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MEMORANDUM

From: Dentons US LLP

Date: May 4, 2023

Subject: Proposed Revisions to Medicaid Managed Care Rule

On May 3, 2023, the Centers for Medicare & Medicaid Services ("CMS") published a Proposed Rule in the Federal Register titled *Medicaid Program: Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality* (the "Proposed Rule"), available at 88 Fed. Reg. 28092 (May 3, 2023). The Proposed Rule proffers significant changes to existing Medicaid managed care and Children's Health Insurance Program ("CHIP") regulations in a number of areas, including with respect to access requirements, requirements with respect to quality, and permissions regarding "in lieu of" services. Significant changes are proposed with respect to State directed payments, which have experienced substantial growth since being authorized by CMS in the 2016 Medicaid managed care overhaul.

This memorandum is intended to provide some detail regarding key provisions of the Proposed Rule, along with some preliminary assessment of the potential implications of CMS's various proposals. It is designed to highlight key sections and is not comprehensive. We are more than happy to provide additional information and analysis concerning the CMS proposal upon request.

Comments on the Proposed Rule are due July 3, 2023. Because the Proposed Rule would affect many different stakeholders in a variety of different ways, we expect extensive comment on the rule. Please do not hesitate to contact us if you would like assistance in assessing the potential impact of the Proposed Rule or in drafting comments.

Given the large number of topics included in the 161-page Proposed Rule, we are providing the following outline of the topics to be covered in this memorandum. Note that these categories (and the order of these categories) does not track the order in the Proposed Rule itself, although we have tried to provide citations so that additional information can be found in the rule itself.

OUTLINE

I. Managed Care State Directed Payment ("SDP") Proposed Changes (§ 438.6(c))

The Medicaid Managed Care Final Rule published on May 6, 2016 (the "2016 Final Rule") introduced the possibility for States to include special contract provisions in their contracts with managed care organizations ("MCOs") whereby States may direct MCOs[1] to make payments to certain Medicaid providers through value-based purchasing, delivery system reform models, and other provider payment initiatives. These exceptions to the general rule prohibiting States from directing MCO expenditures are now commonly referred to as state directed payments ("SDPs"). CMS notes in the preamble to the Proposed Rule that "the scope, size, and complexity of the SDP arrangements submitted by States for approval has also grown steadily and quickly" since CMS introduced SDPs in the 2016 Final Rule. In calendar year ("CY") 2017, CMS received 36 SDP proposals (commonly referred to as "preprints")[2] from 15 States. By CY 2021, CMS received 223 preprints from 39 States, and for CY 2022, CMS received 298 preprints in total. As of December 2022, CMS has reviewed more than 1,100 SDP proposals and approved 993 proposals since the 2016 Final Rule. CMS is clearly concerned about the growth of SDPs, and at one point in the Proposed Rule the agency requests comment on overall expenditure limits for SDPs.[3]

The current regulations at § 438.6(c) specify the parameters for how and when States may direct the expenditures of their Medicaid managed care plans and the associated requirements and prohibitions on such arrangements. Among other mandates, SDPs must be based on the utilization and delivery of services, and States must submit a preprint to CMS for review and approval prior to implementing an SDP.[4]

In light of the increasing volume of preprint submissions and costs of SDP programs nationwide, CMS is proposing a number of changes related to SDPs. CMS explains that the proposed changes 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

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1 Per 42 C.F.R. § 438.6(c), a State may direct an MCO, prepaid inpatient health plan ("PIHP") or prepaid ambulatory health plan ("PAHP") to make payments to certain Medicaid providers. Unless otherwise stated, references in this Memorandum to MCOs are intended to include MCOs, PIHPs and PAHPs.

2 The "preprint" is the CMS template that States use for all State directed payment requests. The preprint implements the prior approval process, required pursuant to § 438.6(c)(2), and must be completed, submitted to, and approved by CMS before implementing any of the specific payment arrangements. SDPs based on a State plan fee schedule are exempt from the written prior approval process. As discussed herein, CMS now additionally proposes to exempt SDPs that are based on approved Medicare rates from the written approval requirement.

3 88 Fed. Reg. 28092, 28127 (May 3, 2023).

4 In January 2021, CMS published additional guidance for States to clarify existing SDP policy, and also issued a revised preprint form that States must use for rating periods beginning on or after July 1, 2021. *See* State Medicaid Directors Letter ("SMDL") #21-001 (Jan. 8, 2021). The revised preprint form is more comprehensive than the initial preprint published in 2017, and "is designed to systematically collect the information that CMS identified as necessary as part of [its] review of SDPs to ensure compliance with the Federal regulatory requirements." 88 Fed. Reg. at 28111.

3. CMS and States have the appropriate fiscal and program integrity guardrails in place to strengthen the accountability and transparency of SDP payment arrangements.

We set forth below a summary of CMS's proposed changes to the regulation governing use of SDPs.

A. SDP Payment Options and Related Requirements

1. Payments Based on Utilization and Delivery of Services

Current regulations require that States demonstrate in writing that SDPs are based on the utilization and delivery of services to Medicaid enrollees covered under the contract between the State and the managed care plan ("Medicaid MCO Contract"). CMS has interpreted this requirement, and clarified in SMDL #21-001, to mean that SDPs must be conditioned upon the utilization or delivery of services during the applicable rating period. CMS is now proposing to codify this clarification with respect to provider payment initiatives (*i.e.*, minimum fee schedules, maximum fee schedules, and uniform increases) in a new § 438.6(c)(2)(vii)(A), which expressly would require that any and all payments made under the SDP be conditioned on the utilization and delivery of services under the Medicaid MCO Contract only for the applicable rating period.

This change would preclude States from making any SDP payment based on a historical basis (or any other basis) that is not tied to the delivery of services to the rating period itself (*see also* below CMS's proposals regarding interim payments). Consistent with CMS's position in SMDL #21-001, CMS reaffirms in the Proposed Rule preamble that States can use historical data to inform the capitation rate development, however, payment to providers for an SDP must be made based on the delivery and utilization of covered services rendered to Medicaid beneficiaries during the rating period documented for the approved SDP. This section would be effective no later than the first rating period beginning on or after 2 years after the effective date of the final rule.

2. Total Payment Rate for Each SDP

As part of the proposed revisions in § 438.6(c)(2)(ii), CMS is proposing a new standard that each SDP ensure that the "total payment rate" for each service and each provider class included in the SDP be "reasonable, appropriate and attainable." Consistent with information required under Table 2 of the current SDP preprint template, CMS proposes to define the new "total payment rate" standard as the aggregate for each managed care program of:

- The average payment rate paid by all MCOs to all providers included in the specified provider class for each service identified in the SDP;
- The effect of the SDP on the average rate paid to providers included in the specified provider class for the same service for which the state is seeking written prior approval;
- The effect of any and all other SDPs on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking written prior approval; and

- The effect of any and all allowable pass-through payments, as defined in § 438.6(a), paid to any and all providers in the provider class specified in the SDP for which the State is seeking written prior approval on the average rate paid to providers in the specified provider class.[5]

While the total payment rate would be collected for each SDP, CMS proposes to assess if the total payment level across all SDPs in a managed care program is reasonable, appropriate and attainable. Upon request from CMS, the State would be obligated to provide documentation demonstrating the total payment rate for each service and provider class. Based on CMS's ongoing monitoring of payment rates, the agency may issue guidance further detailing documentation requirements and a specified format to demonstrate that the total payment rate is reasonable, appropriate and attainable for all services provided. This section would be effective as of the effective date of the final rule.

3. Average Commercial Rate

CMS acknowledges that many States have been submitting preprints with total payment rates up to the average commercial rate ("ACR"). In the Proposed Rule, CMS proposes to formally incorporate the ACR as a regulatory limit on the projected total payment rate for (a) inpatient hospital services, (b) outpatient hospital services, (c) qualified practitioner services at an academic medical center, and (d) nursing facility services (together, the "Four Services").[6]

CMS proposes in the regulatory text to limit the projected total payment rate for each of these Four Services to the ACR for any SDP, excluding minimum fee schedules based on State plan or Medicare rates. While States must calculate the total payment rate for each SDP, the proposed total payment limit would apply across all SDPs in a managed care program; States would not be able to, for example, create multiple SDPs that applied, in part or in whole, to the same provider classes and be projected to exceed the ACR.

In order to ensure compliance with the Four Services payment rate limitations, CMS proposes to require States to provide two pieces of documentation: (1) an ACR demonstration;[7] and (2) a total payment rate comparison to the ACR.[8]

The ACR demonstration would be submitted with the initial preprint submission (new, renewal, or amendment) following the effective date of this section, as finalized, and then updated at least every 3 years, so long as the State continues to include the SDP in one or more managed care contracts. CMS proposes that the ACR demonstration use payment data that: (1) is specific to the State; (2) is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section; (3) is specific to the service(s) addressed by the SDP; (4) includes the total reimbursement by the third party payer and any patient liability, such as cost sharing and deductibles; (5) excludes payments to federally qualified health centers ("FQHCs"), rural health clinics ("RHCs") and any non-commercial payers such as Medicare; and (6) excludes any payment data

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5 88 Fed. Reg. at 28119.

6 *Id*. At this time, CMS is not proposing to establish the ACR as a payment rate ceiling for services other than the Four Services. While SDPs for all other services will still need to meet the proposed total payment rate standard, CMS believes further research is needed before codifying a specific payment rate limit for these other services to ensure that such limits do not result in inappropriately reducing payment rates and/or negatively affecting access to care.

7 *See* proposed 42 C.F.R. 438.6(c)(2)(iii)(A), (C).

8 *See* proposed 42 C.F.R. 438.6(c)(2)(iii)(B).

for services or codes that the applicable Medicaid managed care plans do not cover under the contracts with the State that will include the SDP.[9]

With regards to requiring that data be specific to the State, CMS makes clear that CMS would not accept regional or national analyses. Further, CMS acknowledges that requiring States to use data that is specific to the service type(s) included in the SDP would be a change from current operational practice in which States are required to compare the total payment rate for each service ***and*** provider class to the corresponding service and provider class specific ACR. CMS now believes that requiring an ACR analysis that is specific both to the service and provider class can have "deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries."[10]

The total payment rate comparison to the ACR would be submitted with the preprint as part of the request for approval of each SDP and updated with each subsequent preprint submission (each amendment and renewal). CMS proposes that the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which written prior approval is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as a percentage of the ACR for each of the Four Services included in an SDP.[11]

CMS explains the proposed comparison of the total payment rate to the ACR would generally align with current practice. However, CMS is proposing to codify that the total payment rate comparison would be specific to each Medicaid managed care program to which the SDP would apply. Further, CMS is proposing that the total payment rate comparison to the ACR must be specific to both the service and the provider class; this is current practice today but differs from the proposed ACR demonstration, which would be service specific only. This section would be effective no later than the first rating period for contracts beginning on or after the effective date of the final rule.

CMS believes that establishing a total payment rate limit of the ACR for the Four Services appropriately balances the need for additional fiscal guardrails while providing States flexibility in pursuing provider payment initiatives and delivery system reform efforts that further advance access to care and enhance quality of care in Medicaid managed care. CMS also indicates that formally codifying a payment rate limit of ACR for the Four Services may raise some concerns regarding State incentives, SDP objectives, and fiscal integrity. CMS further provides that it is still considering alternatives to the ACR as a total payment rate limit for the Four Services for each SDP, specifically establishing the total payment rate limit at the Medicare rate.[12] Moreover, CMS is considering, and soliciting feedback on, establishing a total payment rate limit for all services, for all SDP arrangements (excluding State Plan and Medicare-based minimum fee schedules) at the Medicare rate.[13] CMS is inviting public comments on these alternatives.

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9 88 Fed. Reg. at 28125.

10 *Id.* CMS further provides "During our reviews of SDP preprints since the 2016 final rule, it has become clear that requiring an ACR analysis that is specific both to the service and provider class can have deleterious effects when States want to target Medicaid resources to those providers serving higher volumes of Medicaid beneficiaries."

11 88 Fed. Reg. 28126.

12 88 Fed. Reg. at 28123.

13 *Id.*

4. Interim Payments and Reconciliation

In practice, CMS has reviewed and approved SDPs in which States require MCOs to make interim payments based on historical utilization, and then, after the close of the rating period, reconcile the payments to actual utilization for the SDP rating period. CMS is concerned with this practice and is proposing a new § 438.6(c)(2)(vii)(B) that would prohibit this practice. Despite having previously approved such arrangements, CMS asserts that SDPs that make payments based on retrospective utilization and include reconciliations to reflect actual utilization, while eventually tying final payment to utilization and delivery of services during the rating period approved in the SDP, are contrary to the nature of risk-based managed care. CMS indicates that prohibiting this practice "would alleviate actuarial and oversight concerns as well as restore program and fiscal integrity to these kinds of payment arrangements."[14] This new section would be effective no later than the first rating period beginning on or after 2 years after the effective date of the final rule.

5. Separate Payment Terms

In the preamble to the Proposed Rule, CMS repeatedly notes the agency's "strong preference that SDPs be included as adjustments to the capitation rates" as the agency believes this method is most consistent with the nature of risk-based managed care.[15] However, CMS also recognizes that States believe there "is utility in the use of separate payment terms for specific programmatic or policy goals."[16] In light of CMS's concern that there is often little or no risk for the managed care plans related to separate payment terms under an SDP, CMS believes that it is necessary to establish regulatory requirements regarding the use of separate payment terms. Proposed regulatory changes include:

- Amending § 438.6(a) to define a "separate payment term" as "a predetermined and finite funding pool that the State establishes and documents in the Medicaid managed care contract for a specific SDP for which the State has received written prior approval. Payments made from this funding pool are made by the State to the MCOs and are made separately and in addition to the capitation rates identified in the contract as required under § 438.3(c)(1)(i)."[17]

- Proposing a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms. For example, the separate payment term could not exceed the total amount documented in an approved SDP preprint. Further, CMS also proposes that required information specific to separate payment terms be included in the State's Medicaid MCO Contracts.

- Proposing 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 MCO Contract and include the separate payment term in the rate certification.

The proposed definition and requirements would largely be effective as of the effective date of the final rule. The requirement that the separate payment term be documented in the Medicaid MCO Contract (§ 438.6(c)(6)(v)) would be effective no later than the first rating period beginning on or after 4 years after the effective date of the final rule.

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14 88 Fed. Reg. at 28134.

15 88 Fed. Reg. at 28134, 28146.

16 88 Fed. Reg. at 28146.

17 88 Fed. Reg. at 28235.

6. Medicare Rates

In the 2020 Medicaid Managed Care Final Rule,[18] CMS exempted from the written approval requirement SDPs that are in the form of a minimum fee schedule reflecting State Plan approved rates. These SDPs must still comply with all other SDP requirements and must be appropriately documented in the Medicaid MCO contracts and rate certification. This exemption, in part, was intended to eliminate unnecessary and duplicative review processes in an effort to promote efficient and effective administration of the Medicaid program.

CMS now believes that, to promote administrative efficiency, the same exemption should apply to SDPs that adopt a minimum fee schedule using Medicare rates. CMS is proposing to exempt from written prior approval SDPs that adopt a minimum fee schedule that is equal to 100 percent of the "total published Medicare payment rates."[19] CMS proposes to define "total published Medicare payment rate" as amounts calculated as payment for specific services that have been developed under Medicare Part A and Part B.[20] Like SDPs based on State Plan approved rates, SDPs based on Medicare rates must still comply with all other applicable requirements. This section would be effective as of the effective date of the final rule.

7. Contract Requirements Considered to be SDPs (Grey Area Payments)

In a November 2017 Informational Bulletin, CMS noted instances where States may include general contract requirements for provider payments that would not be subject to approval under § 438.6(c). CMS also noted that these types of contract requirements and related "undirected payments" would not be pass-through payments subject to the requirements under § 438.6(d). This effectively allowed States to direct payments to providers without being subject to the approval process in § 438.6.[21] In January 2021, CMS sought to close what it characterized as an unintentional loophole created by the November 2017 Informational Bulletin in its State Medicaid Director Letter ("SMDL") #21-001. [22]

In the Proposed Rule, CMS reiterates its intention to close the loophole alluded to in SMDL #21-1001, emphasizing the agency's position that "any State direction of a managed care plan's payments to providers, regardless of specificity or even if tied specifically to utilization and delivery of services, is prohibited unless § 438.6(c) or (d) permits the arrangement."[23] CMS indicates that it does not believe any changes are needed to the regulation text to reflect its current position because the "preamble provides an opportunity to again bring this important information to States' attention; CMS will continue this narrower interpretation of § 438.6(c) and (d)." CMS solicits comment on whether additional clarification

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18 85 Fed. Reg. 72754 (Nov. 13, 2020).

19 88 Fed. Reg. at 28114. To be permissible, States must be using a total published Medicare payment rate in effect no more than 3 years prior to the start of the rating period. *Id.*

20 *Id.*

21 SMDL #21-001 provides that if a State includes a general contract requirement for provider payment that allows for or adds an amount to the provider payment rates, even without directing the specific amount, timing or methodology for the payments, and the provider payments are not clearly and directly linked specifically to the utilization and delivery of a specific service or benefit provided to a specific enrollee, then CMS will require the contractual requirement to be modified to comply with § 438.6(c) or (d) beginning with rating periods that started on or after July 1, 2021.

22 SMDL #21-001 (Jan. 8, 2021), *available at* https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf.

23 88 Fed. Reg. at 28113.

about this grey area concerning payments is necessary or if revision to the regulatory text would be helpful.

B. Value-Based Purchasing SDPs

In an effort to remove provisions that are barriers to the implementation of Value-Based Purchasing ("VBP") SDP initiatives, add specificity to the types of arrangements that can be approved as VBP initiatives, and strengthen the link between SDPs that are VBP initiatives and quality of care, CMS is proposing to:

- Remove the existing requirements that currently prohibit States from setting the amount or frequency of VBP payments under the SDP;[24] and

- Remove the existing requirements that currently prohibit States from recouping unspent funds allocated for VBP SDPs.[25]

Further, "to expand the types of VBP initiatives … and ensure a focus on value over volume," CMS is proposing additional revisions in § 438.6(c)(2)(vi) to distinguish between performance-based payments and the use of proposed population-based or condition-based payments to providers. In doing so, CMS clarifies existing policies regarding performance-based payments and proposes a new § 438.6(c)(2)(vi)(C) to establish requirements for use of population-based and condition-based payments in these types of SDP arrangements.[26]

The VBP proposals would be phased-in over two years, with a majority of the proposals effective no later than the first rating period beginning on or after the effective date of the final rule or the rating period beginning 2 years after the completion of each 12-month rating period that includes an approved SDP.

C. Financing

As in its February 2023 Informational Bulletin ("2023 Informational Bulletin"), CMS asserts that, as part of the agency's review of SDP proposals, it is increasingly encountering issues with State financing of the non-Federal share of SDPs, including use of health care-related taxes and intergovernmental transfer ("IGT") arrangements. CMS expressed particular concern with impermissible hold harmless arrangements resulting from private redistribution arrangements. CMS states that these arrangements "undermine the fiscal integrity of the Medicaid program and are inconsistent with existing statutory and regulatory requirements prohibiting hold harmless arrangements."[27] CMS is proposing to include a new SDP regulatory standard requiring that an SDP comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 C.F.R. § 433, subpart B.[28] CMS is also proposing to require that each SDP:

> [E]nsure that each provider receiving payment under a State directed payment attests that it does not participate in any hold harmless arrangement with respect to any health care related tax as

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24 88 Fed. Reg. at 28135.

25 *Id.*

26 88 Fed. Reg. at 28136

27 88 Fed. Reg. at 28130.

28 The proposal is consistent with Section VI, Questions 34-38 of the current preprint template that requires the State to submit information regarding funding for the non-Federal share.

specified in § 433.68(f)(3) of this subchapter in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the provider harmless for all or any portion of the tax amount, and ensure that such attestations are available upon CMS request.[29]

The proposed standard would be effective no later than the first rating period beginning on or after 2 years after the effective date of the final rule. Interestingly, the regulatory language does not reference the 2023 Informational Bulletin and instead hews closely to the existing statutory and regulatory text regarding hold harmless arrangements. The position in the preamble to the Proposed Rule and the 2023 Informational Bulletin go substantially beyond the existing statutory and regulatory language.

D. Administration

1. Contract Requirements

CMS expresses concern that many of the ways States include SDPs in the State Medicaid MCO Contract lack critical details to ensure that plans implement the contractual requirements consistent with the approved SDP. For example, CMS notes that some States have sought to include a broad contractual requirement that their plans must comply with all SDPs approved under § 438.6(c) with no further details in the contract to describe the specific payment arrangements that the State is directing the managed care plan to implement and follow. To reduce perceived risks and improve clarity for MCOs, CMS is proposing to codify at § 438.6(c)(5) minimum requirements for the content of a Medicaid MCO Contract that includes one or more SDP contractual requirement(s). In addition, CMS proposes that all SDPs must be specifically described and documented in Medicaid MCO contracts no later than 120 days after the start of the SDP or approval of the SDP, whichever is later.

This section would be effective no later than the first rating period beginning on or after 2 years after the effective date of the final rule. The requirement that SDPs be documented in the Medicaid MCO Contract (§ 438.6(c)(5)(vi)) would be effective no later than the first rating period beginning on or after 4 years after the effective date of the final rule.

2. Submission Deadlines

CMS has encouraged States to submit SDP requests for written prior approval 90 days in advance of the start of the rating period, whenever possible. CMS is now proposing at § 438.6(c)(2)(viii) and (ix) to set a deadline for submission of SDP preprints that require written prior approval from CMS.[30] CMS proposes to require that all SDPs that require written prior approval from CMS be submitted no later than 90 days in advance of the end of the rating period to which the SDP applies. If an SDP is proposed to begin less than 90 days before the end of the rating period, the deadline would be the end of the rating period. For amendments to approved SDPs, CMS proposes to require all amendments to SDPs be submitted prior to the end of the applicable rating period. These requirements would be effective no later than the first rating period beginning on or after 2 years after the effective date of the final rule.

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[29] Section VI, Question 36, Table 5 of the preprint template requires the State to identify if any tax contains a hold harmless arrangement that guarantees to return all or any portion of the tax payment to the taxpayer. The current preprint does not require each participating provider to attest that it does not participate in any hold harmless arrangement with respect to any health care related tax as specified in proposed § 433.68(f)(3).

[30] 88 Fed. Reg. at 28116.

3. Reporting

CMS proposes to establish a new requirement at § 438.6(c)(4) for States to annually submit data, no later than 180 days after each rating period, to CMS's Transformed Medicaid Statistical Information System, and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO for SDPs that were in effect for the rating period, including amounts paid to individual providers.[31] CMS proposes to develop and provide the form through which the reporting would occur so that there would be one uniform template for all States to use. Proposed minimum data fields include provider identifiers, enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, and allowed, billed, and paid amounts. Paid amounts would include the amount that represents the MCO's negotiated payment amount, the amount of the SDPs, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider. This section would be effective no later than the first rating period beginning on or after 2 years after the effective date of the final rule.

Further, per a new proposed § 438.6(c)(7), for each SDP, the State would be required to calculate the final State directed payment cost percentage and, if the final State directed payment cost percentage is below 1.5 percent, the State must provide a final State directed payment cost percentage report to CMS. The ''final State directed payment cost percentage'' is the percentage of the total capitation payments for a managed care program that is attributable to a SDP that is paid as a separate payment term. As applicable, the State would be required to submit the final State directed payment cost percentage 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 approved SDP.

4. Non-Network Providers

Existing regulations specify that for a State to require an MCO to implement a provider payment initiative under § 438.6(c)(1)(iii), the provider payment initiative must be limited to "network providers."[32] CMS now believes that limiting these SDPs to only network providers "has proven to be too narrow and has created an unintended barrier to States' and CMS's policy goals to ensure access to quality care for beneficiaries."[33] As such, CMS is proposing to remove the term "network" from the descriptions of SDP fee schedule arrangements. CMS is soliciting public comments on this proposal, particularly whether this change would result in negative unintended consequences. This change would be effective as of the effective date of the final rule.

E. Quality and Evaluation

In an effort to strengthen reporting and to better monitor the impact of SDPs on quality and access to care, CMS is proposing changes at § 438.6(c)(2)(iv) and (v) to improve compliance with the requirement that SDPs advance the State's quality strategy. Currently, § 438.6(c)(2)(ii)(D) requires that States develop an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the State's managed care quality strategy. The proposed changes in § 438.6(c)(2)(iv) provide greater specificity regarding what must be included in an evaluation plan,

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31 88 Fed. Reg. at 28238.

32 This limitation is not included in § 438.6(c)(1)(i) or (ii) for SDP arrangements that are VBP and multi-payer or Medicaid-specific delivery system reform or performance improvement initiatives.

33 88 Fed. Reg. at 28115.

including the requirement that the plan identify at least two metrics and that at least one of the two metrics must measure performance at the provider class level for SDPs that are population- or condition-based payments.[34] For any SDP where the final State directed payment cost percentage is greater than 1.5 percent, the State must complete, submit, and publish an evaluation report no later than 2 years after the conclusion of a 3-year evaluation period, with subsequent evaluation reports submitted to CMS every 3 years. This section would be effective no later than the first rating period beginning on or after 3 years after the effective date of the final rule.

F. Appeals (§ 430.3)

To date, when CMS and States have found themselves unable to reach agreement on an SDP proposal and CMS was unable to issue prior written approval, States have agreed to withdraw the submission. However, CMS believes it is appropriate to begin formally disapproving proposals that cannot comply with the regulations. As such, CMS is proposing to add a new § 430.3(d) that would explicitly permit disputes that pertain to written disapprovals of SDPs under § 438.6(c) to be heard by the U.S. Department of Health and Human Services ("HHS") Department Appeals Board ("the Board") in accordance with procedures set forth in 45 C.F.R. part 16.[35] As an alternative, CMS is considering permitting appeals of SDP written disapprovals to be heard by the CMS Offices of Hearings and Inquiries ("OHI") and the CMS Administrator for final agency action, as governed by 42 C.F.R. part 430, subpart D. While CMS believes the Board would be the most appropriate entity to hear appeals of disapprovals of SDPs proposals, CMS seeks comment on both options.

II. Access

In the proposed rule, CMS suggests new standards to improve State monitoring of access to care by, among other things, requiring States to establish and implement new maximum appointment wait times for certain routine care, use secret shopper surveys to evaluate whether the new appointment wait times and specified provider directory requirements are being met; use enrollee experience surveys to capture enrollee feedback and identify potential access/network adequacy issues, and require that States submit a managed care plan analysis of payment made by plans to providers, for specific services, to provide CMS and States with vital information to assess the adequacy of payments to providers in managed care programs. In addition, the Proposed Rule would adopt enhanced state reporting requirements, add new rules designed to promote prompt redress of identified deficiencies in network access, and impose additional requirements for State websites designed to improve access to required information.

A. Enrollee Experience Surveys (§§ 438.66, 457.1230(b))

CMS proposes to require that, with respect to the Medicaid managed care program, States (i) monitor "enrollee experience" through an annual enrollee experience survey, (ii) use data collected through the annual survey to improve performance under their managed care programs, and (iii) include in their annual reports to CMS information on, and an assessment of, the results of the enrollee experience survey. CMS invites comments on whether the agency should mandate the use of a specific enrollee experience survey, define characteristics of acceptable survey instruments, and/or solicit information regarding the operational considerations of enrollee experience surveys that States currently use. States that contract with MCOs and use external quality review organizations ("EQROs") to administer or validate the proposed enrollee experience surveys may be eligible to receive up to a 75 percent

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[34] 88 Fed. Reg. at 28139.

[35] 88 Fed. Reg. at 28149.

enhanced Federal match, pursuant to § 438.370, to reduce the financial burden of conducting or validating the proposed enrollee experience survey(s). The Medicaid requirements would be effective no later than the first managed care contract rating period that begins on or after 3 years after the effective date of the final rule.

With regard to the separate CHIP program, which currently requires that Consumer Assessment of Healthcare Providers and Systems ("CAHPS") surveys be conducted, CMS proposes that States evaluate the most recent annual CAHPS survey results as a part of the State's annual analysis of network adequacy and post comparative summary results of CAHPS surveys by managed care plans annually on State websites. The CHIP requirement would be effective 60 days after the effective date of the rule, since States already collect data through annual CAHPS surveys.

B. Appointment Wait Times (§§ 438.68(e), 457.1218)

CMS proposes a new network adequacy standard that requires States to establish appointment wait time standards for the Medicaid and separate CHIP programs. The standard would mostly become effective no later than the first managed care contract rating period that begins on or after 3 years after the effective date of the final rule. States would be required to develop and enforce wait time standards for routine appointments for four types of services, if covered in the MCO's contract:

(a) Outpatient mental health and substance use disorder ("SUD") – adult and pediatric: within State established timeframes no longer than ten (10) business days from the date of request;

(b) Primary care – adult and pediatric primary care: within State established timeframes no longer than fifteen (15) business days from the date of the request;

(c) Obstetrics and gynecology ("OB/GYN"): within State established timeframes no longer than fifteen (15) business days from the date of the request, and

(d) An additional type of service determined by the State in an evidence-based manner: within State established timeframes. States can determine the evidence to consider, such as encounter data, appeals and grievance data, and provider complaints.

CMS invites comment on the maximum wait times proposed. States are encouraged to set additional appointment wait time standards for other types of appointments (*e.g.*, telehealth).

MCOs will be deemed compliant within the appointment availability waiting standards proposed when secret shopper results reflect a rate of appointment availability that meets the standards articulated above at least 90 percent of the time.

To promote effective implementation, CMS proposes requiring States to require managed care organizations to, in turn, require network providers to meet the appointment wait times specified.

CMS recognizes that situations may arise when managed care organization may need an exception to the State established provider network standards, including provider appointment times. CMS proposes that States be required to consider the payment rates being offered to relevant providers by managed care organizations when determining whether a managed care plan should be granted an exception for that type of provider. States would need to evaluate if low payment rates are a contributing factor to the plan's inability to meet the standards.

C. Secret Shopper Surveys (§§ 438.68(f), 457.1207, 457.1218)

CMS proposes to require States to use secret shopper surveys (where the caller pretends to be an enrollee) as part of their monitoring activities regarding (a) how often network providers are offering routine appointments within the State's appointment wait time standards, and (b) the accuracy of electronic provider directories. CMS proposes that the results of the secret shopper surveys be reported to CMS annually and that the States be required to post the result on their website within 30 days of submitting the results to CMS.

Under the proposal, States would be required to contract with independent entities to conduct annual secret shopper surveys. The proposed changes would apply equally to separate CHIP plans. This proposal would be effective no later than the first managed care contract rating period that begins on or after 4 years after the effective date of the final rule.

1. Provider Directory Validation

CMS proposes requiring surveys of electronic provider directories for the following types of "high usage" providers: (a) primary care providers, (b) OB/GYN providers, and (c) outpatient mental health and SUD providers, if they are included in the managed care plan's provider directories. CMS likewise proposes to require secret shopper surveys for the provider directory data for the provider type selected by the State for its appointment waiting time standards.

In this context, a secret shopper survey would test the accuracy of four critical pieces of provider directory data that enrollees rely upon: (1) the active network status with the MCO, (2) the street address, (3) the telephone number, and (4) whether the provider is accepting new enrollees.

CMS proposes that States must receive information on all provider directory data errors identified in secret shopper surveys no later than three business days from the identification by the entity conducting the survey and that States must then send that data to the applicable managed care plan within three business days of receipt. Under CMS's proposal, MCOs would be required to use the information from secret shopper surveys to obtain corrected information and promptly update provider directories. The same requirement would apply to separate CHIP programs.

CMS would modify existing regulation to clarify that provider directories must be "searchable" in electronic form and must specify whether each provider offers covered services via telehealth.

2. Compliance with Appointment Wait Time Standards

CMS proposes that States be required to determine each MCO's rate of network compliance with the appointment wait time standards. Appointments offered via telehealth would only be counted towards compliance with appointment wait time standards if the provider also offers in-person appointments, and telehealth visits offered during the secret shopper survey would need to be separately identified in the survey results. Secret shopper surveys to determine plan compliance with appointment wait time standards would have to be completed for a statistically valid sample of providers and (a) use a random sample, and (b) include all areas of the State covered by the MCO's contract.

D. Provider Payment Analysis (§§ 438.207(b), 457.1203(b))

To ensure comparability in managed care plans' payment analyses, CMS proposes to require a payment analysis for Medicaid and separate CHIP programs that managed care plans would submit to States and that States would review and include in their assurance of adequate capacity and services analysis

submitted to CMS. CMS intends for this analysis of payments to provide States and CMS with vital information to assess the adequacy of payments to providers in managed care programs, particularly when network deficiencies or quality of care issues are identified, or grievances are filed by enrollees regarding access or quality.

CMS proposes requiring that MCOs submit annual documentation of a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract with the State. The analysis would use paid claims data from the immediate prior rating period to determine the total amount paid for evaluation and management ("E&M") current procedural terminology ("CPT") codes for primary care, OB/GYN, and mental health, and SUD services. Claims for FQHCs and RHCs would be excluded from the analysis, as would payments for claims for services for which the managed care plan is not the primary payer.

The payment analysis would reflect a ratio comparison of how much the managed care plan paid to published Medicare payment rates, including claim-specific factors such as provider type, geographic location where the services were rendered, and site of service. The managed care plans' analysis would include separate total amounts paid and separate comparison percentages to Medicare for primary care, OB/GYN, mental health, and SUD services. CMS proposes that the percentages be reported separately if they differ between adult and pediatric services.

CMS also proposes 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 fee-for-service ("FFS") program would have paid for the same claims. A separate total and percentage would need to be reported for homemaker services, home health aid services, and personal care services. Moreover, if the percentage differs between adult and pediatric services, the percentages would need to be reported separately.

This requirement would be effective no later than the first managed care contract rating period that begins on or after 2 years after the effective date of the final rule.

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

Currently, States are required to review the documentation submitted by their managed care plans, as required by existing regulations, and then submit to CMS an assurance of their managed care plan's compliance with § 438.68 (Network Adequacy Standards) and § 438.206 (Availability of Services). To make States' assurances and analysis more comprehensive, CMS proposes to explicitly require States to include the results from the secret shopper surveys and the provider payment analysis for each MCO in connection with their assurance and analyses reporting. As proposed, States must submit the assurance of compliance required in a format prescribed by CMS and post the report on the State's website within 30 calendar days of submission to CMS.

The information to be provided by the State includes a State-level payment percentage for each service type specified, produced using the number of member months for the applicable rating period to weight each MCO's reported percentages. Different timeframes for submission apply to Medicaid and separate CHIP programs. CMS proposes that States must make available to CMS all documentation collected by the State from the MCOs, as well as documentation from all secret shopper surveys.

This requirement would be effective no later than the first managed care contract rating period that begins on or after 2 years after the effective date of the final rule.

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

Under a new § 438.207(f), CMS proposes that when the State, MCO, or CMS identifies an issue with a managed care plan's performance with regard to any State Medicaid program standard for access to care, including any access issues with the standards specified in § 438.68 (Network Adequacy Standards) and/or § 438.206 (Availability of Services), the State would be required to: (a) submit to CMS for approval a remedy plan no later than 90 calendar days following the date that the State becomes aware of an MCO's access issue, (b) develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, times for implementation and completion, and responsible parties, (c) ensure that improvements in access are measurable and sustainable; and (d) submit quarterly progress updates to CMS on implementation of the remedy plan. If the remedy plan does not result in 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.

This requirement would be effective no later than the first managed care contract rating period that begins on or after 4 years after the effective date of the final rule.

G. Website Enhancements (§§ 438.10(c), 438.602(g), 457.1207 and 457.1285)

To increase the effectiveness of States' websites for Medicaid and CHIP and add consistency to website users' experience, CMS proposes that States:

- must, when providing required content on their website by linking to individual managed care entity websites, provide links on their website that map to the specific page that includes the requested information;
- make all information, or links to information, that is required under Part 438 available on the State's website from one page;
- check websites at least quarterly to verify that all websites are functioning as expected and that the information is the most current available; and
- explain on their websites that assistance in accessing the information is available at no cost to viewers, including information on the availability of oral interpretation in all languages and written translation in each prevalent non-English language, alternative formats, auxiliary aids and services and a toll-free TTY/TDY telephone number.

This requirement would be effective no later than the first managed care contract rating period that begins on or after 2 years after the effective date of the final rule.

H. Other Provisions (§ 438.214(d)(2)

CMS proposes, consistent with an existing statutory mandate, a new regulatory provision that requires States, through their managed care contracts, to mandate that providers of services or persons terminated from participation under Titles XVII, XIX and XXI of the Social Security Act be terminated from participating as a provider in any Medicaid managed care plan network.

III. Contract Requirements for Overpayments (§§ 438.608(a)(2), 438.608(d)(3) and 457.1285)

The current rules governing the Medicaid managed care and CHIP programs require that State contracts with managed care plans include provisions specifying that managed care plans must report the recoveries of overpayments annually. This reporting to the State is critical to the actuarial soundness of capitation rates because managed care plans must exclude overpayments from their incurred claims. Through two proposed modifications to the rule, CMS proposes changes designed to ensure that Medicaid and CHIP managed care plans report comprehensive overpayment data to States in a timely manner, which are intended to better position States to execute program integrity efforts and develop actuarially sound rates.

Because CMS has determined that States interpret the obligation for "prompt" reporting inconsistently, CMS proposes that the term "prompt" mean within 10 business days of identifying or recovering an overpayment. CMS believes that this period "would provide a managed care plan sufficient time to investigate overpayments and determine whether they are due to potential fraud or other causes, such as billing errors, and also quickly provide the State with awareness to mitigate other potential overpayments across its networks and managed care programs."[36] CMS is seeking public comment on this proposed timeframe and whether reporting should be from the date of identification or recovery, or instead on a routine basis, such as monthly.

CMS proposes to revise both Medicaid and separate CHIP regulations to clarify its original intent that any overpayment (whether identified or recovered) must be reported by Medicaid or CHIP managed care plans to the State. This requirement would be effective 60 days after the effective date of the final rule.

IV. In Lieu of Services

In the 2016 Final Rule, CMS specified in § 438.3(e)(2) that MCOs have flexibility under risk contracts to provide a substitute service or setting to enrollees for a service or setting covered under the State Plan, when medically appropriate and cost effective, at the MCO and the enrollee's option. As outlined in guidance issued on January 7, 2021 and on January 4, 2023 respectively,[37] CMS provides that these In Lieu of Service or Setting ("ILOSs") programs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address social determinants of health ("SDOHs") and health related social needs ("HRSNs"), and as immediate or longer-term substitutes for State Plan-covered services and settings.

To ensure clarity on the use of the term "in lieu of service or setting" and the associated acronym "ILOS," CMS now proposes to add a definition in § 438.2 to define an "in lieu of service or setting (ILOS)" as "a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2). 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."

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36 88 Fed. Reg. at 28159.

37 State Health Official Letter, *Opportunities in Medicaid and CHIP to Address Social Determinants of Health*, SHO# 21-001 (Jan. 7, 2021), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf; *Additional Guidance on Use of In Lieu of Services and Settings in Medicaid Managed Care*, SMDL #23-001 (Jan. 4, 2023), *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.

Notably, CMS is proposing to create a new § 438.16 requiring that, as a general rule, an ILOS must be approvable as a service or setting through a Section 1915(c) waiver or a State Plan amendment, including Section 1905(a), 1915(i), or 1915(k) of the Social Security Act. The proposed regulation also includes, but is not limited to, proposed documentation, evaluation, and oversight requirements. The proposed requirements would apply to the MCO rating period beginning on or after 60 days following the effective date of the final rule..

V. Quality Assessment and Performance Improvement Program

A. Quality Assessment and Performance Improvement Program Updates (§438.330)

CMS proposes clarifying Medicaid regulations related to performance improvement projects ("PIPs") by removing an outdated reference to a Medicare Advantage ("MA") quality improvement project ("QIP").[38] In addition, the agency would allow States to permit Medicaid managed care plans exclusively serving dually-eligible individuals ("duals") to substitute an MA Chronic Care Improvement Program ("CCIP") conducted under § 422.152(c) for one or more of the plan's Medicaid PIP requirements under the Quality Assessment and Performance Improvement Program. Because the QIP requirement was removed in 2019, CMS expects some States to already have CCIPs in place in lieu of QIPs, and proposes to require States to comply with the update no later than the rating period for contracts beginning after the effective date of the final rule.

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

States are required to draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by (1) Medicaid MCOs and CHIP managed care plans and by (2) primary care case management ("PCCM") entities whose contracts with the State provide financial incentives for improved quality outcomes (*i.e.*, risk-based contracts). Given that the quality strategy is a foundational tool for States to set goals and objectives related to quality of care and access for care management programs, CMS proposes to add the following additional comment, transparency, and review requirements:

- **Public Comment.** CMS proposes a new requirement for States to make their quality strategy available for public comment at the 3-year renewal stage, regardless of whether the State intends to make significant changes to its strategy or its State Plan;

- **Evaluation Transparency.** CMS proposes to clarify that States should post on the agency's website the results of its 3-year review of the effectiveness of its quality strategy for Medicaid and CHIP, including the State's full evaluation; and

- **Submission of Quality Strategy to CMS.** CMS proposes to establish a requirement for States to submit to CMS, prior to finalizing a revised or renewed quality strategy as final, a copy of the revised strategy, every three years following the review and evaluation of the strategy (in addition to when significant changes are made, which requires separate review). This would allow CMS to offer feedback periodically to help States strengthen their managed care quality strategies before

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[38] CMS removed a QIP reference from MA program requirements in the final rule titled "Medicare Programs; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program," 83 Fed. Reg. 16,440, 16,669 (Apr. 16, 2018), but neglected to remove a reference to the QIP in Medicaid regulations at 42 C.F.R. § 438.330(d)(4).

they are finalized, whether or not significant changes are made to the State's strategy or to their Medicaid or CHIP programs.

The agency also makes a technical correction to § 438.340(c)(3)(ii) that would correct an improper reference relating to the definition of "significant changes."

C. External Quality Review (§ 438.364)

PCCM entities[39] engaged in a shared savings, incentive payments or other financial reward for the entity for improved quality outcomes are currently subject to a number of requirements under 42 C.F.R. part 438, subpart E, including an annual External Quality Review ("EQR") that assesses quality, timeliness, and access to care for managed care beneficiaries. CMS proposes to remove these PCCM entities from the scope of the mandatory EQR to, in part, alleviate the regulatory burden on States and PCCM entities, effective upon the effective date of the final rule.

CMS proposes additional changes to the EQR regulations with the goal of making the review a better tool to drive quality improvement. Proposed EQR changes include the following:

- **12-Month Review Period Definition**. To improve uniformity in the review period, CMS adds a new paragraph that defines the 12-month review period for all but one EQR-related activity. 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. CMS also proposes that certain EQR activities must be performed in the 12 months preceding the finalization of the annual report.

- **New Optional EQR Activity**. The agency also creates a new optional EQR activity to help States consolidate and meet the current and proposed evaluation requirements for quality strategies, SDPs, and ILOS within the scope of the EQR activities.

- **Avoiding Duplication of EQR Activities with Medicare or Accreditation Review**. Another proposal would make it easier for States to exempt managed care plans from duplicative EQR-related activities by removing the requirement at § 438.360(a)(1) that private, national accreditation organizations ("PAOs") apply for MA deeming authority from CMS in order for States to rely on PAO accreditation reviews in lieu of EQR activities.

- **Data Requirements in EQR Technical Reports**. CMS proposes to expand the requirements for EQR technical reports at § 438.364(a)(2)(iii) to (1) include outcomes data and results from quantitative assessments for the applicable EQR activities (in addition to the already required validated performance measurement data), and (2) require the same type of data from the mandatory network adequacy validation activity to also be included in the technical report. CMS requests comment on potentially adding guidance in the EQR protocols for States to stratify performance measures collected in the EQR reports under the performance measure validation activity.

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[39] PCCM Entities are defined in §§ 438.2 and 457.10 as organizations that provide one or more specified functions in addition to primary care case management services (e.g., intensive case management, development of care plans, etc.).

- **Updated Date for Finalizing and Posting EQR Technical Reports**. States are currently required to complete and make available on the State's website EQR technical reports no later than April 30 of each year. CMS seeks comment on changing the posting date to December 31 to align better with HEDIS timeframes, and requests States that believe more time is needed beyond December 31 to identify how much time is required and why.

- **Notifying CMS when Annual EQR Technical Reports are Posted**. CMS proposes requiring States to notify the agency when their EQR technical report has been completed and posted on the State's website within 14 days of the actual posting (no such notification requirement currently exists).

- **Maintaining Historical EQR Technical Reports**. CMS is proposing that States maintain at least 5 years of past EQR technical reports on their website. CMS seeks comment on whether this would add significant burden on States.

D. Medicaid Managed Care Quality Rating System (§§ 438.334 and 457.1240; Part 438, Subpart G[40])

CMS proposes building on requirements currently found at § 438.334(b)(1) to create a new C.F.R. Part 438, subpart G, which would include an enhanced Medicaid and CHIP Managed Care Quality Rating System ("MAC QRS") framework that includes mandatory quality measures, a methodology for calculating quality ratings (either the CMS-developed methodology or an alternate methodology approved by CMS), and a mandatory website display format (a new requirement). CMS explains in the preamble of the Proposed Rule that the goal of the MAC QRS is to "provide a one-stop-shop where beneficiaries can access information about Medicaid and CHIP eligibility and managed care; compare plans based on quality and other factors key to beneficiary decision making. . .; and ultimately select a plan that meets their needs."[41]

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

CMS proposes and seeks comment on an initial mandatory quality measure set (made up of 18 measures) that would apply to Medicaid and CHIP and is described in the Proposed Rule in Table 1.[42] These proposed mandatory measures reflect a wide range of preventative and chronic care measures representative of Medicaid and CHIP beneficiaries. Under the CMS proposal, States could include other additional measures outside the mandatory measure set.

The agency also proposes a sub-regulatory process to guide how CMS can modify the mandatory measure set over time (either by adding measures, making substantive updates to existing measures, or by removing measures), which is the same process CMS used to identify the initial mandatory measure set. The proposed process would generally involve a two-step exercise to obtain input and recommendations from States and other interested parties prior to finalizing certain types of changes to

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40 CMS is proposing to create a new subpart G in 42 C.F.R. Part 438 to implement the MAC QRS framework and establish standards which States must meet for CMS to approve adoption of an alternative QRS and related requirements. Existing regulations at § 438.334 would be redesignated to the newly created Subpart G with proposed revisions.

41 88 Fed. Reg. at 28181.

42 88 Fed. Reg. at 28287.

the mandatory measure set in the future. CMS seeks comment on the proposed sub-regulatory process to add and remove measures.

CMS proposes to set the implementation deadline for each State's MAC QRS per proposed § 438.505(b) to be no later than the fourth calendar year following publication of the final rule, so if the proposed rule is finalized in 2024, States would be required to implement the mandatory measure set by December 31, 2028, with the first measurement year as 2026.[43]

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

To communicate modifications to the mandatory measure set and the timelines States would be given to implement such modifications, CMS proposes using a technical resource manual to be updated annually. States would be given at least two calendar years from the start of the measurement year immediately following issuance of the technical resource manual in which the mandatory measure was added or substantively changed to display the measurement results and ratings using the updated measures. For example, if the technical resource manual finalized updates in August 2026, and the next measurement year after August started in January 2027, States would have at a minimum until January 2029, before they would be required to display the ratings for the mandatory measure updates in their MAC QRS (although States may choose to display such measures sooner). As two years from the start of the measurement year would always be in January, CMS seeks comment on whether there is a need for States to have the flexibility to update their quality ratings by the end of the second calendar year, which, based on the example above, would give States the flexibility to update the ratings between January and December 2029. CMS is not proposing a specific deadline for States to stop display of a measure that has been removed from the mandatory measure set because States have the option to continue to display such measures.

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

CMS describes in detail new proposals related to the methodology used to calculate the quality ratings for States' managed care plans, which include:

- **Data collection and validation**. At § 438.515(a), CMS proposes more specific requirements for States to collect and validate data used to calculate and issue quality ratings for each mandatory measure for Medicaid and separate CHIP on an annual basis. If adopted, States will be required to collect data from MCOs that meet a minimum enrollment threshold of 500 or more enrollees on July 1 of the measurement year (the same threshold for the Qualified Health Plan ("QHP") quality rating system). States would also be required to collect available data from the State's Medicaid FFS program, from Medicare (including MA plans), or both if all necessary data cannot be provided by the MCOs (and as long as the collection does not impose an undue burden on the State).

  For example, if a State delivers behavioral health services through a managed care program and all other services through its FFS program, the State would, as proposed, need to collect both managed care and FFS data to calculate quality ratings for the managed care plans participating in its behavioral health program for many of the proposed behavioral health mandatory measures. CMS believes that its proposal for States to collect and use data from multiple sources will

[43] 88 Fed. Reg. at 28192.

mitigate the risk of underreporting mandatory measures. The "without undue burden" standard is intended to facilitate a gradual implementation of contract or system changes necessary to collect the data required to calculate and issue quality ratings.

- **Calculation of Performance Rates for MCOs**. If adopted, States would calculate, for each mandatory measure, a measure performance rate for each MCO whose contract includes a service or action being assessed by the measure. CMS provides examples of how States will be able to identify plans whose contracts include mandatory services, acknowledging that States choose to deliver Medicaid services through different managed care programs.

  For example, the proposed Follow-Up After Hospitalization ("FUH") measure requires data on two services: hospitalization and mental health services. In a State that offers behavioral and physical health services through separate managed care programs, the State would need hospitalization data from plans participating in the physical health program and mental health services data from managed care plans participating in the behavioral health program to calculate FUH performance rates. CMS's proposal would require States to determine which service or action is being assessed by the measure.

- **Annual Quality Rating**. States are currently required to collect data from each managed care plan with which they contract and issue an annual quality rating for each such plan based on the data collected (that is, a single rating). Based on feedback from beneficiaries, CMS proposes to revise that policy and instead require States to issue to each MCO a quality rating for each mandatory measure for which the MCO is accountable (that is, multiple ratings). These quality ratings would be issued as an individual percentage rate per measure. CMS seeks comment on this proposal and seeks additional input on whether the agency should require additional percentage ratings to reflect a national baseline for each mandatory measure.

- **Plan Level Ratings by Program**. CMS proposes to require States to calculate quality ratings at the managed care plan level by program. A managed care plan that participates in multiple managed care programs would receive a distinct rating for each of the programs in which it participates, using validated data from only those beneficiaries in the distinct program.

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

Current regulations require States to prominently display the quality rating issued for each MCO on a website that must comply with certain standards. CMS proposes to establish new requirements for the website display that include: (1) clear information that is understandable and usable for navigating a MAC QRS website; (2) interactive features that allows users to tailor specific information (*e.g.*, a formulary, provider directory, etc.) based on their entered data; (3) standardized information that allows users to compare MCO programs and plans; (4) information that promotes beneficiary understanding of and trust in the displayed quality ratings, such as data collection timeframes and validation confirmation; and (5) access to Medicaid and CHIP enrollment and eligibility information (either directly on the website or through external resources). The display requirements would be implemented in two phases, with the first phase allowing for access to information on plan providers, drug coverage, quality ratings, etc., and the second phase incorporating the more technically difficult searching and sorting functions to provide a more interactive user experience. CMS provides States two website display prototypes – a simple website displaying information needed by the proposed implementation date and a more interactive website that includes display features and more technology-intensive features that will be phased-in.

CMS also proposes navigational requirements for the MAC QRS website display and required orienting information, and a requirement for State websites to allow users to view available managed care plans for

which the user may be eligible based on the users' age, geographic location, and dual eligibility status, as well as other demographic data.

If adopted, States would also be required to display, for each MCO, standardized information identified by CMS that allows users to compare available plans and programs, premium and cost sharing information, a summary of covered benefits, certain access and performance metrics, and whether the MCO offers an integrated Medicare-Medicaid plan.

Additional, relatively prescriptive requirements (*e.g.*, a plain language description requirement) are also included in the Proposed Rule.

I. MAC QRS Reporting Requirements

CMS proposes annual State reporting requirements for information related to their MAC QRS to support program oversight and compliance, including: a list of all measures included in the State's MAC QRS, an attestation that displayed quality ratings for all mandatory measures were calculated and issued according to the proposals described above, and other requested information. CMS notes an intention to establish an online portal that States could access to submit the required reporting information.

VI. Changes to Medical Loss Ratio Standards (§§ 438.8, 438.3, and 457.1203)

CMS is making changes to the Medicaid and CHIP managed care medical loss ratio ("MLR") requirements, many of which are intended to better align with the MLR requirements that apply to marketplace plans under the Affordable Care Act, which were modified in 2022. CMS proposes a number of revisions, most of which are proposed to take effect immediately 60 days after the effective date of the final rule. Proposed MLR changes include the following:

- A requirement for increased specificity regarding clinical or quality improvement standards for provider incentive arrangements (to avoid plan incentives to increase the MLR numerator under the guise of paying incentives),
- A prohibition on the inclusion of indirect or overhead administrative expenses for quality improvement activities,
- Additional requirements regarding expense allocation among different payers,
- Requirements regarding separate reporting for SDPs, and
- Reporting of overpayments.

Some additional proposed MLR changes reduce burdens or add clarity, such as those relating to: (1) removal of a requirement to annually update the credibility adjustment factor, (2) clarification that resubmission of MLR reports is only required when there is a change to capitation rates, and (3) clarification that MLR summary reports from States to CMS must be at the plan level.

Dentons would be happy to assist you with preparation of comments in response to the Proposed Rule.

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