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SUMMARY: CMS Managed Care Final Rule (CMS-2408-F)

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Executive Summary

On November 13, 2020, the Centers for Medicare and Medicaid Services (CMS) published "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care" (CMS-2408-F), finalizing regulations CMS first proposed in November 2018. CMS believes the final rule reflects their efforts to streamline the Medicaid and CHIP managed care regulatory framework by relieving regulatory burdens; supporting state flexibility and local leadership; and promoting transparency, flexibility, and innovation in the delivery of care.

Most provisions are effective 30 days following publication in the *Federal Register*, with several exceptions noted below. The final rule amends or adds the following provisions. Those noted in **bold** have been amended or otherwise changed from the initial CMS proposal:

- **Standard Contract Requirements (§ 438.3(t))**
- **Option to Develop and Certify a Rate Range (§ 438.4(c))**
- **Capitation Rate Development Practices that Increase Federal Costs and Vary with the Rate of Federal Financial Participation (FFP) (§ 438.4(b)(1) and (d))**
- Rate Development Standards: Technical Correction (§ 438.5(c)(3)(ii))
- Risk-Sharing Mechanism Basic Requirements (§ 438.6(b))
- **Delivery System and Provider Payment Initiatives under MCO, PIHP, or PAHP Contracts (§ 438.6(a) and (c))**
- **Pass-Through Payments under MCO, PIHP, and PAHP Contracts (§ 438.6(d))**
- Payments to MCOs and PIHPs for Enrollees that are a Patient in an Institution for Mental Disease (IMD) (§ 438.6(e))
- **Rate Certification Submission (§ 438.7)**
- Medical Loss Ratio (MLR) Standards: Technical Correction (§ 438.8)
- Non-Emergency Medical Transportation PAHPs (§ 438.9)
- **Language and Format (§ 438.10(d))**
- Information for All Enrollees of MCOs, PIHPs, PAHPs, and PCCM Entities: General Requirements (§ 438.10(f))
- Information for All Enrollees of MCOs, PIHPs, PAHPs, and PCCM Entities: Enrollee Handbooks (§ 438.10(g))
- Information for All Enrollees of MCOs, PIHPs, PAHPs, and PCCM Entities: Enrollee Handbooks (§ 438.10(g))
- Disenrollment: Requirements and Limitations (§ 438.56)
- Network Adequacy Standards (§ 438.68)
- Adoption of Practice Guidelines (§ 438.236)
- Enrollee Encounter Data (§ 438.242(c))
- **Medicaid Managed Care Quality Rating System (MAC QRS) (§ 438.334)**
- **Managed Care State Quality Strategy (§ 438.340)**
- Activities Related to External Quality Review (§ 438.358)
- **Exemption from External Quality Review (§ 438.362)**
- External Quality Review Results (§ 438.364)
- **Grievance and Appeal System: Statutory Basis and Definitions (§ 438.400)**

- Grievance and Appeal System: General Requirements (§§ 438.402 and 438.406)
- Resolution and Notification: Grievances and Appeals (§ 438.408)
- Compliance Dates for Part 457 Managed Care Provisions
- Information Requirements (§ 457.1207)
- Structure and Operations Standards (§ 457.1233)
- **Quality Measurement and Improvement (§ 457.1240)**
- **Grievance System (§ 457.1260)**
- **Sanctions (§ 457.1270)**
- **Program Integrity Safeguards (§ 457.1285)**
- **CHIP conforming changes to reflect Medicaid managed care proposals**

Below, we summarize only those provisions in the CMS final rule that have been amended or deleted from the initial proposal. We also highlight areas where CMS sought public feedback but declined to make further revisions to the final rule. For a full summary of the 2018 proposal that includes provisions not amended in the final rule, please refer to the Kaiser Family Foundation summary.

Option to Develop and Certify a Rate Range (§ 438.4(c))

Regulatory Background

The 2016 Final Rule prohibited the use of rate ranges. That prohibition was driven by CMS concerns that states use the rate ranges to shift costs to the federal government without asking more from Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs).

CMS noted examples where the prohibition led to a weakened bargaining position for some states, and increased state administrative burdens and costs. The proposed rule returns the use of rate ranges. The final rules modifies the initial CMS proposal by allowing states to make +/- 1 percent changes within rating periods and requiring states to publicly post certain information about the rate ranges before adoption.

Summary of New or Amended Provisions

- Section 438.4(c)(a) establishes the option for states to adopt rate ranges, provided certain conditions are met:
    - The rate certification must identify and justify assumptions, data, and methodologies for both the upper and lower bounds;
    - Both the upper and lower bounds must be certified as actuarially sound;
    - Limits the upper bound of the range to no more than 5% greater than the lower bound;
    - The rate certification documents the state's criteria for paying managed care entities at different points within the rate range; and
    - The state does not use criteria for paying managed care entities at different points within the rate range based on willingness or agreement by managed care entities or their network providers to enter into intergovernmental transfer agreements (IGTs), or based on the amount of funding provided through IGTs.

- Section 438.4(c)(2)(iii) allows a state to increase or decrease the capitation rate per rate cell within the rate range up to 1 percent of each certified rate during the rating period.
- Section 438.4(c)(2)(iv) requires states to post the following information on their websites before executing managed care contracts with rate ranges:
    - The upper and lower bounds of each rate cell;
    - A description of all assumptions that vary between the upper and lower bounds of each rate cell, including for the assumptions that vary, and the specific assumptions used for the upper and lower bounds of each rate cell; and
    - A description of the data and methodologies that vary between the upper and lower bounds of each rate cell, including for the data and methodologies that vary, and the specific data and methodologies used for the upper and lower bounds of each rate cell.

Effective Date

States that elect to adopt rate ranges must comply with § 438.4(c) as amended effective July 1, 2021 for Medicaid managed care rating periods starting on or after July 1, 2021.

Capitation Rate Development Practices that Increase Federal Costs and Vary with the Rate of Federal Financial Participation (FFP) (§ 438.4(b)(1) and (d))

Regulatory Background

Proposed changes are intended to clarify the 2016 Final Rule's existing restrictions on cost-shifting practices. CMS declined to adopt a section from the 2018 proposal that provided examples of prohibited rate development practices. CMS noted the list of practices originally listed "generally increase Federal costs and vary with the rate of FFP, and as such, are prohibited in most cases." These prohibited practices in the proposal included methodologies that: use a higher profit margin, operating margin or risk margin; factor additional cost of contractually-required provider fee schedules (e.g., minimum fee schedules), above the costs of similar provider fee schedules; and use a lower remittance threshold for a medical loss ratio. In declining to adopt the examples, CMS acknowledged there could be limited but "legitimate and actuarially sound reasons for varying pricing assumptions between rate cells" independent of differing levels of FFP.

Summary of New or Amended Provisions

- Amended paragraph § 438.4(b)(1) requires that variations in the assumptions, methodologies, and factors states use to develop capitation rates must be tied to actual cost differences. Variations cannot be tied to differences that increase federal costs and vary with the rate of FFP.
- Section 438.4(b)(1) also allows CMS to require a state to provide written documentation and justification that any differences in assumptions, methodologies, or factors used to develop capitation rates represent actual cost differences based on the characteristics or mix of the covered population or contract.

Effective Date

Effective 30 days after publication

Delivery System and Provider Payment Initiatives under MCO, PIHP, or PAHP Contracts (§ 438.6(a) and § 438.6(c))

Regulatory Background:

In the 2018 proposed rule, CMS set forth a new minimum fee schedule (MFS) approach that would not require CMS prior approval in order to reduce administrative burden for states. In describing this MFS approach, CMS further explained that supplemental payments contained in a state plan are not, and do not constitute, state plan approved rates, which CMS described as the per unit price of particular services. Supplemental payments, being divorced from services rendered on behalf of an individual beneficiary, are separate and distinct from state approved rates.

Among the existing directed payments options are a minimum fee schedule, a maximum fee schedule, and a uniform percentage add-on. CMS proposed to add an option that would allow states to require MCOs to adopt a cost-based rate, a Medicare equivalent rate, a commercial rate, or other market-based rate.

CMS recognized states are pursuing payment models that are based on value and overall delivery system reform rather than utilization or volume, such as global payments, and are tailored to produce optimal results for their local markets. Thus, CMS proposed removing a subsection to facilitate this activity.

CMS issued an Information Bulletin (CIB) on November 2, 2017, setting forth criteria for multi-year approvals for directed payment arrangements to support state multi-year delivery system reform efforts. The proposed rule codified the criteria that CMS initially set forth in the CIB.

Summary of New or Amended Provisions:

- Section 438.6(a) refines the definition of "state plan approved rates" by deleting the proposed phrase "per unit price per services" and replacing it with "for specific services identifiable as having been provided to an individual beneficiary."
- Section 438.6(a) refines the definition of "supplemental payments" to specifically exclude disproportionate share hospital (DSH) and graduate medical education (GME) payments. CMS originally proposed this change in § 438.6(c)(1)(iii)(A).
- Section 438.6(a) revises the definition of "supplemental payments" from the proposed phrase "amounts calculated through an approved state plan rate methodology" to "state plan approved rates."
- Section 438.6(c)(2)(ii) finalizes the provision that a directed payment to implement a MFS using a state plan approved rate would not need prior approval.
- Removes proposed § 438.6(c)(1)(iii)(E) and (c)(2)(ii)(C) allowing cost-based rates, Medicare-equivalent rates, commercial rates or other market-base rates. CMS will consider addressing these and other state directed payment policies in future rulemaking.

Effective Date

30 days after publication.

Pass-Through Payments under MCO, PHP, and PAHP Contracts (§ 438.6(d))

Regulatory Background:

In the 2018 proposed rule, CMS proposed to allow states to continue to make pass-through payments to hospitals, nursing facilities or physicians when they were moving populations and/or services from fee-for-service (FFS) to managed care. CMS further clarified the aggregate pass-through payments made under the managed care transition period must be less than or equal to the payment amounts actually paid as FFS supplemental payments to hospitals, nursing facilities or physicians made during the 12-month period immediately 2 years prior to the first managed care program rating period. The 2018 proposed rule also included a four-step formula for calculating these amounts and set a maximum three year transition period for these pass-through payments.

Summary of New or Amended Provisions:

- CMS maintained most of the provisions in the 2018 proposed rule, but added technical amendments to §438.6(d)(iii)(A) through (C) to change the phrase "payment rates" to "State plan approved rates." CMS also clarified states should exclude supplemental payments from ratio calculations.

Effective Date for the Provision:

Effective July 1, 2021 for managed care rating periods starting on or after July 1, 2021.

Payments to MCOs and PIHP for Enrollees that are a Patient in an Institution for Mental Disease (IMD) (§438.6(e))

Regulatory Background:

In the 2016 final rule, CMS limited FFP for full month MCO capitation payments for individuals 21 to 64 years of age who received inpatient treatment in an institution for mental diseases (IMD) for no more than 15 days in any month.

NOTE: CMS did not propose any changes to this provision in the 2018 proposed rule, but solicited feedback regarding the 15-day limit. CMS did not make any changes in this final rule, noting several other mechanism available to states to address the concerns raised regarding states' inability to obtain FFP for medically necessary longer lengths of stay in IMDs, such as Section 1115 Research and Demonstration Waivers, or through a state plan option afforded under section 5052 of the SUPPORT for Patients and Communities Act.

Rate Certification Submission (§ 438.7)

Regulatory Background

The 2016 Final Rule provided *de minimis* rate adjustments (±1.5%) do not affect actuarial soundness. CMS adopted this provision with minor changes from the 2018 proposal.

Summary of New or Amended Provisions

- Section 438.7(c)(3) allows states to make *de minimis* adjustments without submitting justification or revised rate certifications, unless CMS requests justification. The final rule clarifies states can only make such adjustments "during the rating period."
- Section 438.7(e) formalizes current practices by requiring CMS to issue annual guidance on capitation rate development, including updates or developments in the rate review process.

Effective Date

Effective 30 days after publication.

Information Requirements, Language and Format (§438.10)

Regulatory Background:

The 2016 final rule included standards for written materials, including requirements for publishing certain taglines in prevalent non-English languages and in large print, specifically at least 18-point font. Taglines required to be in large print are those that explain the availability of written translation or oral interpretation, how to request auxiliary aids and services for individuals with limited English proficiency or a disability, and the toll-free phone numbers for the entity providing choice counseling services and the managed care plan's member/customer service unit.

Summary of New or Amended Provisions:

- Section 438.10(d)(2) deletes the definition of large print as "no smaller than 18- point" and adopting the "conspicuously visible" standard codified in 45 CFR 92.8(f)(1), which implements the non-discrimination section of the ACA.
    - CMS declines to include a definition of "conspicuously visible" and relies on the Office of Civil Rights test, which "is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the information."
- Section §438.10(d)(2) replaces the requirement to include taglines on "all written materials" with a requirement for taglines only to be included on materials for potential enrollees that are "critical to obtaining services." This is the new minimum requirement and states may include taglines on more documents than those critical to obtaining services.
    - CMS declines to include a definition for "critical to obtaining services" and encourages states and MCOs to conduct due diligence to determine which of their documents are critical outside of the non-exhaustive list provided in §438.10(d)(3).
- Section 436.10(d)(6) removes the 18-point font minimum standard for MCO, PHP, PAHP, and PCCM materials.
- The 2020 final rule revised §438.10(d)(2) and (d)(3) by adding "information on how to request auxiliary aids and services" to the list of information required in taglines.

Effective Date

30 days after publication.

Medicaid Managed Care Quality Rating System (MAC QRS) (§ 438.334)

Regulatory Background:

Section 438.334 requires states to operate a managed care quality rating system (QRS). CHIP regulations at § 457.1240(d) incorporate § 438.334 in its entirety by cross-reference. This provision gives states the option to use the CMS QRS or create a state-specific ("state-alternative") QRS if the alternative produces substantially comparable information on plan performance. CMS must approve all state-alternative QRS.

Summary of New or Amended Provisions:

- Revises §438.334(b) to include a MAC QRS framework, including the identification of a set of mandatory performance measures and a methodology. CMS will align the measures with appropriate QHP rating systems, the appropriate Medicare Advantage 5-Star Rating System, and other CMS quality rating approaches. CMS will go through a formal notice and comment process to publish the mandatory performance measures and methodology. These will serve as a minimum rating system where states can add other quality indicators as appropriate for their Medicaid programs.
- Redesignates §438.334(c)(1)(i) as (c)(1)(ii) and now allows states to consider feasibility when requiring that information in a state-alternative QRS be substantially similar to the CMS QRS, as there are differences between state programs that complicate comparability.
- CMS revised §438.334(c)(4), regarding stakeholder engagement, by changing the phase "in consultation" to "after consultation." After consulting with states and other stakeholders, the Secretary will develop sub-regulatory guidance on the "substantially similar" standard.
- The proposed rule planned to remove the requirement that CMS approve state-alternative QRS, but the final rule will not incorporate this change since it leads to uncertainty and potentially wasted resources among states.

Effective Date

30 days after publication.

Managed Care State Quality Strategy (§ 438.340) and Children's Health Insurance Program (CHIP) Quality Measurement and Improvement (§ 457.1240)

Regulatory Background:

Section 438.340 sets forth the minimum elements of a managed care state quality strategy and the requirements for development, evaluation, revision and public display of the quality strategy. The provisions in the 2018 proposed rule required that the state's quality strategy address health disparities for enrollees with disabilities, using a broader definition of disability.

Summary of New or Amended Provisions:

- Section 438.340(b)(6) modifies the current regulatory meaning of "disability status" to include, at a minimum, whether the individual qualified for Medicaid on the basis of a disability. A state quality strategy must include the state's definition of disability status and how the state

determines whether a Medicaid enrollee meets the standard, including any data sources the state will use to identify disability status.
- CMS did not include the term "PCCM entity" in §438.340(b)(6).
- CMS moved the proposed requirement for transmitting information from § 438.340(b)(6) to § 438.54, which requires the state provide demographic information for each Medicaid enrollee to the individual's MCO, PIHP, PAHP, or PCCM entity at the time of enrollment.
- Makes a grammatical correction to change language in § 438.340(b)(3)(i) to require States to identify which quality measures and performance outcomes the State will publish at least annually on their website.
- Makes technical changes to § 438.340(b) and (c) by removing subsections (b)(9),(10) and (11) and (c)(3)(iii) and renumbering those as subsections (b)(8), (9) and (10), respectively.
- Section 457.1240(e) sets forth that the State must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished to CHIP enrollees as described in § 438.340, with the exception of the requirement for consultation with the Medical Care Advisory Committee described in § 438.340(c)(1)(i).

Effective Date

States must comply with § 438.340 and § 457.1240(e) as amended for all Medicaid and CHIP Quality Strategies submitted after July 1, 2021.

Exemption from External Quality Review (§ 438.362)

Regulatory Background:

The provisions in the 2018 proposed rule required states to annually post, on the state agency website, which health plans are exempt from External Quality Review (EQR) and the date when the exemption began.

Summary of New or Amended Provisions:

- Section 438.362(c) finalizes the requirement for states to identify MCOs exempt from Medicaid EQR requirements, including an additional requirement that the state identify if no MCOs are exempt from the EQR requirement.
- Section 438.364(a)(7) is added to also require states EQR technical reports to include the names of the MCOs the state exempted from EQR, including the beginning date of the current exemption period, or specify that no MCOs are exempt.
- Section 438.364, as amended and finalized, also applies to separate CHIPs through an existing cross reference in § 457.1250(a).

Effective Date

States must comply with § 438.364 and § 457.1250(a) for all external quality reports submitted on or after July 1, 2021.

Grievance and Appeal System: Statutory Basis and Definitions (Medicaid) (§ 438.400)

Regulatory Background:

The 2016 final rule required Medicaid managed care entities to provide enrollees timely written notice of adverse benefit determinations. The 2018 proposed rule sought to clarify notice is not required when a Medicaid managed care plan denies payment because a claim does not meet the definition of a "clean claim."

Summary of New or Amended Provisions:

- Section 438.400(b)(3) clarifies the Medicaid definition of "adverse benefit determination" by adding the word "solely." The enrollee notice requirement is not triggered when a managed care plan denies a claim, in whole or in part, *solely* on the basis that it does not meet the definition of a "clean claim."

Effective Date

30 days after publication.

Grievance System (CHIP) (§ 457.1260)

Regulatory Background:

The 2018 proposed rule clarified multiple items relating Medicaid and CHIP grievance and appeals system alignment.

Summary of New or Amended Provisions:

- Section 457.1260(a)(2)(i) clarifies the CHIP definition of "adverse benefit determination." CHIP members in rural areas with only one plan do not have a right to choose out of network providers under §438.52. Requests to obtain services from out of network providers therefore do not qualify as "adverse benefit determinations" for these CHIP members.
- Section 457.1260(b)) removes duplicative external medical review requirements.
- Section 457.1260(c)(3) clarifies technical issues regarding the timing and content of adverse benefit determinations. Rather than applying Medicaid notice timeframes, the 2020 final rule requires CHIP plans to provide notices in a "timely" manner. An exception applies to expedited service authorizations, which must comply with Medicaid timeliness standards.
- Section 457.1260(d) requires CHIP plans to comply with Medicaid requirements in §438.406, regarding the handling of grievances and appeals.
- Section 457.1260(e) adds requirements for resolution of grievances and appeals, including a requirement for CHIP members to exhaust managed care entities' appeals processes before requesting state external reviews. The final rule also requires states to give members at least 90 calendar days but no more than 120 calendar days after the plan's notice of resolution to request a state external review.
- Section 457.1260(e) clarifies the circumstances under which a CHIP enrollee can request a state external review, and the timing of these requests.

- In response to comments, CMS clarified a CHIP managed care plan is not required to continue benefits while the outcome of a state external review is pending; therefore, CMS did not incorporate Medicaid continuation of benefit requirements into the final rule.

Effective Date

30 days after publication.

Sanctions (CHIP) (§ 457.1270)

Regulatory Background:

The 2018 proposed rule clarified requirements regarding sanctioning CHIP managed care plans, including states' ability to sanction PCCMs and PCCM entities. The proposed rules also clarified requirements for temporary management.

Summary of New or Amended Provisions:

- Section 457.1270(a) updates cross-references to Medicaid requirements in 42 C.F.R. Part 438, Subpart I, regarding sanctions, and clarified states can establish sanctions for PCCMs and PCCM entities.
- CMS updated § 457.1270(b) and (c) in the final rule by adding parentheticals to help readers understand cross-references to Medicaid rules. The amended rules outline the requirements for imposing optional and mandatory temporary management sanctions on CHIP plans.

Effective Date

30 days after publication.

CHIP Program Integrity Safeguards (§ 457.1285)

Regulatory Background:

§457.1285 sets for the CHIP requirements for program integrity safeguards for managed care entities by adopting the Medicaid requirements in subpart H of part 438 with, in relevant part, an exception for the Medicaid actuarial soundness requirement.

Summary of New or Amended Provisions:

- CMS revises cross-references to Medicaid regulations to exclude §438.604(a)(2) and §438.608(d)(4). These regulations require collection and submission of and reference to data used to certify actuarial soundness, and do not apply to CHIP.

Effective Date

30 days after publication