these reports.  To correct this issue, we propose to amend §438.74(a) to note explicitly that State MLR summary reports must include the required elements for each MCO, PIHP, or PAHP that is contracted  with the State. | Yes  **§457.1203** |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.74 and §457.1203(e) as proposed except not finalizing 438.74(a)(3) through (4) to require State and plan line-level reporting of SDPs. | | | |

| **Proposed Changes/Notes** | | | |
| --- | --- | --- | --- |
| **Proposed Changes Related to Transparency** | | | |
| **Proposed Citation/Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **§438.10**  ***Revising §***438.10(c)(3), (d)(2), (g)(2)(ix),(h)(1)(introductory text) and (h)(2)(iv)  ***Adding* §**438.10(c)(3)(i) through (iv); (h)(1)(ix); and (h)(3)(iii)  ***Applicability dates*—**  §438.10(c)(3) the first rating period that begins on or after 2 years after the effective date of the final rule. §438.10(d)(2) the first rating period that begins on or after 3 years after the effective date of the final rule. §438.10(h)(1) July 1, 2025.  §438.10(h)(3)(iii) the rating period that begins on or after 4 years after the effective date of the final rule. | **§438.10—*Information Requirements***  **(c)(3)** The State must operate a website  that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity web pages, specified at §438.602(g) and elsewhere in this Part. States must:  (i) Include all content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, on one web page;  (ii) Include clear and easy to understand labels on documents and links;  (iii) Verify no less than quarterly, the accurate function of the website and the timeliness of the information presented; and  (iv) Explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.  **§438.10(d)(2)** Make oral interpretation available in all languages and written translation available in each prevalent non- English language. Written materials that are critical to obtaining services for potential enrollees and **experience surveys for enrollees** must include taglines in the prevalent non-English languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, **information on how to request auxiliary aids and services**, and the toll-free telephone number of the entity providing choice counseling services as required by §438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously visible font size.  **§438.10(g**) *Information for enrollees of MCOs,*  *PIHPs, PAHPs and PCCM entities—*  *Enrollee handbook.*  **(2)(ix)** Enrollee rights and responsibilities, including the elements specified in §438.100 and, if applicable, §438.3(e)(2)(ii).  **§438.10(h)(1)** Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and searchable electronic form, the following information about its network providers:  **(ix)** Whether the provider offers covered services via telehealth.  **§438.10(h)(2)** The provider directory must include the information in paragraph (h)(1) of this section for each of the following provider types covered under the contract:  **(iv)** Mental health and substance use  disorder providers;  **§438.10(h)(3)** *Provider Directory*  (i) A paper provider directory must be updated at least—  (A) Monthly, if the MCO, PIHP, PAHP, or PCCM entity does not have a mobile-enabled, electronic directory; or  (B) Quarterly, if the MCO, PIHP, PAHP, or PCCM entity has a mobile enabled, electronic provider directory.  (ii) An electronic provider directory  must be updated no later than 30 calendar days after the MCO, PIHP, PAHP, or PCCM entity receives updated provider information.  (iii) MCOs, PIHPs, or PAHPs must use the information received from the State pursuant to §438.68(f)(1)(iii) to update provider directories no later than the timeframes specified in (h)(3)(i) and (ii). | Current regulations at §438.10(c)(6)(ii) require certain information to be ‘‘prominent and readily accessible’’ and §438.10(a) defines ‘‘readily accessible’’ as ‘‘electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C’s Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.’’ Despite these requirements, we have received input from numerous and varied interested parties since the 2016 final rule about how challenging it  can be to locate regulatorily required information on some States’ websites.  We acknowledge that States and managed care plans may have information accessible through their websites that is not public facing; for example, enrollee specific protected  health information. Proper security mechanisms should continue to be utilized to prevent unauthorized access to non-public facing information, such as the establishment of a user account and password or entry of other credentials. Data security must always be a priority for States and managed care plans and the proposals in §438.10(c)(3) in no way diminish that obligation for States.  To increase the effectiveness of States’ websites and add some consistency to website users’ experience, we propose to revise ‘‘websites’’ to ‘‘web pages’’ in the reference to managed care plans. We propose this change to clarify that if States provide required content on their website by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, the link on the State’s site would have to be to the specific page that includes the requested information. We believe this would prevent States from showing links to a landing page for the managed care plan that then leaves the user to start searching for the specific information needed.  Next, we propose to add ‘‘States must:’’ and propose to require that all information, or links to the information,  required in this Part to be posted on the State’s website, be available from one page. We believe that when website users have to do repeated searches or click through multiple pages to find information, they are more likely to give up trying to locate it. As such, we have carefully chosen the information that is required in 42 CFR Part 438 to be posted on States’ websites (see §438.602(g)to ensure effective communication of information and believe it represents an important step toward eliminating common obstacles for States’ website users.  We note that State and managed care plan websites must be compliant with civil rights laws, including the Americans with Disabilities Act (ADA), section 504 of  the Rehabilitation Act, Title VI of the Civil Rights Act of 1964, and section 1557 of the Affordable Care Act. In this proposed rule, we believe that there are several minimal qualities that all websites should include, such as being  able to:  • Function quickly and as expected by the user;  • Produce accurate results;  • Use minimal, logical navigation steps;  • Use words and labels that users are familiar with for searches;  • Allow access, when possible, without conditions such as establishment of a user account or password;  • Provide reasonably comparable performance on computers and mobile devices;  • Provide easy access to assistance via chat; and  • Provide multilingual content for individuals with LEP. | Yes **§457.1201** **§457.1207** (except  §438.10(c)(2) ,(g)(2)(xi)(E),  and (g)(2)(xii) |
| **Final Rule: Publish date 5/10/24**   * §438/10(c)(3) **Clarification**: There are several qualities that all websites should include, such as being able to:   + Function quickly and as expected by the user;   + Produce accurate results;   + Use minimal, logical navigation steps;   + Use words and labels that users are familiar with for searches;   + Allow access, when possible, without conditions such as establishment of a user account or password,   + Provide reasonably comparable performance on computers and mobile devices,   + Provide easy access to assistance via chat; and   + Provide multilingual content for individuals with LEP. * **Clarifications**:   + Existing regulation text at §438.10(c)(3) requires “The State must operate a Web site that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity Web sites, ....” This means that the link to an MCO’s, PIHP’s, PAHP’s or PCCM entity’s website must be to the required *content*, not just to a random location on the MCO’s, PIHP’s, PAHP’s, or PCCM entity’s website. Our proposal to revise “web sites” to “webpages” was intended to make that clearer, not alter this existing requirement.   + While the requirements of §438.10(c)(3) are applicable to State websites, States can certainly apply them to their managed care plans through their managed care plan contract, and we encourage States to ensure that their plans’ websites meet at least the same minimum standards. * Finalizing §438.10(c) and (g), §457.1201 and §457.1207 as proposed. | | | |
| **§438.602**  ***Adding***  (g)(5) through (13)  ***Applicability dates***  **(**g)(5) through (13) apply to the first rating  period beginning on or after 2 years after the effective date of the final rule. | **§438.602—*State responsibilities***  (g) *Transparency.* The State must post on its Web site, as required in§438.10(c)(3), the following documents and reports:  (5) Enrollee handbooks, provider directories, and formularies required at §438.10(g), (h), and (i).  (6) The information on rate ranges required at §438.4(c)(2)(iv), if applicable.  (7) The reports required at §438.66(e) and §438.207(d).  (8) The network adequacy standards required at §438.68(b)(1) through (2) and (e).  (9) The results of secret shopper surveys required at §438.68(f).  (10) State directed payment evaluation reports required in §438.6(c)(2)(v)(C).  (11) Information on all required Application Programming Interfaces including as specified in §431.60(d) and (f).  (12) Quality related information as required in §438.332(c)(1), §438.340(d), §438.362(c) and §438.364(c)(2)(i). (13) Documentation of compliance with requirements in Subpart K—Parity in Mental Health and Substance Use Disorder Benefits. | To help States monitor their website for required content, we propose to revise §438.602(g) to contain a more complete list of information. | **Yes**  **§457.1285**  (Except §638.602(g)  (6), §438.602(g)  (10)  Exclude  references to LTSS as not applicable to separate CHIP.  **Exclude** the reference to §438.362(c)  since MCO EQR exclusion is not applicable to separate CHIP.  References to Subpart  K under Part 438 should be read to refer to parity requirements at §457.496 |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.602(g), and §457.1285 as proposed. | | | |

| **Proposed Changes/Notes** | | | |
| --- | --- | --- | --- |
| **Proposed Changes Related to Access** | | | |
| **Proposed Citation/Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **§438.68**  ***Revising***  **(**b)(1) introductory text, (b)(1)(iii), (d)(1), (d)(2)  and (e);  ***Adding***  (f) through (g).  ***Applicability dates***  (b)(1) the first rating period beginning on or after 3 years after the effective date of the final rule.  (d)(1)(iii)  beginning on or after 2 years after the effective date of the final rule.  (e) the first rating period beginning on  or after 3 years after the effective date of the final rule.  (f) the first rating period beginning on or after 4 years after the effective date of the final rule.  (g) the first rating period that begins on or after 3 years after the effective date of the final rule. | **§438.68—*Network adequacy standards***  (b) *Provider-specific network adequacy standards.*  (1) *Provider types.* At a minimum, a State must develop a quantitative network adequacy standard, other than appointment wait times, for the following provider types, if covered  under the contract:  (iii) Mental health and substance use disorder, adult and pediatric.  (d) *Exceptions process.* (1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must be:  (1) To the extent the State permits an exception to any of the provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must:  (i) Be specified in the MCO, PIHP or  PAHP contract.  (ii) Be based, at a minimum, on the number of providers in that specialty practicing in the MCO, PIHP, or PAHP service area.  (iii) Include consideration of the payment rates offered by the MCO, PIHP, or PAHP to the provider type for which an exception is being requested.  (2) States that grant an exception in accordance with paragraph (d)(1) of this section to an MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under §438.66(e).  (e) ***Appointment wait time standards****.*  States must establish and enforce appointment wait time standards.  (1) *Routine appointments.* Standards must be established for routine appointments with the following provider types and within the specified limits:  (i) If covered in the MCO’s, PIHP’s, or PAHP’s contract, outpatient mental health and substance use disorder, adult and pediatric, within State-established time frames but no longer than 10 business days from the date of request. | In the 2020 final rule, we revised §438.68(b)(1) and (2) by replacing the requirement for States to set time and distance standards with a more flexible requirement that States set a quantitative network adequacy standard for specified provider types. We explained that quantitative network adequacy standards that States may elect to use included minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation requirements (for example, extended evening or weekend hours); and combinations of these quantitative measures. We encouraged States to use the quantitative standards in combination- not separately- to ensure that there are not gaps in access to, and availability of, services for enrollees.  Key to the effectiveness of the Medicaid and CHIP program is ensuring that it provides timely access to high quality services in a manner that is equitable and consistent. Current network adequacy standards might not reflect actual access and new methods are needed that account for physicians’ willingness to serve Medicaid patients.  We are persuaded about the need for increased oversight of network adequacy and overall access to care, and propose a new quantitative network adequacy standard. Specifically, we propose to redesignate existing §438.68(e) regarding publication of network adequacy standards to §438.68(g) and create a new §438.68(e)  titled ‘‘**Appointment wait time standards**.’’  Analyses have shown that the vast majority of services  delivered to Medicaid beneficiaries are provided by a small subset of health providers listed in managed care plan provider directories, with a substantial share of listed providers delivering little or no care for Medicaid beneficiaries.  We propose to require States to use **secret shopper surveys** as part of their monitoring activities. We believe that secret shopper surveys could provide unbiased, credible, and representative data on how often network providers are offering routine appointments within the State’s appointment wait time standards and these data would aid managed care plans as they assess their networks, pursuant to §438.207(b), and provide an assurance to States that their networks have the capacity to serve the expected enrollment in their service area. | Yes  **§457.1207**  **§457.1218**  **§457.1230** |
|  | (ii) If covered in the MCO’s, PIHP’s, or PAHP’s contract, primary care, adult and pediatric, within State-established time frames but no longer than 15 business days from the date of request. (iii) If covered in the MCO’s, PIHP’s, or PAHP’s contract, obstetrics and gynecological within State-established time frames but no longer than 15 business days from the date of request.  (iv) State-selected, other than those listed in paragraphs (e)(1)(i) through (iii) of this section, chosen in an evidence based manner within State-established time frames.  (2) *Minimum compliance.* MCOs, PIHPs, and PAHPs will be deemed compliant with the standards established in paragraph (e)(1) of this section when secret shopper results, consistent with paragraph (f)(2) of this section, reflect a rate of appointment availability that meets the standards established at paragraph (e)(1)(i) through (iv) of at least 90 percent.  (3) *Selection of additional types of providers.* After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of providers to be added to paragraph (e)(1) of this section.  (f) ***Secret shopper surveys****.* States must contract with an entity, independent of the State Medicaid agency and any of its contracted MCOs, PIHPs and PAHPs subject to the survey, to conduct annual secret shopper surveys of each MCO’s, PIHP’s, and PAHP’s compliance with the provider directory requirements in §438.10(h) as specified in paragraph (f)(1) of this section and appointment wait time requirements as specified in paragraph (f)(2) of this section.  (1) *Provider directories.* (i) A secret shopper survey must be conducted to determine the accuracy of the information specified in paragraph (f)(1)(ii) of this section in each MCO’s, PIHP’s, and PAHP’s most current electronic provider directories, as required at §438.10(h), for the following provider types:  (A) Primary care providers, if they are included in the MCO’s, PIHP’s, or PAHP’s provider directory;  (B) Obstetric and gynecological providers, if they are included in the MCO’s, PIHP’s, or PAHP’s provider directory;  (C) Outpatient mental health and substance use disorder providers, if they are included in the MCO’s, PIHP’s, or PAHP’s provider directory; and  (D) The provider type chosen by the State in (e)(1)(iv).  (ii) A secret shopper survey must assess the accuracy of the information in each MCO’s, PIHP’s, and PAHP’s most current electronic provider directories for at least:  (A) The active network status with the MCO, PIHP, or PAHP;  (B) The street address(es) as required at §438.10(h)(1)(ii);  (C) The telephone number(s) as required at §438.10(h)(1)(iii); and  (D) Whether the provider is accepting new enrollees as required at §438.10(h)(1)(vi).  (iii) States must receive information, sufficient to facilitate correction by the MCO, PIHP, or PAHP, on errors in directory data identified in secret shopper surveys from the entity conducting the secret shopper survey no later than 3 business days from the day the error is identified by the entity conducting the secret shopper survey.  (iv) States must send information required in paragraph (f)(1)(iii) of this section to the applicable MCO, PIHP, or PAHP no later than 3 business days from receipt.  (2) *Timely appointment access.* A secret shopper survey must be used to determine each MCO’s, PIHP’s, and PAHP’s rate of network compliance with the appointment wait time standards in paragraph (e)(1) of this section.  (i) After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of appointments to be added to a secret shopper survey.  (ii) Appointments offered via telehealth can only be counted toward compliance with the appointment wait time standards in paragraph (e)(1) of this section if the provider being surveyed also offers in-person appointments to the MCO’s, PIHP’s, or PAHP’s enrollees and must be identified separately from in-person appointments in survey results.  (3) *Independence.* An entity will be considered independent of the State as specified in paragraph (f)(3)(i) of this section and independent of the MCOs, PIHPs, or PAHPs subject to the surveys as specified in paragraph (f)(3)(ii) of this section.  (i) An entity will be considered independent of the State if it is not part of the State Medicaid agency.  (ii) An entity will be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if the entity is not an MCO, PIHP, or PAHP, is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.  (4) *Methodological standards.* Secret shopper surveys required in this paragraph must:  (i) Use a random sample;  (ii) Include all areas of the State covered by the MCO’s, PIHP’s, or PAHP’s contract; and  (iii) For secret shopper surveys required in paragraph (f)(2) of this section for appointment wait time standards, be completed for a statistically valid sample of providers.  (5) *Results reporting.* Results of the secret shopper surveys conducted pursuant to paragraphs (f)(1) and (2) of this section must be analyzed, summarized, and:  (i) Reported to CMS using the content, form, and submission times as specified at §438.207(d); and  (ii) Posted on the State’s website required at §438.10(c)(3) within 30 calendar days of submission to CMS.  (g) ***Publication of network adequacy standards****.* States must publish the standards developed in accordance with paragraphs (b)(1) and (2), and (e) of this section on the website required by §438.10(c)(3). Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services. | |  |
| **Final Rule: Publish date 5/10/24**   * **Clarification**:Appointment wait time standards proposed in §438.68(e) cannot be the quantitative network adequacy standard required in §438.68(b)(1). * Added “routine” to required appointment wait time standards, and did not propose a maximum appointment wait time standard for the State-selected provider type. * Declined to define “routine” and encourage States to work with their managed care plans and their network providers and even other States to develop a definition of “routine” appointment to ensure consistency within and across their managed care programs. At a minimum, we expect any definition of a “routine” appointment to include appointments for services such as well-child visits, annual gynecological exams, and medication management. * Decline to define “urgent” or “emergent” (referring to §438.114 for the definition of emergency medical condition) or develop wait time standards for such. * Finalized as proposed except replaced “provider types” with “services” in §438.68(e)(1) and (e)(3) and for consistency in §438.68(d) with the adoption of “services”, we are finalizing minor wording revisions. In paragraph (d)(1), we are removing “provider-specific” to be more inclusive of all network standards in §438.68; in (d)(1)(iii), we are adding “or for the service type;” and in paragraph (d)(2), we are adding “or service” after “provider type”. * Finalized a revision to §438.68(e)(1)(iv) to add “and covered in the MCO’s, PIHP’s, or PAHP’s contract” after “[…]other than those listed in paragraphs (e)(1)(i) through (iii) of this section.” This will clarify that States do not need to develop appointment wait time standards or perform secret shopper surveys for services other than mental health and SUD for PIHPs and PAHPs that cover mental health and SUD services only. * Finalizing §438.68(h), and §457.1218 as proposed.   **Secret Shopper Surveys:**   * Finalizing §438.68(f), §457.1207 and §457.1218 as proposed. * **Clarification**: Because secret shopper surveys will be used to measure compliance with appointment wait time standards and provider directory accuracy, we intentionally proposed an applicability date (for §438.68(f)) that was 1 year after the applicability date for appointment wait time standards. * **Clarification**: Our goal with the initial implementation of the appointment wait time standards and secret shopper surveys is to determine if enrollees can access care when they request it. As such, we believe that being offered an appointment by any provider in a practice is sufficient for determining compliance with appointment wait time standards. However, we want to clarify that when verifying the accuracy of provider directory data, secret shopper surveys must verify the published information. Meaning, if the provider directory lists Dr. X, then the active network status, address, phone number, and open panel status for Dr. X must be verified; a directory reflecting accurate information for other providers in the same practice is not sufficient for Dr. X’s data to be considered “accurate” for compliance with §438.68(f)(1)(ii). * **Clarification**: Section §438.68(f)(1)(iii) specifies that States must receive information on errors in directory data identified in secret shopper surveys no later than 3 business days from the day the error is identified. Section §438.68(f)(1)(iv) requires States to send that information to the applicable managed care plan no later than 3 business days from receipt. As such, the 3 business day timeframes are for data transmission, not correction of the erroneous data. Section §438.10(h)(3)(iii) specifies that managed care plans must use the information received from the State to update provider directories no later than the timeframes specified in §438.10(h)(3)(i) and (ii) (included in separate CHIP regulations through an existing cross-reference at §457.1207). | | | |
| **§438.206**  ***Revising***  (c)(1)(i)  ***Applicability date***  The first rating  period that begins on or after 4 years after the effective date of the final rule. | **§438.206—*Availability of services***  (c) *Furnishing of services*  The State must ensure that each contract with a MCO, PIHP, and PAHP complies with the following requirements:  (1) *Timely access.* Each MCO, PIHP,  and PAHP must do the following:  (i) Meet and require its network providers to meet State standards for timely access to care and services taking into account the urgency of the need for services as well as **appointment wait times** specified in §438.68(e). | To ensure that managed care plans’ contracts reflect their obligation to comply with the appointment wait time standards, we propose to revise §438.206(c)(1)(i) to include appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts. We believe this is necessary since our proposal at §438.68(e)(1) to develop and enforce appointment wait time standards is a State responsibility; proposing this revision to §438.206(c)(1)(i) would specify the corresponding managed care plan responsibility. | Yes  **§457.1230(a)** |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.206(c) as proposed. * **Technical Correction: Because §438.68(b) was proposed and is being finalized as the first rating period beginning on or after 3 years after July 9, 2024 (effective date of the final rule), so should §438.206(c)(1)(i) and §457.1230(a). Therefore, in this final rule, §438.206(d) (cross reference §457.1230(a)) is being finalized with an applicability date for §438.206(c)(1)(i) of; on the first rating period beginning on or after 3 years after July 9, 2024.** | | | |
| **§438.207**  ***Revising***  (d) (e), and (f)  ***Adding***  (b)(3); (g)  ***Applicability dates***  (b)(3) and (d)(2)  the first rating period  beginning on or  after 2 years after the effective date of the final rule.  (d)(3) the first rating  period beginning on or after 1 year after  the effective date of the final rule.  (e) the rating period beginning on or after 4  year after the effective date of the final rule.  (f) the first rating period beginning on or after 4 years after the effective date of the final rule. | **§438.207—*Assurances of adequate capacity and services***  (a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State’s standards for access to care under this Part, including the standards at §\438.68 and §438.206(c)(1).  (b) ***Nature of supporting documentation****.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State, to demonstrate that it complies with the following requirements:  **(3)** Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO’s, PIHP’s, or PAHP’s contract, provides a payment analysis using paid claims data from the immediately prior rating period that demonstrates each MCO’s, PIHP’s, or PAHP’s level of payment as specified in paragraphs (b)(3)(i) and (ii) of this section.  (i) The payment analysis must provide the total amount paid for evaluation and management current procedural terminology codes in the paid claims data from the prior rating period for primary care, OB/GYN, mental health, and substance use disorder services, as well as the percentage that results from dividing the total published Medicare payment rate for the same services. | Currently at §438.207(d), States are required to review the documentation submitted by their managed care plans,  as required at §438.207(b), and then submit to CMS an assurance of their managed care plans’ compliance with §438.68 and §438.206. To make States’ assurances and analyses more comprehensive, we propose to revise §438.207(d) to explicitly require States to include the results from the secret shopper surveys proposed in §438.68(f)  We further propose to require that MCOs, PIHPs, and PAHPs submit annual documentation to the State that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan’s contract. We propose to require that each MCO, PIHP, and PAHP 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. Due to the unique payment requirements in section 1902(bb) of the Act for Federally qualified health centers and rural health clinics, we propose in §438.207(b)(3)(iv) to exclude these provider types from the analysis.  We also propose to require that the payment analysis 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. | Yes  **§457.1230(b)** |
|  | (A) A separate total and percentage must be reported for primary care, obstetrics and gynecology, mental health, and substance use disorder services; and  (B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.  (ii) For homemaker services, home health aide services, and personal care services, the payment analysis must provide the total amount paid and the percentage that results from dividing the total amount paid by the amount the State’s Medicaid FFS program would have paid for the same services.  (A) A separate total and percentage must be reported for homemaker services, home health aide services, and personal care services; and  (B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.  (iii) Payments by MCOs, PIHPS, and PAHPs for the services specified in §438.207(b)(3)(i) but for which the MCO, PIHP, or PAHP is not the primary payer are excluded from the analysis required in this paragraph.  (iv) Services furnished by a Federally qualified health center as defined in section 1905(l)(2) and services furnished by a rural health clinic as defined in section 1905(l)(1) are excluded from the analysis required in this paragraph.  **§438.207(d) *State review and certification to CMS.***After the State reviews the documentation submitted by the MCO, PIHP, or PAHP as specified in paragraph (b) of this section and the secret shopper evaluation results as required at §438.68(f), the State must submit an assurance of compliance to CMS, in the format prescribed by CMS, that the MCO, PIHP, or PAHP meets the State’s requirements for availability of services, as set forth in §438.68 and §438.206.  (1) The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.  (2) The analysis in paragraph (d)(1) of this section must include the payment analysis submitted by each MCO, PIHP, or PAHP, as required in paragraph (b)(3) of this section, and contain:  (i) The data provided by each MCO, PIHP, and PAHP in paragraph (b)(3) of this section; and  (ii) A State level payment percentage for each service type specified in paragraphs (b)(3)(i) and (ii) of this section produced by using the number of member months for the applicable rating period to weight each MCO’s, PIHP’s, or PAHP’s reported percentages, as required in paragraph (b)(3) of this section.  (3) States must submit the assurance of compliance required in paragraph (d) of this section as specified in paragraphs (i) through (iii) of this section and post the report on the State’s website required in §438.10(c)(3) within 30 calendar days of submission to CMS.  (i) At the time it submits a completed readiness review, as specified at §438.66(d)(1)(iii).  (ii) On an annual basis and no later than 180 calendar days after each rating period.  (iii) At any time there has been a significant change as specified in paragraph (c)(3) of this section and with the submission of the associated contract, as required at §438.3(a).  **§438.207(e) *CMS’ right to inspect documentation.*** TheState must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP as well as documentation from all secret shopper surveys required at §438.68(f).  **§438.207(f) *Remedy plans to improve access****.*  (1) When the State, MCO, PIHP, PAHP, or CMS identifies an area in which an MCO’s, PIHP’s, or PAHP’s access to care under the access standards in this Part could be improved, including the standards at §438.68 and §438.206, the State must:  (i) Submit to CMS for approval a remedy plan as specified in paragraph (f)(ii) of this section no later than 90 calendar days following the date that the State becomes aware of an MCO’s, PIHP’s, or PAHP’s access issue;  (ii) Develop a remedy plan that addresses the identified access issue within 12 months and that identifies specific steps with timelines for implementation and completion, and responsible parties. State’s and managed care plans’ actions may include a variety of approaches, including, but not limited to: increasing payment rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization;  (iii) Ensure that improvements in access are measurable and sustainable; and  (iv) Submit quarterly progress updates to CMS on implementation of the remedy plan.  (2) If the remedy plan required in paragraph(f)(1) of this section does not result in addressing the MCO’s, PIHP’s, or PAHP’s access issue by improving access within 12 months, CMS may require the State to continue the remedy plan for another 12 months and may require revision to the remedy plan required in paragraph (f)(1) of this section. | |  |
| **Final Rule: Publish date 5/10/24**   * **Clarification** that §438.207(b)(1) through (3) will all be required for Medicaid managed care, and for separate CHIP through an existing cross-reference at §457.1230(b). * Finalizing §438.207(b)(3)(i) to state that the payment analysis must provide the total amount paid for evaluation and management CPT codes in the paid claims data from the prior rating period for primary care, OB/GYN, mental health, and substance use disorder services, as well as the percentage that results from dividing the total amount paid by the published Medicare payment rate for the same services. * Finalizing §438.207(b)(3) as “Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO’s, PIHP’s, or PAHP’s contract, provides an annual payment analysis using paid claims data from the immediate prior rating period….” * Finalizing §438.207(b)(3)(ii) by moving “personal care” before “and” and adding “habilitation services” after “and.” * Reiterated that homemaker and home health aide services will be included in the managed care plan’s analysis if Medicaid was the primary payer for the claim. * Finalizing §438.207(b)(3) and (g), and §457.1230(b) as proposed, except for a minor wording correction in §438.207(b)(3)(i) and to add habilitation in §438.207(b)(3)(ii). * §438.207(d): On July 6, 2022, we published a CIB (*https://www.medicaid.gov/federal-policy-guidance/downloads/cib07062022.pdf*) that provided a reporting template Network Adequacy and Access Assurances Report54 for the reporting required at §438.207(d). To be clear that States will have to use the published template, we proposed to explicitly require that States submit their assurance of compliance and analyses required in §438.207(d) in the “format prescribed by CMS.” * Finalizing §438.207(d) and §457.1230(b) as proposed except for a revision to §438.207(d)(3)(i) to revise the submission time to enable contract approval. * Finalizing §438.207(f) as proposed. | | | |

| **Proposed Changes/Notes** | | | |
| --- | --- | --- | --- |
| **Proposed Changes Related to Quality** | | | |
| **Proposed Citation/Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **§438.310**  ***Revising***  (b)(5) introductory text, and (c)(2)  ***Applicability date***  The effective date of final rule. | **§438.310—*Basis, scope, and applicability***  (b) *Scope.* This Subpart sets forth:  (5) Requirements for annual external  quality reviews of each contracting  MCO, PIHP, PAHP including—  **§438.310(c)** *Applicability*  (2) The provisions of §438.330(b)(2)  and (3), (c), and (e), and §438.340 apply  to States contracting with PCCM entities  whose contracts with the State provide  for shared savings, incentive payments  or other financial reward for the PCCM  entity for improved quality outcomes. | Our reviews of State’s contracts have led us to reevaluate the policy to require an annual EQR of PCCM entities described in §438.310(c)(2), as these contracts exhibit wide variability in the size, structure, and scope of case management and other services provided by risk-bearing PCCM entities. This variation calls into question the appropriateness of EQR as an oversight tool for many of the PCCM entities.  Therefore, we propose to remove PCCM entities described in §438.310(c)(2) from the managed care entities subject to EQR under §438.350. Other requirements in 42 CFR Part 438, Subpart E that currently apply to risk bearing  PCCM entities described at §438.310(c)(2) are not impacted by this proposed rule. We note that States may perform additional oversight and monitoring activities that are similar to external quality reviews for PCCM providers at their discretion, and may choose to use an entity that is also an EQRO for these activities, however these activities would not be subject to Part 438 Subpart E regulations for EQR. Further, we believe that the removal of all PCCM entities from the mandatory scope of EQR will alleviate burden on States and PCCM entities while retaining appropriate tools for quality monitoring and  oversight.  We propose conforming amendments to remove reference to PCCM entities described in §438.310(c)(2) in §438.310(b)(5), §438.358(a)(1), §438.364(a)(3) through (6), and §438.364(c)(2)(ii), and to remove the reference to §438.350 from §438.310(c)(2). We also propose removing the current provision at §438.358(b)(2) that applies risk-bearing PCCM entities to the mandatory EQR  activities, to conform with the proposed changes at §438.350, and reserve this provision for future use. We maintain that EQROs must be independent from any PCCM entities they review at the State’s discretion, as currently required under §438.354(c), and propose a  modification at §438.354(c)(2)(iii) to clarify this. | **Yes**  (Except we propose to **exclude** all PCCM entities from EQR  requirements at §457.1201(n)  (2), §457.1250(a)and §457.1240(f).) |
| **Final Rule: Publish date 5/10/24**   * **Not** finalizing the applicability date proposed at §438.310(d)(1), since separate applicability dates are only required if the effective date is different from that of the final rule. | | | |
| **§438.330**  ***Revising***  (d)(4)  ***Applicability***  The rating period beginning after the effective date of the final rule. | **§438.330—*Quality assessment and***  ***performance improvement program***  (d) *Performance improvement projects.*  (1) The State must require that MCOs, PIHPs, and PAHPs conduct performance improvement projects, including any performance improvement projects required by CMS in accordance with paragraph (a)(2) of this section, that focus on both clinical and nonclinical areas.  (4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA organization chronic care improvement program conducted under §422.152(c) of this chapter for one or more of the performance improvement projects otherwise required under this section. | Through previous rulemaking, in the 2016 final rule (81 FR 27682), we implemented a policy, at §438.330(d)(4), to allow States to permit Medicaid managed care plans  exclusively serving dually eligible individuals to substitute an MA plan’s quality improvement project (QIP). We  removed the QIP from the requirements for MA organizations at §422.152, because we determined that they did not add significant value and many were duplicative of existing activities, such as the Chronic Care Improvement Program (CCIP) (83 FR 16669). Due to an  oversight at that time, we neglected to remove a reference to the QIP from §438.330(d)(4) to conform with the  changes at §422.152. We are now proposing to replace the outdated reference at §438.330(d)(4) to §422.152(d) (which previously described the now-removed QIP), with a reference to the CCIP requirements for MA organizations in §422.152(c). | No  **§438.330**  **(d)(4)**  does not apply to separate CHIP because we did not apply  §438.330(d)  (4) to separate CHIP in the  2016 final rule, |
| **Final Rule: Publish date 5/10/24**   * Finalizing §438.330(d)(4) as proposed. | | | |
| **§438.334—Quality Rating System [Removed and reserved] Quality Rating System proposed and finalized at Subpart G—Medicaid Managed Care Quality Rating System §438.500 through §438.535.** | | | |
| **Final Rule: Publish date 5/10/24**   * Finalizing most provisions related to the mandatory measure list, the flexibility for States to request to implement an alternative MAC QRS, the proposed subregulatory process to make updates to the mandatory measure list in the future, and the ability for States to include additional measures in their MAC QRS. We are finalizing several modifications from our proposal to clarify the scope of the alternative QRS and to reduce the implementation resources States need for their MAC QRS, including when, or if, a State chooses to adopt an alternative QRS. * We proposed to change the existing QRS rule (reflected in the regulation at §438.334(c)), to allow States to include additional measures, meaning that States would include these measures in addition to the CMS-identified mandatory measures for the QRS. Upon review of the comments, we realized that this was misinterpreted, and that commenters thought that our proposal was intended to allow States to implement alternative mandatory measures to replace CMS-identified selected measures as opposed to being in addition to those measures. * A number of commenters also misunderstood our proposal and thought that we proposed to allow States to request alternatives to the website display features proposed in §438.520 as a third MAC QRS framework component. * **Clarification**: States must request CMS approval to apply an alternative methodology but need not seek CMS approval to include additional measures or additional website display features in their MAC QRS. We stress that these changes in the final rule compared to the proposed rule are merely organizational. Under this final rule, States will have the flexibility to display *additional* measures not included in the mandatory measure set, as well as to develop *additional* QRS website display features, as proposed. | | | |
| **§438.340**  ***Revising***  (b)(4), (c)(1) introductory  text, (c)(2)(ii), and (c)(3)  ***Applicability date***  No later than 1 year  from the effective date of the final rule. | **§438.340—*Managed care State quality***  ***strategy***  (b) Elements of the State quality strategy. At a minimum, the State’s quality strategy must include the following:  (4) Arrangements for annual, external independent reviews, in accordance  with §438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, and PAHP contract.  **§438.340(c)***Development, evaluation, and*  *revision*  In drafting or revising its quality strategy, the State must:  (1)Make the strategy available for  public comment before submitting the strategy to CMS for review in accordance with paragraph (c)(3) of this section, including:  **§438.340(c)(2)** Review and update the quality  strategy as needed, but no less than once  every 3 years.  (ii) The State must make the results of the review, including the evaluation conducted pursuant to paragraph (c)(2)(i) of this section, available on the website required under §438.10(c)(3).  **§438.340(c)(3)** Prior to adopting as final, submit to CMS the following:  (i) A copy of the initial strategy for CMS comment and feedback.  (ii) A copy of the strategy—  (A) Every 3 years following the review in paragraph (c)(2) of this section;  (B) Whenever significant changes, as defined in the State’s quality strategy per paragraph (b)(10) of this section, are made to the document;  (C) Whenever significant changes occur within the State’s Medicaid program. | We propose to remove PCCM entities described in §438.310(c)(2) from the managed care entities subject to EQR under §438.350.  At **§438.340(c)** we are proposing to clarify when States must submit a copy of their quality strategy to CMS. Current regulations at §438.340(c)(3) require that States submit to CMS a copy of their initial quality strategy for feedback and a copy of the revised quality strategy whenever significant changes are made. The current regulations do not require States to submit to CMS  subsequent versions of their quality strategy unless the State has made significant changes to the document or  to their Medicaid program. We are proposing to modify §438.340(c)(3)(ii) to require that States, prior to finalizing a revised or renewed quality strategy as final, submit a copy of the revised strategy to CMS at minimum every 3  years, following the review and evaluation of the strategy described at §438.340(c)(2), in addition to when significant changes are made. | **Yes**  §457.1201(n)(2), §457.1250(a)  §457.1240(e) and  §457.1240(f). |
| **Final Rule: Publish date 5/10/24**   * Finalizing a technical correction to replace “paragraph (b)(11)” with “paragraph (b)(10)” in §438.340(c)(3)(ii). * Finalizing the rules for the quality strategy and the applicability dates as proposed. | | | |
| **§438.350**  ***Revising***  The introductory text and paragraph (a)  ***Applicability date***  The effective date of the final rule. | **§438.350—*External quality review***  Each State that contracts with MCOs,  PIHPs, or PAHPs must ensure that—  (a) Except as provided in §438.362, a  qualified EQRO performs an annual  EQR for each such contracting MCO,  PIHP, or PAHP. | {Removed PCCM entities} see above | Yes  **§457.1250(a)** |
| **§438.354**  ***Revising***  (c)(2)(iii)  ***Applicability date***  The effective date of the final rule. | **§438.354—*Qualifications of external quality***  ***review organizations***  (c)*Independence.* The EQRO and its  subcontractors must be independent  from the State Medicaid agency and  from the MCOs, PIHPs, PAHPs, or  PCCM entities (described in  §438.310(c)(2)) that they review. To  qualify as ‘‘independent’’—  (2) An EQRO may not:  (iii) Conduct, on the State’s behalf,  ongoing Medicaid managed care  program operations related to oversight  of the quality of MCO, PIHP, PAHP, or  PCCM entity (described in  §438.310(c)(2)) services, except for the  related activities specified in §438.358; | We maintain that EQROs must be independent from any PCCM entities they review at the State’s discretion, as currently required under §438.354(c), and propose a  modification at §438.354(c)(2)(iii) to clarify this. | Yes  **§457.1250(a)** |
| **Final Rule: Publish date 5/10/24**   * Finalized as proposed. | | | |
| **§438.358**  ***Revising***  (a)(1); (b)(1)  introductory text, (b)(1)(i), (ii), and (iv) (c) introductory  text and (c)(6);  ***Adding***  (c)(7)  ***Removing and Reserving***  (b)(2)  ***Applicability***  For the EQR-related activities described in §438.350(b)(1) and (c) of this Subpart (except §438.350(b)(1)(iii)), the review period begins on the first day  of the most recently concluded contract  year or calendar year, whichever is nearest to the date of the EQR-related activity, and is 12 months in duration.  ***Remainder***—no later than December 31, 2025 | **§438.358—*Activities related to external***  ***quality review***  (a) *General Rule*  (1) The State, its agent that is not an  MCO, PIHP, or PAHP or an EQRO may  perform the mandatory and optional  EQR-related activities in this section.  {Removed PCCM entities}  **§438.358(b) *Mandatory activities.***  (1) For each MCO, PIHP, or PAHP the  following EQR-related activities must be  performed **in the 12 months preceding**  **the finalization of the annual report**:  (i) Validation of performance improvement projects required in accordance with §438.330(b)(1) that were underway during the EQR review period per paragraph (a)(3) of this  section.  (ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with §438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the EQR review period described in  paragraph (a)(3) of this section.  (iv) Validation of MCO, PIHP, or PAHP network adequacy during the EQR review period per paragraph (a)(3) of this section to comply with requirements set forth in §438.68 and, if the State enrolls Indians in the MCO,  PIHP, or PAHP, §438.14(b)(1).  **§438.358(c**) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in §438.310(c)(2)), the following activities may be performed in the 12 months preceding the annual report by using information derived during the EQR review period described in paragraph (a)(3) of this section:  (6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with 42 CFR Part 438, Subpart G.  (7) Assist with evaluations required  under §438.16(e)(1), §438.340(c)(2)(i),  and §438.6(c)(2)(iv) and (v) pertaining to  outcomes, quality, or access to health  care services. | We are proposing several changes to the EQR regulations  that seek to accomplish two overarching goals:  (1) Eliminate unnecessary burdensome requirements; and (2) make EQR more meaningful for driving quality improvement.  (2) EQR Review Period—The current regulations provide that most EQR activities are performed using information derived from the preceding 12 months, but do not clearly indicate to which 12-month period the activity should pertain. In addition, we do not currently specify in the  regulations when the EQR activity must take place relative to the finalization and posting of the annual report. The  result is a lack of uniformity in the review periods included in States’ annual EQR technical reports each year. In some cases, for example, States have reported on the results of EQR activities conducted three or more years ago, while other States have reported on the results of EQR activities conducted relatively close to the completion of the report. To support States’ and CMS’  ability to use the reports for quality improvement and oversight, we are proposing modifications to ensure  consistency and align the data in the annual reports with the most recently available information used to conduct  the EQR activities. We propose to add a new paragraph  (a)(3) in §438.358 to define the 12-month review period for all but one the EQR-related activities described in  §438.358(b)(1) and the optional activities described in §438.358(c). The one exception is the activity described  in §438.350(b)(1)(iii), which requires a review within the previous 3 years. Under proposed §438.358(a)(3), 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.  In addition, through existing EQR activities at §438.364(b), and, if finalized, the newly proposed optional activity at §438.64(c)(7) {Note: HSAG believes this is a typo in the preamble and is meant to say §438.358(c)(7)}, discussed in the proposed rule, we believe States could leverage the CMS-developed protocol or their EQRO to assist with evaluating the impact of ILOSs on quality of care. We believe this new optional activity could reduce burden associated with these new evaluation requirements for ILOSs. The elements we have proposed in the evaluation should communicate a complete narrative about the State, managed care plans, and enrollees’ experience with ILOSs. As key thresholds and limits on ILOSs, the projected and final ILOS cost percentages would be another element that CMS would consider as part of the overall mosaic to understand the impact that an ILOS might have on each managed care program. | Yes  **§457.1200(d)** |
| **Final Rule: Publish date 5/10/24**   * Finalizing the rules for the removing EQR requirements for PCCM entity with modifications at §438.358(b)(2), and at §438.358(c)(3) and (4). * Finalizing §438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which would give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs. * Finalizing with modifications at §438.358(c) and finalizing the applicability at §438.310(d)(2) for Medicaid and at §457.1200(d) for separate CHIP. * Finalizing the addition of an EQR optional activity at §438.358(c) as proposed. | | | |
| **§438.360**  ***Revising***  (a)(1)  ***Applicability***  The effective date of the final rule. | **§438.360—*Nonduplication of mandatory***  ***activities with Medicare or accreditation***  ***review***  (a) *General rule.* Consistent with guidance issued by the Secretary under §438.352, to avoid duplication the State may use information from a Medicare or private accreditation review of an MCO, PIHP, or PAHP to provide information for the annual EQR (described in §438.350) instead of conducting one or more of the EQR activities described in §438.358(b)(1)(i) through (iii) (relating to the validation of performance  improvement projects, validation of  performance measures, and compliance  review) if the following conditions are met:  (1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a  private accrediting organization recognized by CMS; | We believe the current regulation creates an unnecessary administrative burden on both CMS and private accrediting organization (PAOs) and may  restrict the availability of the EQR nonduplication option for States. We also do not believe that the current  requirement is compelled under the statute. Also, we do not read the provision as requiring every private independent entity to be described under section  1852(e)(4) of the Act in order for a State to exercise the nonduplication provision. Rather, we read section  1932(c)(2)(B) of the Act as describing in general terms the types of organizations that would be eligible to participate in nonduplication, and providing organizations described in section 1852(e)(4) of the Act as an example.  Therefore, we propose at §438.360(a)(1) to remove the  requirement that PAOs must apply for MA deeming authority from CMS in order for States to rely on PAO  accreditation reviews in lieu of EQR activities. We are proposing conforming changes to the title of §438.362(b)(2) to remove language specific to Medicare  Advantage deeming. Additionally, we are proposing to remove the requirements for PAOs related to MA  deeming authority at §438.362(b)(2)(i). This proposal would remove paragraph (b)(2)(i)(B) and modify paragraph (b)(2)(i) to include current §438.362(b)(2)(i)(A). We believe this proposed change will reduce administrative burden among the private accreditation industry, as well as create more flexibility for States to leverage PAO reviews for nonduplication. We note that under §438.360(a)(2) States will still be  required to ensure the review standards used by any PAO are comparable to standards established through the EQR  protocols under §438.352, and pursuant to §438.360(c), will need to explain the rationale for the State’s determination that the activity is comparable in their quality strategy at §438.340. | Yes  **§457.1250** |
| **Final Rule: Publish date 5/10/24**   * Finalizing the changes to non-duplication at §438.360(a)(1) as proposed. | | | |
| **§438.362**  ***Revising***  (b)(2) paragraph heading and  (b)(2)(i)  ***Applicability***  The effective date of the final rule. | **§438.362**—***Exemption from external quality***  ***review***  (b) *Information on exempted MCOs.*  When the State exercises this option, the State must obtain either of the following:  (2) *Medicare information from a private accrediting organization.*  (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used to fulfill certain requirements  for Medicare external review under Subpart D of Part 422 of this chapter. | We are proposing conforming changes to the title of §438.362(b)(2) to remove language specific to Medicare  Advantage deeming. Additionally, we are proposing to remove the requirements for PAOs related to MA  deeming authority at §438.362(b)(2)(i). This proposal would remove paragraph (b)(2)(i)(B) and modify paragraph (b)(2)(i) to include current §438.362(b)(2)(i)(A). We believe this proposed change will reduce administrative burden among the private accreditation industry, as well as create more flexibility for States to leverage PAO reviews for nonduplication. We note that under §438.360(a)(2) States will still be  required to ensure the review standards used by any PAO are comparable to standards established through the EQR  protocols under §438.352, and pursuant to §438.360(c), will need to explain the rationale for the State’s determination that the activity is comparable in their quality strategy at §438.340.  We currently require at §438.364(c) that EQR technical reports be completed and available on the State’s website  required under §438.10(c)(3) no later than April 30th of each year. However, we understand that most States with  managed care programs use Healthcare Effectiveness Data and Information Set (HEDIS) measures. HEDIS measures  represent the majority of measures included in the performance measure validation EQR activity. Data on these measures from the previous calendar year are audited and finalized in June annually. We therefore are proposing to revise §438.364(c)(1) and (c)(2)(i) to  change the April 30th date to December 31st. We believe this proposed change would align better with the HEDIS  timeframes because the EQR performance measurement activity could then follow the HEDIS audit.  In addition, current regulations do not require States to notify CMS that their EQR technical report has been completed and posted on the State’s website. We  propose to revise §438.364(c)(2)(i) to require that States notify CMS within 14 calendar days of posting their EQR  technical reports on their website. | Yes **§457.1250(a)** |
| **Final Rule: Publish date 5/10/24**   * Finalized as proposed. | | | |
| **§438.364**  ***Revising***  (a)(1), (a)(2)(iii), (a)(3)  through (6), (c)(1) and (c)(2)  ***Applicability***  December 31, 2025. | **§438.364—*External quality review results***  (a)(1) A description of the manner in  which the data from all activities  conducted in accordance with §438.358  were aggregated and analyzed, and  conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, or PAHP.  (2)(iii) The data and a description of data  obtained, including validated performance measurement, any outcomes data, and results from quantitative assessments, for each  activity conducted in accordance with  §438.358(b)(1)(i), (ii) and (iv) of this  Subpart; and  (3) An assessment of each MCO’s, PIHP’s, or PAHP’s-strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.  (4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, or PAHP, including how the State can target goals and objectives in the quality strategy, under §438.340, to better support improvement in the quality, timeliness,  and access to health care services furnished to Medicaid beneficiaries.  (5) Methodologically appropriate, comparative information about all MCOs, PIHPs, or PAHPs, consistent with guidance included in the EQR protocols issued in accordance with  §438.352(e).  (6) An assessment of the degree to which each MCO, PIHP, or PAHP has addressed effectively the recommendations for quality  improvement made by the EQRO during  the previous year’s EQR.  (c) *Availability of Information*  (1) The State must contract with a qualified EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The State must finalize the annual technical report by December 31st of each year.  (2) The State must—  (i) Post the most recent copy of the annual EQR technical report on the website required-under §438.10(c)(3) by December 31st of each year and notify CMS, in a form and manner determined by CMS, within 14 calendar days of the Web posting.  (ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interestedparties such as participating health care providers, enrollees, and potential enrollees of the MCO, PIHP, or PAHP beneficiary advocacy groups, and members of the general public.  (iii) Maintain at least the previous 5 years of EQR technical reports on the on the website required under §438.10(c)(3). | Conforming changes in **§438.364(a)** to remove PCCM entity from EQR.  The regulations, limited the data included in  the reports to performance measurement data; the regulations did not require other types of data used to measure the outcomes associated with a PIP, such as percentages of enrollees that participated in the PIP or data on patient satisfaction based on services received from the plan, be included in the annual reports. The result was that reports often focused on whether the methods  used to implement or evaluate the PIP were validated, but did not include the measurable data reflecting the outcomes of the PIP. Additionally, the regulations did not require the reports to include any data obtained from the mandatory network adequacy validation activity.  We believe validation alone was insufficient to provide CMS and interested parties with insight into plan performance on PIPs or States’ effectiveness in driving quality improvement through PIPs. We also believe data on network adequacy validation was critical to understanding plan performance regarding timeliness and access to care. Therefore, we propose to revise  §438.364(a)(2)(iii) in two ways: (1) to require that the EQR technical reports include “any outcomes data and results from quantitative assessments” for the applicable EQR activities in addition to whether the data has been validated, and (2) to require this type of data from the  mandatory network adequacy validation activity to also be included the EQR technical report. | Yes  **§457.1250(a)**  and  **§457.1200(d)** |
| **Final Rule: Publish date 5/10/24**   * Finalizing the changes to the data included in EQR reports at §438.364(2)(iii) as proposed. * As noted in the proposed rule, we intend to release an updated EQR protocol in accordance with §438.352 to implement the changes finalized at §438.364(a)(2)(iii). * **Not** finalizing the proposed change to the annual due date for EQR technical reports and are maintaining the current requirement for posting annually by April 30. With this change we are also not finalizing the corresponding change at §438.364(c)(2)(i), as well as the proposed applicability date of December 31, 2025, and the reference to §438.364(c)(2)(iii) was removed from §438.310(2). * Finalizing the change to require States to notify CMS when their EQR reports are posted as proposed. Finalizing the change to the website posting requirements for EQR at §438.364(c)(2)(iii) as proposed. | | | |
| **Add Subpart G—Medicaid Managed Care Quality Rating System**  §438.500 through §438.535  ***Applicability***  The fourth calendar year following publication of the final rule.  §438.535(g)(5) through (13) apply to the first rating period beginning on or after 2 years after the effective date of the final rule. | **§438.500—*Definitions***  (a) Definitions. As used in this Subpart, the following terms have the indicated meanings:  ***Measurement period***means the period for which data are collected for a measure or the performance period that a measure covers.  ***Measurement year***means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.  ***Medicaid managed care quality rating***  ***system framework (QRS framework)***  means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in §438.530, the methodology for calculating quality ratings described in §438.515, and the website display  described in §438.520 of this Subpart.  ***Medicare Advantage and Part D***  ***5-Star Rating System (MA and Part D***  ***quality rating system)***means the rating systemdescribed in Subpart D of Parts 422 of 423 of this chapter.  ***Qualified health plan rating system***  ***(QHP quality rating system)***means the health plan quality rating system developed in accordance with 45 CFR 156.1120.  ***Quality rating***means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.  ***Technical resource manual***means the guidance described in §438.530.  ***Validation***means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data  collection and analysis. | We are proposing to create a new Subpart G in 42 CFR  Part 438 to implement the MAC QRS framework  required under §438.334 of the current regulations and establish the standards which States must meet for CMS to  approve adoption of an alternative QRS and related requirements. Existing regulations at §438.334 are redesignated to newly-created proposed sections in  Subpart G with proposed revisions.  If the proposed rule is finalized in 2024, the implementation deadline for each State’s MAC QRS per proposed §438.505(b) (which provides for such  implementation to be no later than the fourth calendar year following publication of the final rule) would be December 31, 2028, and the first measurement year would be 2026. Since we are proposing to finalize our initial  measure set **(see attached Table 1)** in this rulemaking, any updates to the initial mandatory measure list made pursuant to the subregulatory process proposed at §438.510(b) would be effective no earlier than the year after the implementation of each State’s MAC QRS. We believe it would be appropriate to initiate the proposed subregulatory process for the second display year (for example, 2029 if the rule is finalized in 2024) because the mandatory measure list would be 5 years old by then, and at least biennially thereafter (in line with proposed §438.510(b)(2)).  We proposed that newly-proposed Subpart G apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The proposed provisions at §438.505(a) and (b) are  also proposed to apply to separate CHIP through a cross-reference at §457.1240(d), but **excluding** all references to beneficiary support systems. We note that the current and  proposed regulations in Subpart G **do not apply to PCCM entities**, consistent with current regulations at  §438.10(c)(2) and §457.1207; nonemergency medical transport PAHPs are also not included in the MAC QRS, in accordance with §438.9 and §457.1206(b). In addition, our proposal for the MAC QRS framework **excludes**  contracts between States and MA Dual Eligible Special Needs Plans (D–SNP) where the contract is only for the D–SNP to provide Medicaid coverage of Medicare cost sharing for the D–SNP enrollees; this is reflected in proposed §438.505(b). | Yes  **§457.1240(d)** |
| **§438.505—*General rule and applicability***  (a) *General rule.* As part of its quality assessment and improvement strategy for its managed care program, each State contracting with an applicable managed care plan, as described in paragraph (b) of this section, to furnish services to  Medicaid beneficiaries must—  (1)(i) Adopt the QRS framework developed by CMS; or (ii) Adopt an alternative managed care quality rating system in accordance with §438.525 of this Subpart.  (2) Implement such managed care quality rating system by the end of the fourth calendar year following [the effective date of the final rule published in the Federal Register], unless otherwise specified in this Subpart. (3) Use the State’s beneficiary support system implemented under §438.71 to provide the services identified at §438.71(b)(1)(i) and (ii) to beneficiaries,  enrollees, or both seeking assistance using the managed care quality rating system implemented by the State under this Subpart.  (b) *Applicability.* The provisions of this Subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The provisions of this Subpart do not apply to States contracting with Medicare Advantage Dual Eligible Special Needs Plans for only Medicaid coverage of Medicare cost sharing.  (c) *Continued alignment.* To maintain the QRS framework, CMS aligns the mandatory measure set and methodology described in §438.510 and §438.515 of this Subpart, to the extent appropriate, with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the MA and Part D quality rating system, and other similar CMS quality measurement and rating initiatives. | | |
| **§438.510—*Mandatory QRS measure set for Medicaid managed care quality rating system***  ***Outline of §438.510***  (a) *Measures required.* The quality rating system implemented by the State must include the measures in the mandatory QRS measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual, and may include other measures identified by the State as described in §438.520(b).  (b) *Subregulatory process to update mandatory measure set.*  (c) *Standards for adding mandatory measures.*  (d) *Removing mandatory measures.*  (e) *Updating existing mandatory measures.*  (f) *Finalization and display of mandatory measures and updates.* | | |
| **§438.515—*Medicaid managed care quality rating system methodology***  ***Outline and Summary of §438.515***  (a) Collection of validation data each year for each health plan  (b) Includes data for all enrollees who receive coverage through the health plan and are issued by health plan by program  (c) implement domain-level quality ratings | | |
| **§438.520—*Website display***  ***Outline and Summary of §438.520***  (a) Prominent display on the State’s Website, accessible format (508 compliance), information to assist members in using the rating system, search capability and interactivity  (b) Method to obtain user input to display additional measures  (c) CMS evaluation of the QRS | | |
| **§438.525—*Alternative quality rating system***  ***Outline and Summary of §438.525***  (a) States may implement an alternative rating system: include mandatory measures, substantially comparable, CMS approval  (b) Prior input from input from the State’s Medical Care Advisory Committee and public comment  (c) Mechanism to receive CMS approval | | |
| **§438.530—Annual technical resource manual.**  ***Outline and Summary of §438.530***  (a) No later than August 1, 2025, CMS will publish a Medicaid managed care quality rating system technical resource manual, and update it annually thereafter.  (b) CMS will take into account whether stratification is currently required by the measure steward | | |
| **§438.535—*Reporting***  ***Outline and Summary of §438.535***   1. Annual Medicaid managed care quality rating system report 2. 90 day timeline for submission | | |
| **Final Rule: Publish date 5/10/24**   * Finalizing the definitions as proposed with the minor technical correction the term “Qualified health plan (QHP) rating system, which is QHP quality rating system). * Finalizing §438.505 largely as proposed, with some modifications. See State Medicaid Director Letter #22-001, <https://www.medicaid.gov/sites/default/files/2023-06/smd22001.pdf>. As finalized, §438.505(a)(1) reflects changes to clarify the scope of flexibility for States regarding the methodology used in the QRS and to clarify that States may display additional quality measures and website features in addition to the mandatory minimum measures specified by CMS and the mandatory minimum content of the MAC QRS website identified in §438.520(a). In addition, we are finalizing minor changes throughout paragraph (a) to improve the readability of the provision. * Modifying §438.510(a) (finalized as §438.510(a)(1)) for Medicaid, and for separate CHIP by cross-reference through an amendment at §457.1240(d), to narrow the scope of measures that must be included in a State’s MAC QRS to those measures in the mandatory measure set that are applicable to the State because the measures assess a service or action covered by a managed care program established by the State. We stress that when the service or action assessed by the measure is provided to the beneficiary through *Medicare* and not the Medicaid managed care plan for which the rating is being calculated, we are not *requiring* States to include dually eligible individuals in quality ratings for MAC QRS measures. * Finalizing the reporting requirement in §438.535(a)(1) with modifications to require that States provide a list of any mandatory measures identified as not applicable by the State under §438.510(a)(1) along with a brief explanation for why the measure is not applicable to the State’s managed care program(s). * Finalizing §438.510(a), including the cross-reference at §457.1240(d) to apply the mandatory minimum measure set (see final Table 2). * Finalizing §438.510(c) as proposed except for revisions to §438.510(c)(1)(ii) and (v). * Finalizing paragraph §438.510(c)(1)(ii) with the additional phrase “to the extent appropriate” to clarify that if alignment is appropriate, it should be considered when determining whether a measure meets this criterion. * Finalizing §438.510(c)(1)(v), with a modification to include provider burden when considering whether a measure meets the feasibility criterion established in §438.510(c)(1) of the final rule. * **Not** finalizing the proposal to include the two MLTSS measures in the initial mandatory measure set. * Finalizing the provisions to add mandatory measures using a subregulatory process (rather than regulatory processes) as proposed. * Finalizing §438.510(d) and §457.1240(d) as proposed. * Finalizing proposed §438.510(e) and §457.1240(d) substantively as proposed. * Finalizing §438.510(f) and §457.1240(d) regarding the finalization and display of mandatory measure updates as proposed. * Finalizing §438.515(a)(1)(ii), (a)(2), and (a)(3) with modifications to clarify that, for Medicare and Medicaid FFS data, the requirements of these provisions apply “to the extent feasible without undue burden.” “To the extent feasible without undue burden” will apply at each of the three stages of quality rating production described in §438.515(a), but not to the standard in paragraph (a)(4). (assessed each year) * Finalizing an option for States to request a one-time, one-year extension to fully comply with one or more of the requirements of the MAC QRS rating methodology under §438.515(b) and certain website display requirements under §438.520(a), if the State, despite a good faith effort, would be unable to fully implement the requirements in §438.515(b) or §438.520(a)(2)(v) and (a)(6) by the implementation deadline specified for CMS in Subpart G. * Finalizing a deadline of September 1 of the fourth calendar year following the effective date of the final rule for requests for a one-year extension to be submitted to CMS. * **Clarification:** We reiterate that the undue burden standard permits States to exclude the specific data for which the undue burden applies. Where it is feasible to collect, validate, and use necessary data without undue burden, the State must ensure that these steps are completed, and the data are used in the calculation of MAC QRS measures. * Modifying §438.515(a) for Medicaid, and for separate CHIP by cross-reference at §457.1240(d), in the final rule to use language that does not mandate that the State directly perform the necessary data collection and measure calculation activities. Specifically, we are removing the terms “Must collect”, “Must ensure that”, “Must use” and “Must issue” from §438.515(a)(1) through (4), respectively. (States may use their EQRO to assist with quality ratings for the MAC QRS under the optional EQR activity at §438.358(c)(6) for Medicaid, which applies to separate CHIP through an existing cross-reference at §457.1250(a). Such assistance could include both calculation of performance measure rates and/or validation of the data used to calculate the rates. * Finalizing §438.520(a)(1) and (5) as proposed. * Finalizing §438.515(a)(2) with modification by adding language to require that the validation of data must not be performed by any entity with a conflict of interest, including managed care plans. We do not believe plans are an appropriate entity to validate data collected pursuant to §438.515(a)(2) because they are not free from bias. * Finalizing a new provision, at §438.515(c)(3), to further establish the scope of the flexibility to implement an alternative methodology. As finalized, (c)(3) establishes that CMS will not review or approve requests to implement a MAC QRS that does not comply with the requirements to include mandatory measures established in §438.510(a)(1), the general requirements for calculating quality ratings established in §438.515(a)(1) through (4), or the requirement to include the website features identified in §438.520(a)(1) through (6). * Finalizing the approach that States will implement a MAC QRS in two phases. In the first phase of implementation, States must fully comply with all MAC QRS requirements, except for requirements under §438.520(a)(6), by the implementation date specified in §438.505(a)(2) (by the end of the fourth calendar year following July 9, 2024. States must implement a MAC QRS by December 31, 2028. States granted an extension for eligible first phase requirements—those under §438.515(b) or §438.520(a)(2)(v)—will have until December 31, 2029, to fully comply with these requirement(s). * Requirements under §438.520(a)(6) will be implemented in a second phase. CMS will specify the implementation date of the second phase in the future, but this date must be no earlier than 2 years after implementation of the first phase as per §438.520(a)(6). Therefore, States will be required to implement the requirements under §438.520(a)(6) no earlier than calendar year 2030, and States granted an extension for requirements under §438.520(a)(6) will have until at least until calendar year 2031 to fully comply with the requirement. * Finalizing §438.520(a)(2) and §457.1240(d) as proposed. * Finalizing §438.520(a)(6) with modification to narrow the scope of the requirements proposed in §438.520(a)(6)(i) and (ii) that States would be required to display a search tool that enables users to identify available managed care plans that provide coverage for a drug identified by the user and a search tool that enables users to identify available managed care plans that include a specific provider in the plan’s network. We are applying these requirements only to managed care plans that participate in managed care programs with two or more participating plans. * Modifying §438.520(a) to further clarify our policy to include language establishing that the requirements described in §438.520(a) must be both prominently displayed *and* accessible to the public on the website required under §438.10(c)(3). * Modifying §438.520(a)(1)(iii) to avoid implying that States may require users to provide log-in credentials prior to using or accessing a State’s QRS. * Finalizing §438.520(a)(3) and §457.1240(d) as proposed and with a modification at §438.520(a)(3)(iv) to add discretion for CMS to require States to include on the MAC QRS website, other similar information on benefits such as whether access to the benefit requires prior authorization from the plan. * Finalizing §438.520(a)(4) and (c) as proposed. * Finalizing the provisions proposed at §438.520(b) largely as proposed, except that we are finalizing these provisions at §438.520(c)(2) to address the addition of new paragraph §438.520(b) **finalizing an implementation extension for certain website requirements.** * Modifying paragraph §438.520(c) to clearly establish that States may implement additional website features not described in §438.520(a) in their MAC QRS, including the display of additional measures not included in the mandatory measure set. * **Not** finalizing §438.525(a)(1), which proposed that an alternative QRS includes the mandatory measures identified by CMS under §438.510(a). This provision is duplicative of finalized §438.510(a)(1), which requires States to include applicable mandatory measures in their MAC QRS, regardless of whether the State uses the CMS or an alternative methodology. * Addressing technical errors in the proposed rule. Proposed §438.525(a) should have cited §438.515(b) instead of §438.510(a)(3). Additional conforming technical changes to the provision proposed at §438.525(a)(2), which is moved to §438.515(c)(i) in the final rule, by citing specifically to §438.515(b) describing the CMS methodology instead of more broadly to §438.515. * Finalizing §438.530(a) with modifications to change the date for the first annual technical resource manual to no later than CY 2027. * Adding §438.530(c) to indicate that the measure list in §438.530(a)(1)(i) and subset of measures that must be stratified, and by which factors, in and §438.530(a)(1)(iii) will be released no later than August 1, 2025. * Making a technical change to §438.530(a)(4) to indicate that a summary of public comments would be included in the technical resource manual only in the years when the engagement with interested parties occurs. * Finalizing §438.535 largely as proposed: Finalizing §438.535(a)(1) with modifications, which will also apply to separate CHIP, to add content to the required report:   + (1) identification of mandatory measures that are not included in their MAC QRS because they are not appliable to the State’s Medicaid managed care program;   + (2) for any measures identified as inapplicable to the State’s managed care program, a brief explanation of why the State determined that the measure is inapplicable; and   + (3) for any measure identified as applicable to the State’s managed care program, the managed care programs to which the measure is applicable. This modification aligns with revisions we are also finalizing in §438.510(a), which are discussed in section I.B.6.e. of the final rule. * Adding new paragraph (a)(8) to include additional reporting requirements related to Medicare and Medicaid data that is not included in MAC QRS quality ratings, as discussed in section I.B.6.f of this final rule. * Finalizing minor changes in references to other regulations to take into account changes made in this final rule compared to the proposal. | | | |

| **Proposed Changes/Notes** | | | |
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| **Proposed Changes Related to Program Integrity** | | | |
| **Proposed Citation/Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **§438.214**  ***Revising***  (b)(1)  ***Adding***  (d)(2)  ***Applicability***  The effective date of the final rule. | **§438.214—*Provider Selection***  **(b)(1)** Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, **mental health, substance use disorders**, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies.  **§438.214(d)** *Excluded providers*  (1) MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from  participation in Federal health care  programs under either section 1128 or  section 1128A of the Act.  (2) States must ensure through its contracts that MCOs, PIHPs, and PAHPs terminate any providers of services or persons terminated (as described in section 1902(kk)(8) of the Social Security Act) from participation under this title, title XVIII, or title XXI **from**  **participating as a provider in any network**. | Section 1932(d)(5) of the Act requires that, no later than July 1, 2018, contracts with MCOs and PCCMs, as applicable, must include a provision that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under this title,  title XVIII, or title XXI must be terminated from participating as a provider in any network. Although  States have had to comply with this provision for several years, we believe we should reference this important  provision in 42 CFR Part 438, as well as use our authority under section 1902(a)(4) of the Act to apply it to PIHPs  and PAHPs. To do this, we propose a new §438.214(d)(2). |  |
| **Final Rule: Publish date 5/10/24**   * Finalized as proposed. | | | |
| **§438.608**  ***Revising***  (a)(2) and (d)(3)  ***Adding***  (e)  ***Applicability dates***  60 days after the  effective date of the final rule. | **§438.608—*Program integrity requirements***  ***under the contract***  (a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste, and abuse.*  The State, through its contract with the MCO, PIHP or PAHP, must require that the MCO, PIHP, or PAHP, or subcontractor to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the State and the MCO, PIHP, or PAHP, implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:  (2) Provision for reporting within 10 business days all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.  (d) *Treatment of recoveries made by the MCO, PIHP or PAHP of overpayments to providers.* (1) Contracts with a MCO, PIHP, or PAHP must specify:  (3) Each MCO, PIHP, or PAHP must report annually to the State on all overpayments identified or recovered.  (e) *Standards for provider incentive or bonus arrangements.* The State, through its contract with the MCO, PIHP or PAHP, must require that incentive payment contracts between managed care plans and network providers meet the requirements as specified in §438.3(i)(3) and (4). | In the 2016 final rule, we aimed to strengthen State and Medicaid and CHIP managed care plan responsibilities to  protect against fraud and other overpayments in State Medicaid and CHIP programs, in part, by enhancing reporting requirements to support actuarial sound, payment provisions and program integrity efforts. These overpayments may be the result of fraud, waste, abuse, or other billing errors. Regardless of cause, overpayments should be excluded from the capitation rate because they do not represent reasonable, appropriate, or attainable costs.  This proposed rule seeks to modify §438.608(a)(2), which requires managed care plan contracts to include a provision for the prompt reporting of all overpayments identified or recovered (specifying those due to potential fraud) to the State; and §438.608(d)(3), which requires managed care plan contracts to include annual reports on plan recoveries of overpayments. The proposed changes aim to ensure that Medicaid and CHIP managed care plans report comprehensive overpayment data to States in a timely manner, which would better position States to execute program integrity efforts and develop actuarially sound capitation rates.  Current regulations require that States include a provision  in their contracts with managed care plans for the prompt reporting to the State of all overpayments identified or recovered, specifying the overpayments due to potential fraud. However, the term ‘‘prompt’’ is not defined. As a result, managed care plans may not report identified or recovered overpayments within a timeframe that enables States to effectively and swiftly investigate and take appropriate administrative action against providers that may be committing fraudulent activities across networks and managed care programs. We believe that establishing a uniform definition of the term ‘‘prompt’’ would provide clarity to States and managed care plans, thereby enhancing ongoing communication between managed care  plans and States, particularly as it relates to program integrity practices. Therefore, we propose to define ‘‘prompt’’ as within 10 business days of identifying or recovering an overpayment. | Yes  **§457.1285**  (Except that §438.66(e), §438.362(c), §438.602(g)  (6) and (10), §438.604(a)(2) and §438.608(d)  (4) do not apply, references to LTSS of this chapter do not apply, and references to Subpart K under Part 438 should be read to refer to parity requirements at §457.496.) |
| **Final Rule: Publish date 5/10/24**   * Finalizing proposals for reporting overpayments, both identified and recovered, at §438.608(a)(2) except that States shall require managed care plans to report identified or recovered overpayments within 30 calendar days (not 10 business days as proposed) from the date of identification or recovery of an overpayment. While we are finalizing “prompt” reporting as within 30 calendar days, States still retain the flexibility to require managed care plans to report overpayments within a shorter timeframe. This does not also require that an investigation be completed within that 30-calendar day timeframe. * Because the reporting of overpayments requirements at §438.608 are not included in the provisions that apply to NEMT PAHPs, these provisions do not apply to NEMT PAHPs, and we are removing reference to NEMT PAHPs from these provisions in this final rule. * **Modifying and finalizing an effective date of the first rating period beginning on or after 1 year from the effective date of this final rule.** | | | |

| **Proposed Changes/Notes** | | | |
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| **Proposed Changes Related to the State Monitoring Report to CMS** | | | |
| **Proposed Citation/Effective Date** | **Proposed Rule** | **Notes** | **Extended to Separate CHIP?** |
| **§438.66**  ***Revising***  (b)(4), (c)(5), (e)(2)(vi), and (vii), and (e)(3)(i)  ***Applicability***  The first rating period  beginning on or  after 3 years after the effective date of the final rule.  Since States already collect CAHPS survey data for CHIP and would likely not need the same timeframe to implement as needed for implementing the proposed Medicaid enrollee experience surveys requirement, we propose for the provision at **§457.1230(b)** to be  applicable 60 days after the effective date of the final rule. | **§438.66—*State monitoring requirements***  (a) *General requirement.* The State agency must have in effect a monitoring system for all managed care programs.  (b) The State’s system must address all aspects of the managed care program, including the performance of each MCO, PIHP, PAHP, and PCCM entity (if applicable) in at least the following areas:  (4) Enrollee materials, **enrollee experience**, and customer services, including the activities of the beneficiary support system.  (c) The State must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:  (5) Results from an annual enrollee experience survey conducted by the State and any provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.  (e)(1) The State must submit to CMS no later than 180 days after each contract year, a report on each managed care program administered by the State, regardless of the authority under which the program operates.  (2) The program report must provide information on and an assessment of the operation of the managed care program on, at a minimum, the following areas:  (vi) Availability and accessibility of covered services, including any ILOS, within the MCO, PIHP, or PAHP contracts, including network adequacy standards.  (vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures and results of an enrollee experience survey, including as applicable, consumer report card, provider surveys, or other reasonable measures of performance.  (3) The program report required in this section must be:  (i) Posted on the website required under §438.10(c)(3) **within 30 calendar days of submitting it to CMS**. | In the 2016 final rule, we renamed and expanded §438.66 *State Monitoring Requirements* to ensure that States had  robust systems to monitor their managed care programs, utilize the monitoring results to make program improvements, and report to CMS annually the results of their monitoring activities. Existing regulations at §438.66(c)(5) require States to use the data collected from their monitoring activities to improve the performance of their managed care programs.  To reflect the current proposals in the annual assessment of the operation of the managed care program report called the Managed Care Program Annual Report (MCPAR) required at §438.66(e), we propose conforming edits.  Currently §438.66(e)(3)(i) only requires that the report be posted on the State’s website but does not specify a timeframe; we believe that adding further specificity about the timing of when the report should be posted would be helpful to interested parties and bring consistency to this existing requirement. We propose to revise §438.66(e)(3)(i) to require that States post the report required in §438.66(e)(1) on their website within 30 calendar days of submitting it to CMS. | Yes  **§457.1285** (Except  §438.66(e))  §457.1201e)  §457.1230(b)  §457.1207 |
| **Final Rule: Publish date 5/10/24**   * §438.66(b) (monitoring system) and (c) (use monitoring for health plan performance improvement) finalized as proposed except will not be adopted for separate CHIP plans. States are required to collect enrollee experience data for CHIP through annual CAHPS surveys (Section 2108(e)(4) of the Social Security Act). * §438.66(c)(5) finalized as written is a State obligation with an exemption (for the annual CAHPS survey) for Medicaid Managed Care plans in which all enrollees are enrolled in a Medicare Advantage D-SNP plan (already required for these enrollees under D-SNP rules). Managed Care Plans are still required to use all monitoring data for performance improvement; however, the member experience data will come from the D-SNP surveys for that population. * Finalizing §438.66(e) as proposed. * §457.1230(b) and §457.1207 (use CAHPS to evaluate CHIP network adequacy and post results on the website) **finalized as proposed except the implementation date is extended to 2 years following the effective date of the final rule.** | | | |

1. This document contains excerpts from CMS language within the ***Federal Register***; therefore, “we” refers to CMS throughout this document.

   \* Proposed Rule:[2023-08961.pdf (govinfo.gov)](https://www.govinfo.gov/content/pkg/FR-2023-05-03/pdf/2023-08961.pdf) [↑](#footnote-ref-1)