CMS Proposed Rule on Medicaid and CHIP Managed Care Access, Finance, and Quality

On May 3rd 2023, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule titled *Managed Care Access, Finance, and Quality*. The proposed rule aims to improve access and quality of care provided to Medicaid and CHIP managed care enrollees (see fact sheet here). The rule institutes new access requirements, reforms stated directed payments processes and reporting, institutes new medical loss ratio reporting requirements, codifies in-lieu-of-services guidance, makes changes to the external quality review process, and proposes a new Medicaid managed care quality rating system. Comments are due by July 3rd, 2023.

NOTE: Page numbers refer to the pdf page numbers in the unofficial published inspection document made available on the federal register prior to the official publication of the rule.

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I. Access

A. Enrollee Experience Surveys (section 1.a, pgs. 14 – 20)

Proposed Changes

CMS proposes to revise § 438.66(c)(5) to require that States conduct an annual enrollee experience survey.

CMS proposes to replace "or" with "and" to be explicit that the use of provider survey results alone will not be sufficient to comply with § 438.66(c)(5). CMS proposes that states would have to comply with § 438.66(b) and (c) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule.

Additionally, CMS proposes conforming these edits in § 438.66(e)2(vii) to include the results of an enrollee experience survey to the list of items states must evaluate in their Managed Care Program Annual Report (MCPAR) and add "provider" before "surveys" to distinguish them from enrollee experience surveys.

CMS proposes to revise § 438.66(e)(3)(i) to require that states post the report required in §438.66(e)(1) on their website within 30 calendar days of submitting it to CMS.

CMS proposes to add enrollee experience surveys as a document subject to the requirements in § 438.10(d)(2) to ensure enrollees that receive a state's enrollee experience survey are fully notified that oral interpretation would be readily available, and how to request auxiliary aids and services if needed.

CMS proposes to amend § 457.1230(b) to require states to evaluate annual CAHPS survey results as part of the state's annual analysis of network adequacy as described in § 438.207(d). CMS proposes for the provisions in § 457.1230(b) to be applicable 60 days after the effective date of the final rule.

CMS proposes § 457.1207 to require states to post comparative summary results of CAHPS surveys by managed care plan annually on State websites as described in § 438.10(c)3.

Background/Rationale

CMS believes that using surveys to gather direct input from managed care enrollees is a valuable source of information on enrollees' actual and perceived access to services. CMS wants to ensure that states

have the data from an enrollee experience survey to include in their monitoring activities and improve the performance of managed care programs. For these reasons, CMS wants to require states to conduct an annual enrollee experience survey. While CMS encourages states and MCPs to utilize provider surveys, they believe other proposals such as enrollee surveys and secret shopper surveys may yield information that would inform CMS's decision on the use of provider surveys in the future.

Concerning the proposed changes to § 438.66(e)(3)(i), CMS believes that adding further specificity about the timing of when the report should be posted will be helpful to interested parties and bring consistency to the existing requirement.

In regard to the proposed changes in § 457.1207, CMS believes that access to enrollee experience data is critical in affording separate CHIP beneficiaries the opportunity to make informed decisions when selecting their managed care plan(s).

Comments

CMS requests comments on the cost and feasibility of implementing enrollee experience surveys for each managed care program as well as the extent to which states already use enrollee experience surveys for their managed care programs.

CMS also invites comments on whether they should mandate the use of specific enrollee experience surveys, define characteristics of acceptable survey instruments, and the operational considerations of enrollee experience surveys states currently use.

Additionally, CMS requests comment on the appropriate applicability date for the provision in § 438.66(e)(3)(i).

CMS also seeks public comment on other approaches to including CHIP CAHPS survey data for the dual purposes of improving access to managed care services and enabling beneficiaries to have useful information when selecting a managed care plan.

B. Appointment Wait Time Standards (section 1.b, pgs. 20-31)

Proposed Changes

CMS proposes to create a new § 438.68(e) titled "Appointment wait time standards."

CMS proposes, in § 438.68(e)(1)(i) through (iv), that states develop and enforce wait time standards for routine appointments for four types of services: outpatient mental health and substance use disorder (SUD)- adult and pediatric, primary care- adult and pediatric, obstetrics and gynecology (OB/GYN), and an additional type of service determined by the State (in addition to the three listed) in an evidence-based manner for Medicaid to address an access challenge in their local market. CMS proposes the following maximum appointment wait times:

- No longer than 10 business days for routine outpatient mental health and substance use disorder appointments

- No longer than 15 business days for routine primary care in § 438.68(e)(1)(ii) and OB/GYN appointments

CMS includes "If covered in the MCO's, PIHP's, or PAHP's contract" before the first three service types to be clear that standards only need to be developed and enforced if the service is covered by the MCP's contract. The fourth service must be one that is covered by the plan's contract. CMS proposes to adopt proposed wait time standards for separate CHIP through an existing cross-reference at § 457.1218.

CMS proposes to add "…, other than for appointment wait times…" in § 438.68(b)(1) to be clear that the appointment wait time standards proposed in § 438.68(e) cannot be the quantitative network adequacy standard required in § 438.68(b)(1).

CMS also proposes to revise § 438.206(c)(1)(i) to include appointment wait time standards as a required provision in MCO, PIHP, and PAHP contracts for Medicaid, which is included in separate CHIP regulations through an existing cross-reference at § 457.1230(a).

CMS proposes to revise the existing applicability date in § 438.206(d) for Medicaid, to reflect that states would have to comply with § 438.206(c)(1)(i) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule.

CMS proposes that in § 438.68(e)(2), managed care plans would be deemed compliant with the standards established in paragraph (e)(1) when secret shopper results, as described later in this rule, reflect a rate of appointment availability that meets state established standards of at least 90 percent of the time.

CMS proposes, at § 438.68(e)(3), that CMS may select additional types of appointments to be added to § 438.68(e)(1) after consulting with states and other interested parties and providing public notice and opportunity to comment.

CMS also proposes to add a new standard at § 438.68(d)(1)(iii), for reviews of exception requests, which would require states to consider the payment rates offered by the MCO, PIHP, or PAHP to providers included in the provider group subject to the exception.

CMS proposes a new § 438.214(d)(2) to reflect that states must ensure through their MCO, PIHP, and PAHP contracts that providers of services or persons terminated (as described in section 1902(kk)(8) of the Act) from participation under the title XVIII, or title XXI must be terminated from participating as a provider in any Medicaid Managed care plan network.

CMS also proposes states should have to comply with § 438.68(b)(1),(e), and (g) no later than the first MCO, PHIP, or PAHP rating period that begins on or after 3 years after the effective date of the final rule.

CMS proposes that states should have to comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule.

CMS proposes that states should have to comply with § 438.68(d)(1)(iii) no later than the first MCO, PIHP, or PAHP, rating period that begins on or after 2 years after the effective date of the final rule.

Background/Rationale

Based on RFI comments received, research, engagement with interested parties, and prior experience in monitoring state MCPs, CMS is persuaded about the need for increased oversight of network adequacy and overall access to care and proposes a new quantitative network adequacy standard.

CMS proposes primary care, OB/GYN, and mental health SUD as service types because they are indicators of core population health. CMS believes that requiring states to set appointment wait time standards would have the most impact on access to care for Medicaid and CHIP-managed care enrollees.

CMS believes proposing that states select one of the provider types subject to an appointment wait time standard would encourage states and MCPs to analyze network gaps effectively and then innovate new ways to address the challenges that impede timely access.

In regard to the proposed maximum appointment wait timeframes, CMS states the proposed timeframes were informed by standards for the individual insurance marketplace established under the ACA that will begin in 2024 of 10 business days for behavioral health and 15 business days for primary care services. CMS notes they believe 30- calendar days and 45- calendar days as the maximum wait time may be too long as a standard.

Regarding including appointment wait time standards as a required provision in managed care contracts, CMS believes the revision is necessary since their proposal to develop and enforce appointment wait time standards is a state responsibility. Proposing this revision would specify the corresponding managed care plan responsibility.

Regarding the 90% compliance rate, CMS believes by proposing a minimum compliance rate, CMS would provide states with leverage to hold their managed care plans accountable for ensuring that their network providers offer timely appointments.

Regarding the flexibility for CMS to select additional types of appointments in the future, CMS believes it is necessary to ensure that appointment wait time standards would be an effective measure of network adequacy and that CMS needs some flexibility to add provider types to address new access or capacity issues at the national level. CMS believes it is prudent to explicitly state that they may utilize this flexibility as they deem appropriate in the future.

Comments

CMS requests comments on whether behavioral health PIHPs and PAHPs include provider types other than mental health and SUD in their networks.

CMS also invites comments on aligning with the marketplace standards at 10- and 15-business days, or whether wait time standards should differ, and if so, what standards would be most appropriate.

C. Secret Shopper Surveys (section 1.c, pgs. 31-41)

Proposed Changes

CMS proposes a new § 438.68(f) and proposes to require that states use independent entities to conduct annual secret shopper surveys of managed care plan compliance with appointment wait time standards proposed at § 438.68(e) and the accuracy of certain data in all managed care plans' electronic provider directories required at § 438.10(h)(1). Results from the surveys should be unbiased, credible, and reflect what it is truly like to be an enrollee trying to schedule an appointment.

CMS proposes at § 438.68(f)(3)(i), an entity to be independent of the State if it is not part of the State Medicaid agency and, at § 438.68(f)(3)(ii), to consider an entity independent of a managed care plan subject to the secret shopper survey if the entity is not an MCO, PIHP, or PAHP; is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys; and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the survey.

CMS also proposes to require states to use secret shopper surveys to determine the accuracy of certain provider directory information in MCOs', PIHPs', and PAHPs' most current electronic provider directories at § 438.68(f)(1)(i). Specifically, CMS would require surveys of electronic provider directory data for primary care providers, OB/GYN providers, and outpatient mental health and substance use providers, if they are included in the managed care plan's provider directories. CMS also proposes to require secret shopper surveys for provider directory data for the provider type selected by the state for its appointment wait time standards in § 438.68(e)(1)(iv).

At § 438.68(f)(1)(ii)(A) through (D), CMS proposes to require that states use independent entities to conduct annual secret shopper surveys to verify the accuracy of four pieces of data in each MCO, PIHP, or PAHP electronic provider directory required at § 438.10(h)(1). This includes: the active network status with the MCO, PIHP, or PAHP electronic provider directory; the street address; the telephone number; and whether the provider is accepting new enrollees.

CMS proposes at § 438.68(f)(1)(iii) and (iv) respectively, states must receive information on all provider directory data errors to be identified in secret shopper surveys no later than 3 business days from identification by the entity conducting the secret shopper survey and that states must then send that data to the applicable managed care plan within 3 business days of the receipt.

CMS also proposes in § 438.68(f)(1)(iii) that information sent to the state must be "sufficient to facilitate correction" to ensure that enough detail is provided to enable the managed care plans to quickly investigate the accuracy of the data and make necessary corrections.

CMS proposes § 438.10(h)(3)(iii) to require MCOs, PIHPs, and PAHPs to use the information from secret shopper surveys to obtain corrected information and update provider directories no later than the timeframes specified in § 438.10(h)(3)(i) and (ii), and included in separate CHIP regulations through an existing cross-reference at § 457.1207.

To implement section 5123 of the Consolidated Appropriations act of 2023, CMS proposes to revise § 438.10(h)(1) by adding "searchable" before "electronic form" to require that managed care plan electronic provider directories be searchable. CMS also proposes to add paragraph (ix) to § 438.10(h)(1) to require that managed care plan provider directories include information on whether each provider offers covered services via telehealth.

CMS proposes that secret shopper surveys include verification of certain providers' active network status, street address, telephone number, and whether the provider is accepting new enrollees.

CMS proposes, at § 438.68(f)(2), to require states to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards proposed in § 438.68(e)(1). CMS also proposes that after consulting with states and other interested parties and providing the public notice and opportunity to comment, CMS may select additional provider types to be added to secret shopper surveys of appointment wait time standards. Appointments offered via telehealth will only be counted towards compliance with appointment wait time standards if the provider also offers in-person appointments and that telehealth visits offered during the secret shopper survey be separately identified in the survey results.

CMS proposes at § 438.68(f)(3) that any entity that conducts secret shopper surveys must be independent of the state Medicaid agency and its managed care plans subject to a secret shopper survey. In § 438.68(f)(3)(i) and (ii), CMS proposes the criteria for an entity to be considered independent. In § 438.68(f)(3)(i), CMS proposes that an entity cannot be a part of any state government agency to be independent of the state Medicaid agency, and in § 438.68(f)(2)(i) CMS proposes that to be independent of a managed care plans subject to the survey, an entity would not be, be controlled by, or control an MCO, PIHP, or PAHP.

CMS proposes to define "independent" by using criteria that are similar, but not as restrictive, as the criteria used for the independence of enrollment brokers and specified at § 438.68(b)(1).

CMS proposes in § 438.68(f)(4), that secret shopper surveys would have to be completed for a statistically valid sample of providers and: (1) use a random sample; and (2) include all areas of the state covered by the MCO's, PIHP's, or PAHP's contract. Secret shopper surveys to determine plan compliance with appointment wait time standards would have to be completed for a statistically valid sample of providers to be clear that a secret shopper survey must be administered to the number of providers identified as statistically valid for each plan.

CMS proposes at § 438.68(f)(5), that the results of secret shopper surveys would be reported to CMS and posted on the state's website. Specifically, the results of the secret shopper surveys of provider directory data validation and appointment wait time standards would be reported to CMS annually using the content, form, and submission times proposed in § 438.207(d).

CMS proposes at § 438.68(f)(5)(ii) that states post the results on the state's website required at § 438.10(c)(3) within 30 calendar days of the State submitting them to CMS.

CMS proposed that states would have to comply with § 438.68(f) no later than the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule.

Background/Rationale

CMS believes that the proposal to require states to use secret shopper surveys as part of their monitoring activities will add a greater level of validity and accuracy to states' efforts to measure network adequacy and access. CMS believes the best results are obtained when the survey is done as a secret shopper and the caller pretends to be an enrollee trying to schedule an appointment.

CMS believes that the entity that conducts these surveys must be independent of the state Medicaid or CHIP agency and its managed care plans subject to the survey to ensure unbiased results. CMS believes that given the valuable data the surveys could provide, the use of an independent entity is critical to ensure unbiased results.

In regard to the requirements in § 438.68(f)(1)(i)(A), CMS proposed the provider types because they are the provider types with the highest utilization in many Medicaid managed care programs.

Concerning the proposed changes to § 438.68(f)(1)(ii)(A) through (D), CMS believes these are the most critical pieces of information that enrollees rely on when seeking network provider information. Inaccuracies in this information can have a tremendously detrimental effect on enrollees' ability to access care.

CMS states that while section 1932(a)(5)(B)(i) of the Act for Medicaid does not explicitly include "accurate" to describe "the identity, locations, qualifications, and availability of health care providers," CMS believes it is the intent of the text and therefore, utilizing secret shopper surveys to identify errors in the provider directories would help managed care plans ensure the accuracy of information in their directories.

Regarding use of telehealth, CMS believes it would be appropriate to prohibit managed care plans from meeting appointment wait time standards with telehealth appointments alone and by separately identifying telehealth visits in the results because this would help states determine if the types of appointments being offered by providers is consistent with expectations and enrollees' needs.

Concerning § 438.68(f)(4) and the approach to sample providers for the secret shopper surveys, CMS wants to give states the flexibility to design their secret shopper surveys to produce results that not only validate managed care plans' compliance with directory data accuracy and appointment wait time standards but also provide States the opportunity to collect other information that would assist them in their program monitoring activities and help them achieve programmatic goals.

CMS recognizes the implementation of the secret shopper surveys is a significant undertaking, but believes the data produced by successful implementation of them would be a valuable addition to states' and CMS' oversight efforts.

Comments

CMS states that technical assistance would be available to help states effectively implement and utilize secret shopper surveys. CMS invites comment on the type of technical assistance that would be most useful for States as well as States' best practices and lessons learned from using secret shopper surveys.

D. Assurances of Adequate Capacity, Services - Provider Payment Analysis (section 1.d pgs. 41-47)

Proposed Changes

CMS proposes to require payment analysis that managed care plans would submit to states per § 438.207(b)(3) and states would review and include in the assurance and analysis to CMS per § 438.207(d).

CMS proposes at § 438.207(b)(3) for Medicaid, and for separate CHIP through an existing cross-reference at § 457.1230(b), to require that MCOs, PIHPs, and PAHPs submit annual documentation to the state that demonstrates a payment analysis showing their level of payment for certain services, if covered by the managed care plan's contract. CMS proposes that the analysis would use paid claims data from the immediate prior rating period to ensure that all payments are captured, including those that are negotiated differently than a plan's usual fee schedule. Specifically, CMS will require the analysis for the following services:

- Evaluation and management current procedural terminology (CPT) codes for primary care, OB/GYN, mental health, and SUD services. Federally qualified health centers and rural health clinics are excluded due to unique payment requirements. The should include comparisons to Medicare, derived from dividing the total amount of managed care plan paid by the published Medicare payment rate for the same codes on the same claims. Percentages would have to be reported separately if they differ between adult and pediatric patients. CMS would exclude payments for claims for services for which the managed care plan is not the primary payer.
- Total amount paid for homemaker services, home health aide services, and personal care services and the percentage that results from dividing the total amount paid by the amount the state's Medicaid or CHIP FFS program would have paid for the same claims. CMS proposes two differences between this analysis and the analysis above: first, this analysis would use all codes for the services as there are no evaluation and management CPT codes for these LTSS; and second, CMS proposes the comparison be to Medicaid and CHIP FFS payment rates, as applicable, due to the lack of comparable Medicare rates for these services.

States would have to comply with these requirements no later than the first rating period that begins on or after 2 years after the effective date of the final rule.

Background/Rationale

CMS believes that there needs to be greater transparency in Medicaid and CHIP provider payment rates in order for States and CMS to monitor and mitigate payment-related access to barriers. While many factors affect provider participation, given the important role rates play in assuring access, greater transparency is needed to understand when and to what extent provider payment may influence access in state Medicaid and CHIP programs to specific provider types or for Medicaid and CHIP beneficiaries enrolled in specific plans. CMS also believes that greater transparency and oversight is warranted as managed care payments have grown significantly as a share of total Medicaid payments. CMS believes provider payment rates in managed care are inextricably linked with provider network sufficiency and capacity and wanted to propose a new process through which MCPs must report and states must review and analyze MCP payment rates to ensure comparability in managed care plans' analyses.

CMS believes the proposals in § 438.207(b)(3)(i)(A) and (B) would ensure sufficient detail in the data to enable more granular analysis across plans and states as well as prevent some data from obscuring issues with other data.

Comments

CMS seeks comment on whether in-home habilitation provided to enrollees with IDD should be added to this analysis.

E. Assurances of Adequate Capacity and Services Reporting (section 1.e pgs. 47-51)

Proposed Changes

CMS proposes to revise § 438.207(d) to explicitly require states to include the results from the secret shopper surveys to include in the states' assurances and analysis of adequate capacity and services reporting submitted to CMS. CMS also proposes to require states to include the payment analysis proposed in § 438.207(b)(3) to their assurance and analysis reporting.

Additionally, CMS proposes to explicitly require that states submit their assurance of compliance and analysis required in § 438.207(d) in the "format prescribed by CMS," to make use of a prior reporting template published by CMS on July 6, 2022 (The Network Adequacy and Access Assurances Report).

CMS proposes in § 438.207(d)(2) for Medicaid and included in separate CHIP regulations through § 457.1230(b), that the states' analysis required in § 438.207(d)(1) must include the payment analysis required of plans in § 438.207(b)(3) and provide the elements specified in paragraphs (d)(2)(i) and (ii). Specifically, § 438.207(d)(2)(i) proposes to require states to include the data submitted by each plan and § 438.207(d)(2)(ii) proposes to require States to use the data from its plans' reported payment analysis percentages and weight them using the member months associated with the applicable rating period to produce a Statewide payment percentage for each service type.

CMS proposes to establish submission times in § 438.207(d)(3)(i) through (iii) that correspond to the times for managed care plans to submit documentation to the state in § 438.207(c)(1) through (3). Specifically, for Medicaid, CMS proposes that states submit their assurance an analysis: (1) at the time it submits a completed readiness review; (2) on an annual basis and no later than 180 calendar days after the end of each contract year; and (3) any time there has been a significant change as specified in § 438.207(c)(3) and with the submission of the associated contract. CMS also proposes that states must post the report required in § 438.207(d) on their website within 30 calendar days of submission to CMS. CMS also proposes for separate CHIPs to align with Medicaid for the proposed network adequacy analysis submission timeframes at § 438.207(d)(3)(ii) and (iii) through the existing cross-reference at § 457.1230(b).

CMS proposes a revision to § 438.207(e) to add a reference to the secret shopper evaluations proposed at § 438.68(f) as part of the documentation that states must make available to CMS, upon request, and included in separate CHIP regulations through an existing cross-reference at § 457.1230(b).

CMS also proposes to revise § 438.207(g) to reflect that states would have to comply with paragraph (d)(2) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and paragraph (d)(3) no later than the first managed care plan rating period that begins on or after 1 year after the effective date of the final rule. CMS proposes that states would not

be held out of compliance with the requirements of paragraphs (e) of this section prior to the first MCO, PIHP, or PAHP rating period that begins on or after 4 years after the effective date of the final rule, so long as the states comply with the corresponding standard(s) codified in paragraph (e) contained in the 42 CFR, parts 430 to 481, most recently published before that rule.

CMS proposes that states would have to comply with the secret shopper reporting no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the rule.

Background/Rationale

CMS has a goal of making states' assurances of their managed care plans' compliance with (§§ 438.68 and 438.206 more comprehensive. CMS believes the revisions proposed in § 438.207(d) would be necessary to ensure consistent reporting CMS and enable effective analysis and oversight.

CMS believes the data elements in § 438.207(d)(2)(i) and (ii) would provide valuable data to support states' assurances of network adequacy and access. CMS would revise the Network Adequacy and Access Assurances Report template to add fields for states to easily report data. In the 2016 final rule, CMS made minor revisions to the language but did not address the timing of states' submission of their assurance and analysis. Given the July 22 release of the Network Adequacy template for assurance and analysis, CMS believes it would be appropriate to clarify this important aspect of the reporting requirements.

F. Remedy Plans to Improve Access (section 1.f pgs. 51-54)

Proposed Changes

CMS proposes, in § 438.68(e), a process that would require states to carefully develop and enforce their managed care plans' use of appointment wait time standards to ensure access to care for Medicaid managed care enrollees. As proposed in § 438.207(f), when the state MCO, PIHP, PAHP, or CMS identifies any access issues, including any access issues with the standards specified in §§438.68 and 438.206, the state would be required to submit a plan to remedy the access issues consistent with this proposal. If CMS determines that an access issue revealed under monitoring and enforcement rises to the level of a violation of access requirements under section 1932(c)(1)(A)(i) of the Act, CMS has the authority to disallow Federal financial participation (FFP) for the payments made under the State's managed care contract for the failure to ensure adequate access to care. CMS proposes in § 438.207(f)(1), that when the state, MCO, PIHP, PAHP, or CMS identifies an issue with a managed care plan's performance with regard to any state standard for access to care under this part, states would follow the steps set forth below:

- States would have to submit to CMS for approval a remedy plan no later than 90 calendar days following the date the state becomes aware of an MCO's, PIHP;s, or PAHP's access issue.
- The state would have to develop a remedy plan to address the identified issue that if addressed could improve access within 12 months and that identifies specific steps, timelines for implementation and completion, and responsible parties. CMS also proposes some approaches that states could consider to address the access issue.

- States would need to ensure to ensure that improvements in access are measurable and sustainable.
- States would submit quarterly progress updates to CMS on implementation of the remedy plan so that CMS can determine if the state was making reasonable progress toward completion and that the actions in the plan are effective.

CMS proposes in § 438.207(f)(2) that if the remedy plan required in paragraph (f)(1) does not address the managed care plan's access issue within 12 months, CMS may require the state to continue to take steps to address the issue for another 12 months and may require revisions to remedy the plan.

Background/Rationale

CMS relies on § 447.203(b)(8) to require states to submit corrective action plans. Because of the numerous proposals in this rule that would strengthen states' monitoring and enforcement of access requirements and the importance of timely remediation of access issues, CMS believes they should have a similar process set forth in part 438 for managed care programs. CMS believes that implementation of timely actions to address managed care plan access issues would be an integral operational component of the state's quality assessment and improvement strategy.

G. Transparency (section 1.g pgs. 54-61)

Proposed Changes

CMS proposes in § 438.10(c)(3) to revise "website" to "webpages" in reference to managed care plans. The Medicaid managed care website transparency revisions proposed at § 438.10(c)(3)(i) through (iv) would apply to separate CHIP through the existing cross-reference at § 457.1207. CMS would require the website to adhere to the following:

All information, or links to the information, required in this part to be posted on the states' website, be available from one page.

Use clear and easy-to-understand labels on documents and links so that users can easily identify the information contained in them.

States must check their websites at least quarterly to verify that they are functioning as expected and that the information is the most currently available.

Explain that assistance in accessing the information is available at no cost to beneficiaries, including information on the availability of oral interpretation in all languages and written translation in each prevalent non-English language, alternate formats, auxiliary aids and services, and a toll-free TTY/TDY telephone number.

CMS proposes to revise § 438.602(g) to contain a more completed list of required information. CMS proposes to add nine more items as (g)(5) through (g)(13);

- (5) enrollee handbooks, provider directories, and formularies required at § 438.10(g), (h), and (i);

- (6) information on rate ranges required at § 438.4(c)(2)(iv);
- (7) reports required at §§ 438.66(e) and 438.207(d);
- (8) network adequacy standards required at § 438.68(b)(1) and (2), and (e);
- (9) secret shopper survey results required at § 438.68(f);
- (10) state directed payment evaluation reports required in § 438.6(c)(2)(v)(C);
- (11) links to all required Application Programming Interfaces including as specified in § 431.60(d) and (f);
- (12) quality-related information required in §§ 438.332(c)(1), 438.340(d), 438.362(c), and 438.364(c)(2)(i);
- (13) documentation of compliance with requirements in subpart K – Parity in Mental Health and Substance Use Disorder Benefits.

CMS proposes to revise § 438.10(j) to reflect that states would have to comply with § 438.10(c)(3) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule and that states would have to comply with § 438.10(d)(2) no later than the first managed care plan rating period that begins on or after 3 years after the effective date of the final rule. CMS also proposes that states must comply with § 438.10(h)(3)(iii) no later than the first managed care plan rating period that begins on or after 4 years after the effective date of the final rule.

CMS proposes to add § 438.602(j) to require states to comply with § 438.10(g)(5) through (13) no later than the first managed care plan rating period that begins on or after 2 years after the effective date of the final rule. CMS also proposes to align with Medicaid in adopting most of the consolidation requirements for posting on a state's website proposed at § 438.602(g)(5) through (13) for separate CHIP: CMS proposes to adopt the provisions at § 438.602(g)(5), § 438.602(g)(7), § 438.602(g)(8), § 438.602(g)(9), § 438.602(g)(11), § 438.602(g)(12), and § 438.602(g)(13).

CMS proposes to amend § 457.1285 to state that states must comply with the program integrity safeguards in accordance with the term of subpart H of part 438 of this chapter, except that the terms of §§ 438.66(e), 438.362(c), 438.602(g)(6) and (10), 438.604(a)(2) and 438.608(d)(4) and references to LTSS of this chapter do not apply and that references to subpart K under part 438 should be read to refer to parity requirements at § 457.496.

Background/Rationale

Despite prior requirements, CMS has received numerous comments and input since the 2016 final rule about how challenging it can be to locate regulatory-required information on some states' websites. While some states may meet the current minimum standards in part 438, they do not meet CMS' intent of providing one place for interested parties to look for all required information. CMS believes revisions are necessary to ensure that all States' websites required by § 438.10(c)(3) provide a consistent and easy user experience.

CMS proposes their revision of "website" to "webpages" to clarify that if states provide required content on their website by linking to individual MCO, PIHP, PAHP, or PCCM entity websites, the link on the state's site would have to be to the specific page that includes that requested information. CMS believes this would prevent states from showing links to a landing page for the managed care plan that then leaves the user to start searching for specific information needed. CMS also believes that when website users

have to do repeated searches or click through multiple pages to find information, they are more likely to give up trying to locate it. As such, CMS has carefully chosen the information that is required in 42 CRF part 438 to be posted on states' websites to ensure effective communication of information and believes it represents an important step towards eliminating common obstacles.

CMS believes that its proposals would make states' websites easier to use by incorporating easily understood labels, having all information accessible from one page, verifying the accurate functioning of the site, and clearly explaining the availability of assistance all of which would directly help states fulfill their obligation to provide information materials in a manner and form which may be easily understood.

H. Terminology (section 1.h pgs. 61-62)

Proposed Changes

CMS proposes to change "behavioral health' through 42 CFR part 438 as described here. In the definition of PCCM entity at § 438.2 and for the provider types that must be included in the provider directories at § 438.68(b)(1)(iii), CMS proposes to remove "behavioral health" and the parentheses; and for the provider types addressed in the credentialing policies at § 438.214(b), CMS proposes to replace "behavioral" with "mental health." CMS also proposes the definition of PCCM entity at § 438.2 to replace the slash between "health systems" and "providers" with "and" for grammatical accuracy.

CMS also proposes to change "psychiatric" to "mental health" in § 438.3(e)(2)(v) and § 438.6(e).

Background/Rationale

CMS does not believe that the current definition of behavioral health is an imprecise term that does not capture the full array of conditions that are intended to be included. CMS mentions that some in the SUD treatment community have raised concerns about its use. CMS also does not believe that "psychiatric" captures the full array of services that can be provided by IMDs.

II. State Directed Payments (SDPs)

A. Contract Requirements Considered to be SDPs (section 2.b pgs. 69-72)

Proposed Changes

There are no proposed changes.

Background/Rationale

CMS maintains their interpretation that if a State includes a general contract requirement for provider payment that provides 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.

They believe it is important to further specify their stance 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. State wishing to impose quality requirements or thresholds on managed care plans, such as the requirement that a certain percentage of provider payments be provided through a value-based payment (VBP) arrangement, must do so within the parameters of § 438.6(b).

Comments

CMS requests comments on whether additional clarification about these grey area payments is necessary, or if revision to the regulation text would be helpful.

B. Medicare Exemption, SDP Standards and Prior Approval (section 2.c pgs. 72-78)

Proposed Changes

CMS proposes to exempt SDPs that adopt a minimum fee schedule based on total published Medicare payment rates from written prior approval as it would be unnecessary and duplicative. They propose to amend § 438.6(c) to provide specifically for SDPs that require use of a minimum fee schedule using FFS Medicare payment rates.

CMS proposes to require the managed care plan contract to include certain information about the Medicare fee schedule used in the SDP, regardless of whether the SDP was granted an exemption from written prior approval under § 438.6(c)(1)(iii)(B). That is, for SDPs which use total published Medicare payment rates, the contract would need to specify which Medicare fee schedule(s) the State directs the managed care plan to use and any relevant and material adjustments due to geography, such as rural designations, and provider type, such as Critical Access Hospital or Sole Community Hospital designation.

Background/Rationale

CMS notes their proposal to exempt certain SDPs from written prior approval from CMS is specific to SDPs that require the Medicaid managed care plan to use a minimum fee schedule that is equal to 100 percent of the total published Medicare payment rate. SDP arrangements that use a different percentage (whether higher or lower than 100 percent) of a total published Medicare payment rate as the minimum payment amount or are simply based off of an incomplete total published Medicare payment rate would be included in the SDPs described in paragraph (c)(1)(iii)(C).

CMS also highlights that the review of SDPs includes ensuring that they will result in provider payments that are reasonable, appropriate, and attainable, and will not negatively impact access to care.

Accordingly, they believe that SDPs that propose provider payment rates that are incomplete or either above or below 100 percent of total published Medicare payment rates may not always meet these criteria and thus, should remain subject to written prior approval by CMS.

CMS states that requiring sufficient language in the contract regarding the Medicare fee schedule would provide clarity to CMS, managed care plans, and providers regarding the explicit Medicare payment methodology being used under the contract.

Comments

CMS is soliciting public comments on their proposal to specifically address SDPs that are for minimum fee schedules using 100 percent of the amounts in a total published Medicare payment rate for providers that provide a particular service provided that the total published Medicare payment rate was in effect no more than 3 years prior to the start of the rating period and on their proposal to exempt these specific types of SDP arrangements from the prior written approval requirement in § 438.6(c)(2)(ii).

CMS requests comments on other material or significant information about a Medicare fee schedule that would need to be included to ensure the managed care contract sufficiently describes this type of SDP.

C. Non-Network Providers (section 2.d pgs. 78-81)

Proposed Changes

CMS proposes to remove the term "network" from the descriptions of SDP arrangements in current (and revised as proposed) § 438.6(c)(1)(iii). Under this proposal, the permissible SDPs are described as payment arrangements or amounts "for providers that provide a particular service under the contract" and this will permit States to direct payments under their managed care contracts for both network and non-network providers, subject to the requirements in paragraph (c).

Background/Rationale

CMS notes that existing regulations specify that for a State to require an MCO, PIHP or PAHP to implement a fee schedule under § 438.6(c)(1)(iii), the fee schedule must be limited to "network providers." 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. In our experience working with States, limiting the descriptions of SDP arrangements subject to § 438.6(c)(iii) to those that involve only network providers has proven to be too narrow and has created an unintended barrier to States' and CMS' policy goals to ensure access to quality care for beneficiaries.

Comments

CMS is seeking comment on whether this change would result in negative unintended consequences.

D. SDP Submission Timeframes (section 2.e pgs. 81-87)

Proposed Changes

CMS proposes to require that all SDPs that require written prior approval from CMS must be submitted to CMS no later than 90 days in advance of the end of the rating period to which the SDP applies. This requirement applies if the payment arrangement for which the State is seeking written prior approval begins at least 90 days in advance of the end of the rating period.

CMS proposes to address the use of shorter-term SDPs in response to infrequent events, such as PHEs and natural disasters, by permitting States to submit all required documentation before the end of the rating period for SDP proposals that would start less than 90 days before the end of the rating period.

CMS is proposing to allow an amendment window for the proposal within the first 120 days of each of the subsequent rating periods for which the SDP is approved after the initial rating period. The Agency is proposing that the State be able to amend the approved preprint for the second and third rating periods within the first 120 days of the CY 2026 rating period (for example, by May 1, 2026).

CMS is proposing to require the submission of related contract requirements and rate certification documentation no later than 120 days after the start of the SDP or the date we granted written prior approval of the SDP, whichever is later.

Background/Rationale

CMS notes they are proposing to use a deadline of no later than 90 days prior to the end of the applicable rating period because they believe this minimum timeframe balances the need for State flexibility to address unforeseen changes that occur after the managed care plan contracts and rates have been developed with the need to ensure timely processing of managed care contracts and capitation rates.

CMS believes this flexibility would be appropriate to allow States to effectively use SDPs during the final quarter of the rating period to address urgent situations that affect access to and quality of care for Medicaid managed care enrollees.

CMS highlights that they believe given the nature of SDPs, there should be additional timing restrictions on when revised rate certifications that include SDPs can be provided for program integrity purposes.

Comments

CMS solicits public comments on these proposals.

E. Standard for Total Payment Rates for each SDP, Establishment of Payment Rate Limitations for Certain SDPs, and Expenditure Limit for All SDPs (section 2.f pgs. 87-117)

1. Standard for Total Payment Rates for each SDP (88-92)

Proposed Changes

CMS proposes a new standard at § 438.6(c)(2)(ii)(I) to codify their current policy that each SDP ensure that the total payment rate for each service, and each provider class included in the SDP must be reasonable, appropriate and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class.

"Total payment rate" is defined as the aggregate for each managed care program of: (1) the average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the SDP; (2) 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; (3) 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 (4) 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.

Background/Rationale

CMS reasons that while the total payment rate described above is collected for each SDP, the information provided for each SDP must account for the effects of all payments from the managed care plan (for example, other SDPs or pass-through payments) to any providers included in the provider class specified by the State for the same rating period. They will assess using the information above if the total payment level across all SDPs in a managed care program is reasonable, appropriate and attainable.

Comments

CMS is soliciting comments on the proposed changes.

2. **Proposed Payment Rate Limit for Inpatient Hospital Services, Outpatient Hospital Services, Qualified Practitioner Services at Academic Medical Centers, and Nursing Facility Services (pgs. 98-107)**

Proposed Changes

CMS proposes to include four services – inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center, and nursing facility services – in § 438.6(c)(2)(iii) and limit the projected total payment rate for each of these four services to ACR for any SDP arrangements described in paragraphs (c)(1)(i) through (iii), excluding (c)(1)(iii)(A) and (B), that are for any of these four services. 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.

Background/Rationale

While CMS has not knowingly approved an SDP that includes payment rates that are projected to exceed the ACR, States are increasingly submitting preprints that would push total payment rates up to the ACR. Therefore, CMS aims to move away from the use of an internal benchmark to a regulatory limit on the projected total payment rate, using the ACR for the services identified above.

CMS believes that using the ACR as a limit is likely appropriate as it is generally consistent with the need for managed care plans to compete with commercial plans for providers to participate in their networks to furnish comparable access to care for inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center and nursing facility services.

Based on both CMS' experience with SDPs for inpatient hospital services, outpatient hospital services and qualified practitioner services at an academic medical center as well as data from the National Health Expenditure survey and other external studies examining payment rates across the Medicaid, Medicare and commercial markets, they believe that for these three services, the ACR payment rate limit would likely be reasonable, appropriate and attainable while allowing States the flexibility to further State policy objectives through implementation of SDPs.

Comments

CMS is soliciting feedback on, establishing a total payment rate limit for all services, not limited to just these four services, for all SDP arrangements described in § 438.6(c)(1)(i), (ii), and (iii)(C) through (E) at the Medicare rate in the final rule.

CMS is seeking public comment to further evaluate if Medicare would be a reasonable limit for the total provider rate for the four types of services delivered through managed care that they propose, all services, and/or additional types of services.

CMS is considering limiting the total payment rate for these four services to ACR for value-based initiatives only and further limiting the total payment rate for these four services to the Medicare rate for fee schedule arrangements (for example, uniform increases, minimum or maximum fee schedules). CMS invites public comments on whether this potential alternative should be included in the final rule.

CMS is seeking comment on whether or not CMS should consider a transition period in order to mitigate any disruption to provider payment levels if they adopt one of the alternatives for a total payment rate limit on SDP expenditures in the final rule.

3. Average Commercial Rate Demonstration Requirements (pgs. 107-114)

Proposed Changes

CMS proposes in § 438.6(c)(2)(iii) that States provide two pieces of documentation: (1) an ACR demonstration; and (2) a total payment rate comparison to the ACR. The ACR demonstration would be submitted with the initial preprint submission (new, renewal, or amendment) following the applicability

date of this section 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 to specify the requirements for demonstration of the ACR if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. This demonstration must use payment data that: (1) is specific to the State; (2) is no older than the 3 most recent and complete years prior to the start of the rating period of the initial request following the applicability date of this section; (3) is specific to the service(s) addressed by the SDP; (4) includes the total reimbursement by the third party payer and any patient liability, such as cost sharing and deductibles; (5) excludes payments to FQHCs, RHCs and any non-commercial payers such as Medicare; and (6) excludes any payment data for services or codes that the applicable Medicaid managed care plans do not cover under the contracts with the State that will include the SDP. CMS proposes to require States to use data that is specific to the service type(s) included in the SDP.

CMS proposes to specify the requirements for the comparison of the total payment rate for the services included in the SDP to the ACR for those services if a State seeks written prior approval for an SDP that includes inpatient hospital services, outpatient hospital services, qualified practitioner services at an academic medical center or nursing facility services. Under this proposal, the comparison must: (1) be specific to each managed care program that the SDP applies to; (2) be specific to each provider class to which the SDP applies; (3) be projected for the rating period for which written prior approval is sought; (4) use payment data that is specific to each service included in the SDP; and (5) include a description of each of the components of the total payment rate as defined in § 438.6(a) as a percentage of the average commercial rate, demonstrated pursuant to § 438.6(c)(2)(iii)(A), for each of the four categories of services (that is, inpatient hospital services, outpatient hospital services, nursing facility services or qualified practitioner services at an academic medical center) included in the SDP submitted to CMS for review and approval.

Background/Rationale

CMS notes these proposals are to provide States the flexibility they need to design SDPs to direct resources as they deem necessary to meet their programmatic goals. This would allow States to provide an ACR analysis at just the service level instead of at the service and provider class level.

Comments

CMS is seeking comments on their proposals.

4. **Average Commercial Rate Demonstration and Total Payment Rate Comparison Compliance (pgs. 114-117)**

Proposed Changes

CMS proposes at § 438.6(c)(2)(iii)(C) to require States to submit the ACR demonstration and the total payment rate comparison for review as part of the documentation necessary for written prior approval for payment arrangements, initial submissions or renewals, starting with the first rating period beginning on or after the effective date of this rule.

CMS proposes to require that States update the ACR demonstration once every 3 years as long as the State continues to seek to include the SDP in the MCO, PIHP, or PAHP contract.

Background/Rationale

CMS notes this time period aligns with existing policy for ACR demonstrations for qualified practitioners in Medicaid FFS programs; specifically, those that demonstrate payment at the Medicare equivalent of the ACR.

Comments

CMS solicits public comments on their proposals. CMS also seeks public comment on whether they should adopt a limit on SDP expenditures in the final rule.

CMS seeks public comment on both the overall approach of using a percent of total costs as well as on the appropriateness of 10 to 25 percent or what a reasonable percentage limit for SDP expenditures could be.

F. Financing (section 2.g pgs. 117-133)

Proposed Changes

CMS proposes to revise § 438.6(c)(2)(ii) to add a new paragraph to explicitly require State directed payments (SDPs) comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR part 433, subpart B, as part of the CMS review process.

CMS also proposes to revise § 438.6(c)(2)(ii) to ensure transparency regarding the use of SDPs and to ensure that the non-Federal share of SDPs is funded with a permissible source. Under this proposal, States would be required to ensure that each participating provider in an SDP arrangement attests that it does not participate in any hold harmless arrangement with respect to any health care-related tax as specified in § 433.68(f)(3) 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. These hold harmless arrangements include those that produce a reasonable expectation that taxpaying providers would be held harmless for all or a portion of their cost of a health care-related tax. Furthermore, States would be required to note in the preprint their compliance with this requirement prior to CMS' written prior approval of any contractual payment arrangement directing how Medicaid managed care plans pay providers. States would comply with this proposed requirement by obtaining each provider's attestation or requiring the Medicaid managed care plan to obtain each provider's attestation.

CMS also proposes, at § 438.6(c)(2)(ii)(H) to require that the State ensure that such attestations are available upon request by CMS.

CMS proposes to deny written prior approval of an SDP if it does not comply with the standards in § 438.6(c)(2), including if the financing of the non-Federal share is not fully compliant with all Federal legal requirements and/or the State does not require an attestation from each provider receiving a payment based on the SDP that it does not participate in any hold harmless arrangement. As part of the proposed restructuring of § 438.6(c)(2), these provisions would apply to all SDPs, regardless of whether written prior approval is required.

Background/Rationale

In recent years, CMS has identified instances in which States appear to be funding the non-Federal share of Medicaid SDP payments through health care-related tax programs that appear to involve an impermissible hold harmless arrangement. These arrangements appear designed to redirect Medicaid payments away from the providers that furnish the greatest volume of Medicaid-covered services toward providers that provide fewer, or even no, Medicaid-covered services, with the effect of ensuring that taxpaying providers are held harmless for all or a portion of their cost of the health care-related tax. In the arrangements, a State or other unit of government imposes a health-care related tax, then uses the tax revenue to fund the non-Federal share of SDPs that require Medicaid managed care plans to pay the provider taxpayers. The taxpayers appear to enter a pre-arranged agreement to redistribute the Medicaid payments to ensure that all taxpayers, when accounting for both their original Medicaid payment (from the State through a managed care plan) and any redistribution payment received from another taxpayer(s) or other entity, receive back (and are thereby held harmless for) all or at least a portion of their tax amount.

CMS is concerned that the failure of the current regulations to explicitly require written prior approval of an SDP on the State demonstrating compliance with applicable Federal requirements for the source(s) of non-Federal share potentially compromises CMS' ability to disapprove an SDP where it appears the SDP arrangement is supported by impermissible non-Federal share financing arrangements. Given the growing number of SDPs that raise potential financing concerns, and the growing number of SDPs generally, CMS believes it is important to be explicit in the regulations governing SDPs.

The current lack of transparency for SDPs prevents both CMS and States from having information necessary for reviewing both the proposed non-Federal share financing source and the proposed payment methodology to ensure they meet Federal requirements. However, States have cited challenges with identifying and providing details on redistribution arrangements when CMS has requested such information during the review of SDPs, but CMS is only interested in any business arrangements among private entities that could result in a violation of Federal statutory and regulatory requirements.

CMS recognizes that healthcare-related taxes can be critical tools for financing payments that support the Medicaid safety net but emphasizes that they must be implemented in accordance with applicable statutory and regulatory requirements. This proposed rule would ensure that CMS and States have the necessary information about any arrangements in place that would redistribute Medicaid payments and make clear that CMS has the authority to disapprove proposed SDPs if States identify the existence of such an arrangement or do not provide the required information or ensure the attestations are made and available as required.

The proposed new attestation requirements would help ensure appropriate transparency regarding the use of Medicaid payments and any relationship to the non-Federal share source(s) and aims to do so without interfering with providers' normal business arrangements.

Comments

CMS seeks public comment on these proposals.

G. Tie to Utilization and Delivery of Services for Fee Schedule Arrangements (section 2.h pgs. 133-140)

Proposed Changes

CMS proposes to revise § 438.6(c) to address how different types of SDPs must be based on utilization and delivery of covered services.

CMS proposes to codify its previous rule clarification in a new section, § 438.6(c)(2)(vii)(A) for SDPs about minimum fee schedules, maximum fee schedules, and uniform increases. As proposed, CMS would require that any and all payments made under the SDP are conditioned on the utilization and delivery of services under the managed care plan contract for the applicable rating period only. This would preclude States from making any SDP payment based on historical or any other basis that is not tied to the delivery of services to the rating period itself.

CMS is proposing a new § 438.6(c)(2)(vii)(B) which would prohibit States from requiring managed care plans to make interim payments based on historical utilization and then to reconcile those interim payments to utilization and delivery of services covered under the contract after the end of the rating period for which the SDP was originally approved.

CMS is proposing to prohibit the use of post-payment reconciliation processes for SDPs; specifically, that States establishing fee schedules under § 438.6(c)(1)(iii) cannot require that plans pay providers using a post-payment reconciliation process.

Background/Rationale

A fundamental requirement of SDPs is that they are payments related to the delivery of services under the contract. The current regulations require that States demonstrate in writing that SDPs that require prior written approval be based on the utilization and delivery of services to Medicaid enrollees covered under the managed care plan contract. Requiring SDPs be based on the utilization and delivery of services is a fundamental and necessary requirement for ensuring the fiscal and program integrity of SDPs, but CMS believes further clarification is necessary due to the variety of payment mechanisms that States use in their SDP arrangements.

Under the prior rule, States could not, under CMS' interpretation of the requirement, require managed care plans to make payments for services that were delivered outside of the approved rating period.

However, in working with States, CMS found that this was not always understood and thus seeks to clarify this rule further.

CMS has also seen States have their actuaries submit an amendment to adjust the amount paid to plans after reconciliation. These amendments typically come near to or after the close of the rating period and are most common when the reconciliation would result in increased costs to the plan absent the adjustment. As a result, the risk is essentially removed from the managed care plans participating in the SDP. CMS is concerned with this practice as they believe tying payments in an SDP, even interim payments, to utilization from a historical time-period outside of the rating period approved for the SDP, is inconsistent with prospective risk-based capitation rates that are developed for the delivery of services in the rating period.

CMS believes requiring managed care plans to make interim payments based on historical utilization and then reconciling to actual utilization instead suggests an intent by State to ensure payment of a specific aggregate amount to certain providers or, in some cases, removal of all risk related to these SDPs from managed care plans. Further, CMS believes prohibiting this practice and removing post-payment reconciliation processes as proposed, would alleviate actuarial and oversight concerns as well as restore program and fiscal integrity to these kinds of payment arrangements.

Comments

CMS is soliciting public comments on these proposals.

H. Value-Based Payments and Delivery System Reform Initiatives (section 2.i pgs. 140-151)

Proposed Changes

CMS proposes to redesignate paragraph (c)(2)(iii) as paragraph (c)(2)(vi) with a revision to remove the phrase “demonstrate in writing,”.

CMS proposes the following changes to the requirements that are specific to SDPs that involve VBP initiatives:

1. Remove the existing requirements at § 438.6(c)(2)(iii)(C) that currently prohibit States from setting the amount or frequency of the plan’s expenditures.
2. Remove the existing requirements at § 438.6(c)(2)(iii)(D) that currently prohibit States from recouping unspent funds allocated for these SDPs.
3. Redesignate § 438.6(c)(2)(iii)(B) with revisions and clarifications to § 438.6(c)(2)(vi)(B) to address how performance in these types of arrangements is measured for participating providers.
4. Adopt a new § 438.6(c)(2)(vi)(C) to establish requirements for the use of population-based and condition-based payments in these types of SDP arrangements.

CMS proposes to use new § 438.6(c)(2)(vi)(B) for requirements for SDPs that condition payment on performance, specifically:

- CMS is proposing to require that payments to providers under SDPs that are based on performance not be conditioned upon administrative activities, such as the reporting of data, nor upon the participation in learning collaboratives or similar administrative activities.
- Additionally, CMS is proposing new requirements that are clarifications or extensions of the current requirement that SDPs use a common set of performance metrics.

CMS proposes to permit States to use a performance measurement period that precedes the start of the rating period in which payment is delivered by up to 12 months. Under this aspect of the proposal, States would be able to condition payment on performance measure data from time periods up to 12 months prior to the start of the rating period in which the SDP is paid to providers.

CMS also proposes that all payments would need to be documented in the rate certification for the rating period in which the payment is delivered. Specifically, that a payment arrangement that is based on performance must define and use a performance period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered.

CMS also proposes to require that all SDPs that condition payment on performance include a baseline statistic for all metrics that are used to measure the performance that is the basis for payment from the plan to the provider.

CMS proposes to require that all SDPs that condition payment on performance use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the payment arrangement applies, that demonstrate improvement over baseline data on all metrics selected. CMS is also proposing to establish regulatory pathways for approval of VBP initiatives that may not be conditioned upon specific measures of performance.

CMS proposes to define a "population-based payment" at § 438.6(a) as a prospective payment for a defined Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group; specifically:

- CMS proposes to define a "condition-based payment" as a prospective payment for a defined set of Medicaid service(s), that are tied to a specific condition and delivered to Medicaid managed care enrollees.
- At § 438.6(c)(2)(vi)(C)(1), CMS proposes to require that population-based and condition-based payments be conditioned upon either the delivery by the provider of one or more specified Medicaid-covered service(s) during the rating period or the attribution to the provider of a covered enrollee for the rating period for treatment.
- CMS proposes to add § 438.6(c)(2)(vi)(C)(3) to require that population-based payments and condition-based payments replace the negotiated rate between a plan and providers for the Medicaid covered service(s) being delivered as a part of the SDP to prevent any duplicate payment(s) for the same service.
- Also, at § 438.6(c)(2)(vi)(C)(2), CMS is proposing to add a requirement that prevents payments from being made in addition to any other payments made by plans to the same provider on behalf

of the same enrollee for the same services included in the population- or condition-based payment.

CMS proposes a new § 438.6(c)(2)(vi)(C)(4) to require that States include at least one performance measure that measures performance at the provider class level as a part of the evaluation plan outlined in proposed § 438.6(c)(2)(iv). CMS is also proposing that States would be required to set the target for such a performance measure to demonstrate improvement over baseline.

CMS proposes to modify § 438.6(c)(3)(i) to add that a multi-year written prior approval may be for of up to three rating periods to codify the existing policy; specifically:

- CMS is proposing minor revisions in paragraphs (c)(3)(i)(A) through (C) to use the term "State directed payment" as appropriate and to revise paragraph (c)(3)(ii) to specify it is about written prior approvals.
- CMS is proposing to redesignate paragraph (c)(2)(F) to new paragraph (c)(3)(iii) to explicitly provide that State directed payments are not automatically renewed.

Background/Rationale

Existing regulations at § 438.6(c)(1)(i) and (ii) allow States to direct Medicaid managed care plans to implement value-based purchasing models (VBP) with providers or to participate in delivery system reform or performance improvement initiatives; these types of SDPs require written prior approval from CMS. These provisions were adopted as exceptions to the overall prohibition on States directing the payment arrangements used by Medicaid managed care plans to pay for covered services.

Since the 2016 rule, States have used SDPs to strengthen their ability to use their managed care programs to promote innovative and cost-effective methods of delivering care to Medicaid enrollees, to incent managed care plans to engage in State activities that promote certain performance targets, and to identify strategies for VBP initiatives to link quality outcomes to provider reimbursement.

However, as the number of SDPs for VBP initiatives continues to grow, CMS has found that the existing requirements at § 438.6(c)(2)(iii) can pose unnecessary barriers to implementation of these initiatives.

Currently, § 438.6(c)(2)(iii)(C) prohibits States from setting the amount or frequency of expenditures in SDPs that are VBP initiatives. In the 2015 proposed rule, CMS reasoned that while capitation rates to the managed care plans would reflect an amount for incentive payments to providers for meeting performance targets, the plans should retain control over the amount and frequency of payments. CMS believed that this approach balanced the need to have a health plan participate in a multi-payer or community-wide initiative, while giving the health plan a measure of control to participate as an equal collaborator with other payers and participants. However, VBP initiatives often include, by design, specific payment amounts at specific times. As States began to design and implement VBP initiatives, sometimes across delivery systems or focused on broad population health goals, many found that allowing plans to retain such discretion undermined the State's ability to implement meaningful initiatives with clear, consistent operational parameters necessary to drive provider performance improvement and achieve the goals of the State's program.

Because these types of payment arrangements affect provider revenue differently than the usual per claim payment methodology, establishing strong parameters and operational details that define when and how providers will receive payment is critical for robust provider participation. While allowing States the flexibility to include the amount and frequency of payments when designing VBP and delivery system reform initiatives removes discretion from managed care plans, CMS believes this flexibility is necessary to ensure that States can achieve their quality goals and get value for the dollars and effort that they invest in these arrangements. Creating obstacles for States trying to implement VBP initiatives was not the intent in the 2016 final rule. The goal then and now is to encourage States to implement innovative initiatives that reward quality of care and improved health outcomes over volume of services.

Currently, § 438.6(c)(2)(iii)(D) prohibits States from recouping any unspent funds allocated for SDP arrangements from managed care plans when the SDP arrangement is for VBP, delivery system reform, or performance improvement initiatives. CMS explained that because funds associated with delivery system reform or performance initiatives are part of the capitation payment, any unspent funds would remain with the MCO, PIHP, or PAHP. CMS believed this was important to ensure that the SDPs made to providers were associated with a value relative to innovation and Statewide reform goals and not simply an avenue for States to provide funding increases to specific providers. However, allowing managed care plans to retain unspent funds when providers fail to achieve performance targets can create perverse incentives for States and managed care plans.

CMS believes the best way to address the limitations in current regulation text is to specify different requirements for VBP initiatives that condition payment upon performance from ones that are population or condition-based.

Currently, CMS policy states that the performance measurement period for SDPs that condition payment based upon performance must overlap with the rating period in which the payment for the SDP is made. However, they have found that States frequently experience delays in obtaining performance-based data due to claims run out time and the time needed for data analyses and validation of the data and the results. All of this can make it difficult, if not impossible, to comply with this requirement.

Comments

CMS is seeking comment on whether 12-months is an appropriate time period to allow for claims runout and data analysis, or if the time period that the performance period may precede the rating period should be limited to 6-months or extended to 18- or 24-months, or if the performance period should remain consistent with the rating period.

CMS is seeking public comment on these proposals.

I. Quality and Evaluation (section 2.j pgs. 151-164)

Proposed Changes

CMS proposes at § 438.6(c)(2)(iv) that the State must submit an evaluation plan for each SDP that requires written prior approval that includes four specific elements. CMS further specifies that this

proposal is to establish minimum content requirements for SDP evaluation plans but is not intended to limit States in evaluating their SDP arrangements.

CMS proposes at § 438.6(c)(2)(iv)(A) that the evaluation plan must identify at least two metrics that would be used to measure the effectiveness of the payment arrangement in advancing the identified goal(s) and objective(s) from the State's managed care quality strategy on an annual basis. Furthermore, at least one of those metrics must measure performance at the provider class level for SDPs that are population- or condition-based payments.

CMS also proposes that the metrics must be specific to the SDP and attributable to the performance by the providers for enrollees in all the State's managed care program(s) to which the SDP applies, when practicable and relevant.

CMS proposes that at least one of the selected metrics must be a performance measure.

CMS proposes the standard "when practicable and relevant" to allow flexibility to account for situations in which contract or program level specificity may be either impossible to obtain or may be ineffective in measuring the identified quality goal(s) and objective(s)

CMS proposes at § 438.6(c)(2)(iv)(B) to require States to include baseline performance statistics for all metrics that would be used in the evaluation since this data must be established to monitor changes in performance during the SDP performance period and produce reliable results throughout the entirety of the SDP's implementation.

Furthermore, CMS is also proposing at § 438.6(c)(2)(iv)(C), to require that States include measurable performance targets relative to the baseline statistic for each of the selected measures in their evaluation plan.

CMS is proposing to revise § 438.6(c)(2) to ensure that SDPs further the goals and objectives identified in the State's managed care quality strategy.

CMS is also proposing at § 438.6(c)(2)(iv)(D) that States must provide commitment to submit an evaluation report if the final State directed payment cost percentage exceeds 1.5 percent.

CMS proposes to define "final State directed payment cost percentage" in § 438.6(a) as the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment and each managed care program. In § 438.6(c)(7)(iii)(A), CMS proposes for SDPs requiring prior approval that the final SDP cost percentage numerator be calculated as the portion of the total capitation payments that is attributable to the State directed payment and, actual total amount that is paid as a separate payment term described in § 438.6(c)(6), for each managed care program.

CMS proposes the final SDP cost percentage denominator be calculated as the actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and passthrough payments in effect under § 438.6(d), and the actual total amount of State directed payments that are paid as a separate payment term.

CMS proposes that the final State directed payment cost percentage be calculated on an annual basis and recalculated annually to ensure consistent application across all States and managed care programs.

CMS also proposes at § 438.6(c)(7)(ii) to require that the final SDP cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

CMS proposes a requirement that the State submit the final State directed payment cost percentage annually to CMS for review, when the final State directed payment cost percentage does not exceed 1.5 percent and the State has not voluntarily submitted the evaluation report, as a separate report concurrent with the rate certification submission required in § 438.7(a) no later than 2 years after the completion of each 12-month rating period that included a State directed payment.

CMS is proposing to adopt three requirements for the evaluation reports, at § 438.6 (c)(2)(v)(A).

1. Evaluation reports must include all the elements approved in the evaluation plan required in § 438.6(c)(2)(iv).
2. States must include the 3 most recent and complete years of annual results for each metric.
3. States must publish their evaluation reports on their public facing website as required under § 438.10(c)(3).

CMS also proposes at § 438.6(c)(2)(v)(B) to require States to submit the first evaluation report no later than 2 years after the conclusion of the 3-year evaluation period and that subsequent evaluation reports would have to be submitted to CMS every 3 years after.

CMS also proposes a new standard at § 438.6(c)(2)(ii)(F) requiring that all SDPs must result in achievement of the stated goals and objectives in alignment with the State's evaluation plan.

CMS makes a concurrent proposal at § 438.358(c)(7) to include a new optional EQR activity to support evaluation requirements, which would give States the option to leverage a CMS-developed protocol or their EQRO to assist with evaluating SDPs.

Background/Rationale

Existing regulations at § 438.6(c)(2)(ii)(C) and (D) specify that to receive written prior approval, States must demonstrate in writing, amongst other requirements, that the State expects the SDP to advance at least one of the goals and objectives in the State's managed care quality strategy and has an evaluation plan that measures the degree to which the SDP advances the identified goals and objectives.

CMS analyzed data from 228 renewal preprints submitted by 33 States between April 2018 and February 2021. Over half (63 percent) of the evaluation plans submitted were incomplete, and only 43 percent of the renewal preprints included any evaluation results. This analysis also found only a 35 percent compliance rate with conditions of concurrence requesting States submit SDP evaluation results with the preprint for the following rating period. CMS's policy goals in this area are frustrated by the lack of a regulation requiring submission of these evaluation results. By adopting requirements for submission of evaluation plans and reports, we intend to increase compliance and improve our oversight in this area.

As the volume of SDP preprint submissions and total dollars flowing through SDPs continues to increase, CMS recognizes the importance of ensuring that SDPs are contributing to Medicaid quality goals and objectives and recognizes that meaningful evaluation results are critical for ensuring that these payments

further improvements in quality of care. Moreover, consistent submission of evaluation results is important for transparency and responsiveness to oversight bodies.

Measurable SDP evaluation performance targets that demonstrate performance relative to the baseline measurement allow States to determine whether the payment arrangement is having the intended effect and helping a State make progress toward its quality goals. Our internal analysis showed that nearly 20 percent of performance measures selected by States were not specific or measurable.

CMS believes that the proposed regulations would ensure that States collect and use stronger data for developing and evaluating payment arrangements to meet the goals of their Medicaid programs and would also be responsive to recommendations for more clarity for SDP evaluation plans. However, CMS recognizes and shares the concerns raised by oversight bodies regarding the limited availability of SDP evaluation results for use in internal and external monitoring of the effect of SDPs on quality of care.

CMS recognizes that submitting an evaluation report would impose some additional burden on States, so our proposal takes a risk-based approach to identify when an evaluation report must be submitted to CMS based on the actual total amount that is paid as a separate payment term described in § 438.6(c)(6) or portion of the actual total portion of capitation payments attributable to the SDP, as a percentage of the State's total Medicaid managed care program costs for each managed care program. This approach would allow States and CMS to focus resources on payment arrangements with the highest financial risk. Further. CMS selected the 1.5 percent as it aligns with existing Medicaid managed care policy for when rate amendments are necessary.

CMS believes the final SDP cost percentage should be measured distinctly for each managed care program and SDP, as reflected in the definition proposed for this term. This is appropriate because capitation rates are typically developed by program, SDPs may vary by program, and each managed care program may include differing populations, benefits, geographic areas, delivery models, or managed care plan types.

CMS recognizes and shares the concerns that oversight bodies have expressed regarding the extent to which CMS uses evaluation results to inform SDP written prior approval decisions.

Comments

CMS is soliciting comments on whether the numerator for a minimum or maximum fee schedule SDP that is incorporated into capitation rates as an adjustment to base capitation rates should be calculated in a different manner. CMS is also soliciting comments on whether they should codify this in the regulation text.

CMS is seeking public comments on these proposals and the alternatives under consideration.

J. Contract Term Requirements (section 2.k pgs. 164-169)

Proposed Changes

CMS proposes to codify at § 438.6(c)(5) minimum requirements for the content of a Medicaid managed care contract that includes one or more SDP contractual requirement(s).

At § 438.6(c)(5)(i) through (v), CMS proposed to specify the information that must be documented in the managed care contract for each SDP. Proposed § 438.6(c)(5)(i) would require the State to identify the state date and, if applicable, the end date within the applicable rating period. Proposed § 438.6(c)(5)(ii) would require the managed care contract to describe the provider class eligible for the payment arrangement and all eligibility requirements. Proposed § 438.6(c)(5)(iii) would require the State to include a description of each payment arrangement in the managed care contract. For each type of payment arrangement, CMS proposes (at paragraph (c)(5)(iii)(A)(3)) to require that specific elements be included in the contract at a minimum; this may include the fee schedule the plan must ensure payments are at or above, the procedure and diagnosis codes to which the fee schedule applies, and the applicable fates of services within the rating period for which the fee schedule applies.

CMS proposes at § 438.6(c)(5)(iii)(B)(1) through (5) to require the contract to 1) include whether the uniform increase will be a specific dollar amount or a specific percentage increase over negotiated rates, 2) the procedure and diagnosis codes to which the uniform increase will be applied, 3) the specific dollar amount of the increase or percent or increase, 4) the applicable dates of service within the rating period for which the unform increase applies, and 5) the roles and responsibilities of the State and the plan, as well as the timing of payment(s).

CMS proposes at § 438.6(c)(5)(iii)(C)(1) through (4) to require the contract to include 1) the maximum fee schedule the plan must ensure payments are below, 2) the procedure and diagnosis codes to which the fee schedule applies, 3) the applicable dates of service within the sating period for which the fee schedule applies, 4) details of the States exception process for plans and providers to follow if they are under contract obligations that result in the end to pay more than the maximum fee schedule.

CMS proposes at § 438.6(c)(5)(iii)(D)(1) through (6) to require that managed care plan contracts include a description of the following elements approved in the SDP arrangement: 1) the performance measures that payment will be conditioned upon, 2) the measurement period for those metrics 3) the baseline statistics against which performance will be based, 4) the performance targets that must be achieved on each metric for the provider to obtain the performance-based payment, 5) the methodology to determine if the provider qualifies for the performance-based payment as well as the amount of the payment, and 6) the roles and responsibilities of the State and the plan, the timing of payment(s) what to do with any unearned payments if application.

CMS proposes at § 438.6(c)(5)(iii)(E) to require the contract to describe 1) the Medicaid covered service(s) that the population or condition-based payment is made for, 2) the time period that the population-based or condition-based payment covers, 3) when the population-based or condition-based payment is to be made and how frequently, 4) a description of the attribution methodology, if one is used, 5) the roles and responsibilities of the State and the plan in operationalizing the attribution methodology if used.

CMS proposes at § 438.6(c)(5)(iv) to require the State include in the managed care contract any encounter reporting and separate reporting requirements that the State needs in order to audit the SDP and report provider-level payment amounts to CMS. Proposed § 438.6(c)(5)(v) would require that the State indicate

in the contract whether the State would be using a separate payment term as defined in § 438.6(a) to implement the SDP. CMS proposes to require in § 438.6(c)(5)(vi) that all SDPs must be specifically described and documented in MCO, PIHP, and PAHP contracts no later than 120 days after the start of the SDP or approval of the SDP under § 438.6(c)(2)(i), whichever is later.

Background/Rationale

CMS believes minimum requirements for SDP contract terms would assist states when developing their contacts, ensure that managed care plans receive necessary information on the State's intent and direction for the SDP, facilitate CMS' review of managed care contracts, and ensure compliance with the approved SDP preprint. In addition, these changes would reduce the risk and improve the clarity of SDP's for managed care plans.

Identifying the start and end date of the rating period would ensure the time period for which the SDP applies if clear to the managed care plans. Describing the provider class and payment arrangement would ensure compliance with the scope of the written prior approval issued by CMS.

Pertaining to § 438.6(c)(5)(iii)(C)(1) through (4), CMS believes an exception process is necessary for payment arrangements that limit how much a managed care plan can pay a provider to ensure that the MCO, PIHP, or a PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

Pertaining to § 438.6(c)(5)(vi), CMS highlights the timeframe is consistent with the timeframe being proposed for documenting separate payment terms in the managed care contract under § 438.6(c)(6)(v). They believe proposing to require States to document the SDP within these timeframes is reasonable given that the contracts would only have to document the SDP and the contract action could be submitted to CMS in draft form.

Comments

CMS seeks public comment on these proposals.

K. Including SDPs in Rate Certifications and Separate Payment Terms (section 2.l pgs. 169-187)

Proposed Changes

CMS proposes to re-designate the existing regulatory requirement at § 438.6(c)(2)(i) as § 438.6(c)(2)(ii)(J) to require that each SDP must be developed in accordance with § 438.4 and the standards specified in §§ 438.5, 438.7, and 438.8. This includes proposing to remove the current provision that SDPs must be developed in accordance with generally accepted actuarial principles and practices.

CMS proposes to amend § 438.6(a) to define "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. In addition, CMS proposes a new § 438.6(c)(6) that would specify requirements for the use of separate payment terms, which includes a new § 438.6(c)(6)(i) to require that all separate payment terms are reviewed and approved as part of the review of the SDP in § 438.6(c)(2).

CMS proposes a new requirement at § 438.6(c)(6)(ii) that would expressly prohibit States from using separate payment terms to fund SDPs that are exempted from the written prior approval process, specifically minimum fee schedules during State plan approved rates in § 438.6(c)(1)(iii)(A) and minimum fee schedules using approved Medicare fee schedules, as proposed in § 438.6(c)(1)(iii)(B). At § 438.6(c)(6)(iii), CMS proposes to require that each separate payment term be specific to both an individual SDP approved under r § 438.6(c)(2)(i) and to each Medicaid managed care program to provide clarity in the contract for the plan and facilitate State and Federal oversight of such terms.

CMS proposes a new requirement at § 438.6(c)(6)(iv) that the separate payment term would not exceed the total amount documented in the written prior approval for each SDP for which CMS has granted prior approval. CMS proposes to require as part of § 438.6(c)(6)(v) that States must document the separate payment term in the State's managed care contracts no later than 120 days after the start of the payment arrangement or written prior approval of the SDP, whichever is later. CMS proposes at § 438.6(c)(6)(v)(A) to prohibit States from amending the separate payment term after CMS approval except to account for an amendment to the payment methodology that is first approved by CMS as an amendment to the approved State directed payment.

CMS proposes four pieces of information that would be documented in the State's Medicaid managed care plan contracts in § 438.6(c)(6)(v)(B)(1) through (4), including 1) the total dollars that the State would pay to the plans for the individual SDP that CMS gave written prior approval 2) the timing and frequency of payments that would be made under the separate payment term from the State to the plans 3) a description or reference to the contract requirement for the specific SDP for which the separate payment term would be used, and 4) any reporting that the State requires to ensure appropriate reporting of the separate payment term purposes of MLR reporting under § 438.8.

CMS proposes to add a new § 438.7(f) that would require the State, through its actuary, to certify the total dollar amount for each separate payment term as detailed in the State's Medicaid managed care contract, consistent with the requirements of § 438.6(c)(6). In addition, CMS proposed to codify existing practices that are employed when reviewing State directed payments that use separate payment terms, including the following: the State may pay each MCO, PIHP, or PAHP a different amount under the separate payment term compared to other MCOs, PIHPs, or PAHPs so long as the aggregate total dollars paid to all MCOs, PIHPs, and PAHPs does not exceed the total dollars of the separate payment term for each program (§ 438.7(f)(1)), the State would be required to provide an estimate of the impact of the separate payment term on a rate cell basis (§ 438.7(f)(2)), the State would be required to submit documentation to CMS that includes the total number of the separate payment term in the rate certification consistent with the distribution methodology described in the State directed payment no later than 12 months following the end of the rating period (§ 438.7(f)(3)). Lastly, CMS proposes at § 438.7(f)(4) to require States to submit a rate certification or rate certification amendment incorporating the separate payment term within 120 days of either the start of the payment arrangement or written prior approval of the SDP, whichever is later.

Background/Rationale

Pertaining to including SDPs in rate certifications, CMS is concerned that inclusion of duplicative language "generally accepted actuarial principles and practices" could be interpreted as a requirement for an actuary to be involved in the development of the SDP arrangement and adherence to actuarial standards of practice (ASOPs), which may lead to unnecessary administrative burden. Further CMS believes States should have the flexibility to determine if they wish to involve actuaries in the development of each specific SFP arrangement. CMS clarified that that are not proposing changes to the requirements for actuarially sound capitation rates.

CMS strongly prefers that SDPs are included as adjustments to capitation rates since the method is most consistent with the nature of risk-based managed care. Thus, their proposals to amend § 438.6(a) to add a new definition for separate payment term, the addition of §§ 438.6(c)(6) and 438.7(f) are intended to maintain the State's ability to use separate payment terms while implementing necessary guardrails for fiscal and programmatic oversight.

Comments

CMS seeks public comment on the proposals as well as two alternative approaches, they are considering, which includes 1) requiring all SDPs to be included only through risk-based adjustments to capitation rates and eliminating the State's ability to use separate payment terms altogether and 2) further prohibiting the use of separate payment terms to all SDPs described in paragraph (c)(1)(iii), which would allow States to use separate payment terms for some payment arrangements and could incentivize States to consider quality-based payment models that can better improve health outcomes for Medicaid managed care enrollees.

CMS acknowledges that some States currently use separate payment terms, and these alternative proposals could cause some disruption as States evaluate changes to SDPs. For this reason, CMS also seeks public comment on whether or not CMS should consider a transition period in order to mitigate any disruptions.

L. SDPs Included through Adjustments to Base Capitation Rates (section 2.m pgs. 187-188)

Proposed Changes

CMS proposes at § 438.7(c)(4) that States must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under § 438.7(a) for any special contract provisions related to payment in § 438.6 not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.

CMS proposes to add a new regulatory requirement at § 438.7(c)(5) specifying that retroactive adjustments to capitation rates resulting from an SDP must be the result of an approved SDP being added to the contract.

CMS proposes a new regulatory requirement at § 438.7(c)(6) to require that States must submit the required rate certification documentation for SDPs incorporated through adjustments to base rates (either the initial rate certification or a revised rate certification) no later than 120 days after either the start date of the SDP approved under § 438.6(c)(2)(i) or 120 days after the date CMS issued written prior approval of the SDP, whichever is later.

Background/Rationale

CMS believes that providing the same flexibility for changes to rates for special contract provisions, including SDPs, is incongruent with the existing requirement at § 438.7(b)(6) that the rate certification include a description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract. In addition, CMS believes it is inconsistent with ensuring appropriate program integrity, so they believe their proposal addresses and clarifies the 105 percent threshold requirement.

Specifying that retroactive adjustments to capitation rates resulting from an SDP must be the result of an approved SDP being added to the contract would align with the proposed requirement at § 438.6(c)(6)(v)(A). In addition, CMS believes this proposed regulatory requirement is necessary to ensure the fiscal integrity of SDPs and their impact on rate development. CMS has observed that States through actuaries, submitted amendments to rates for SDPs which do not reflect changes in payment methodology, changes in benefit design, or general actuarial practices, but instead appear to belated to financing of the non-Federal share. CMS also cited the administrative burden for both States and the Federal government by delaying review of associated rate certification.

Comments

CMS seeks public comment on the proposals.

M. Including SDPs in Rate Certifications and Separate Payment Terms (section 2.n pgs. 188-194)

Proposed Changes

CMS proposes 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 Health and Human Services (HHS) Department Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

The State would have 30 days to appeal to the Board after an appellant receives a final written decision from CMS communicating a disapproval of a State directed payment. The case would then be assigned a presiding Board member who would preside over procedural matters and conduct record development in the case. Within 10 days of receiving the notice of appeal, the Board would assess the filing for completeness and jurisdiction. If it is found to be appropriately filed, the Board would acknowledge the notice and outline the next steps in the case. The State would then have 30 days to file its appeal brief, which would contain its argument for why the final decision of CMS was in error, and its appeal file, which would include the documents on which its arguments are based. Then, CMS would have 30 days to

submit its brief in response to the State's brief as well as any additional supporting documentation not already contained in the record. The State would be given fifteen days to submit its optional reply.

Background/Rationale

To be consistent with other CMS processes which issue formal disapprovals, such as those for SPA submissions and disallowances of State Medicaid claims, there should be a formal process for States to appeal should CMS issue disapproval of written prior approval for a State's SDP proposal. The alternative is that a State may seek redress in the courts, which can be costly and slow for both CMS and the States. We believe that States will benefit from and appreciate an established, consistent administrative process with which they are familiar.

CMS believes the Board would be the most appropriate entity to hear appeals of disapprovals of SDPs proposals for the following reasons. Foremost, while both the Board's and CMS Offices of Hearings and Inquiries' (OHI's) processes can resolve disputes, the Board's shorter goal resolution time of 6 to 9 months would better facilitate timely approval of managed care plan contracts and the payment of capitation payments. Medicaid managed care uses a prospective payment system of capitation payments and anything that delays approval of the managed care plans' contracts can have a significant adverse impact on a State's managed care program. Additionally, the Board's processes have the added flexibilities of allowing for mediation under 45 CFR 16.18, as well as not requiring, but allowing, a hearing, as described in 45 CFR 16.11. These differences in the Board regulations give additional options and possible efficiencies to the parties.

Comments

CMS seeks public comment on whether the Board or OHI appeals processes would best serve the purposes of resolving disputes fairly and efficiently.

N. Reporting Requirements to Support Oversight (section 2.o pgs. 194-200)

Proposed Changes

CMS proposes to require that manage care plans include SDPs and associated revenue as separate lines in the MLR reports to States; specifically, the amount of payments to providers made under SDPs that direct the managed care plan's expenditures as specified in § 438.6(c) and the payments from the State to the managed care plans for expenditures related to these SDPs.

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' Transformed Medicaid Statistical Information System (T-MSIS), and in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for SDPs that were in effort for the rating period, including amounts paid to individual providers.

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. In § 438.6(c)(4), they propose the minimum data fields that would need to be collected to provide the data needed to perform proper oversight of SDPs; in § 438.6(c)(4)(i) through (v), they outline the minimum data fields which include provider identifiers,

enrollee identifiers, managed care plan identifiers, procedure and diagnosis codes, and allowed, billed, and paid amounts.

Within § 438.6(c)(4)(i)(E), CMS proposes provider-specific paid amounts would submit a plan's negotiated payment amount, the amount of the State directed payments, the amount for any pass-through payments under § 438.6(d), and any other amounts included in the total paid to the provider to CMS no later than 180 days after each rating period. CMS also proposes that States would have to comply with the new reporting requirement after the rating period that begins after they release reporting instructions for submitting the information requirement by the proposal.

CMS proposes a conforming requirement at § 438.6(c)(5)(iv) to align with the proposal in § 438.6(c)(4); proposed paragraph (c)(5)(iv) would require States to document any reporting requirements necessary to comply with § 438.6(c)(4) in their managed care contracts.

Background/Rationale

The purpose of the data reporting to T-MSIS is to gain more information and insight into actual SDP spending at the individual provider-level. CMS cited MACPAC's June 2022 Report to Congress, which stated State directed payments are a large and rapidly growing form of Medicaid payments to providers, but there is no provider-level data on how the dollars in directed payments are being spent. Further, CMS believes implementing a provider-level SDP reporting requirement would facilitate their understanding of provider-level Medicaid reimbursement across delivery systems.

CMS shared that they considered that there are exiting data collection processes and systems established between CMS and States that could likely support this SDP reporting, like the required data collected through the Medicaid Budget and Expenditure System (MBES) as well as encounter data reported through T-MSIS. Additional data fields can easily be built into T-MSIS to capture more details about the paid amount, which would provide the information needed for analysis and oversight of SDP spending. In addition, CMS believes utilizing T-MSIS would substantially reduce unnecessary and duplicative reporting from States, would be an effective method to collect the data with minimal additional burden on managed care plans and States, and it would enable comprehensive analysis since the data would be included with all other T-MSIS data. They also considered whether to utilize a separate reporting mechanism for the new proposed reporting of SDP provider-level data, like building a new reporting portal, however, they cited the time and resources this would take, ultimately, citing T-MSIS as the most efficient option.

CMS believes 180 days is an adequate time for claims run out, submission of the necessary data to the State, and for the State to format the data for submission to CMS.

Comments

CMS seeks public comment on their proposals; specifically, they seek comment on the proposal to use T-MSIS for this new reporting, or whether another reporting vehicle such as MBES or other alternatives described in the proposed rulemaking would be better suited for SDP reporting. They also seek comment on how T-MSIS or another reporting vehicle could support capturing value-based payment arrangements in which payment is not triggered by an encounter or claim.

O. Applicability and Compliance Dates (section 2.p pgs. 200-202)

Proposed Changes

CMS proposes that States and managed care plans have to comply with § 438.6(a), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) through (J), (c)(2)(vi)(A), (c)(3), (c)(6)(i) through (iv), and 438.7(c)(4), (c)(5), and (f)(1) through (3) upon the effective date of the final rule, as these proposals are either technical corrections or clarifications of existing policies and standards.

CMS proposes that States and managed care plans would have to comply with § 438.6(c)(2)(iii), (vi)(B), (vi)(C)(1) and (2) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after the effective date of the final rule as these newly proposed requirements will provide States with increased flexibility and not require States to make changes to existing arrangements.

CMS proposes that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(H), (c)(2)(vi)(C)(3) and (4), (c)(2)(vii), (c)(2)(viii) and (ix), and (c)(5)(i) through (v) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after the effective date of the final rule.

CMS proposes that States and managed care plans would have to comply with § 438.6(c)(2)(ii)(D), (F), (c)(2)(iv), (c)(2)(v), and (c)(7) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after the effective date of the final rule as they believe States will need a sufficient period of time to address the policy elements within these proposals and operationalize them via various reporting, documentation and submission processes.

CMS proposes that States and managed care plans would have to comply with §§ 438.6 (c)(5)(vi), and (c)(6)(v), and 438.7(c)(6) and (f)(4) no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after the effective date of the final rule.

CMS proposes in § 438.6(c)(4) that States would be required to submit the initial TMSIS report subsequent to the first rating period following the release of CMS guidance on the content and form of the report.

Background/Rationale

CMS believes that beginning on or after 2 years after the effective date of the final rule is a reasonable timeframe for compliance because it allows States sufficient time to operationalize the timelines and requirements for preprint submissions that are newly established in these proposals while balancing the need to strengthen CMS oversight.

CNS chose the first rating period to begin on or after 3 years after the effective date of the final rule because they believe it strikes a balance between the work States would need to do to comply with these proposals and the urgency with which they believe these proposals should be implemented in order to strengthen and ensure appropriate and efficient operation of the Medicaid program.

Because these proposals establish new submission timelines and new requirements for contract and rate certification documentation, and because States could view the new requirements as substantial changes to the SDP process, CMS is proposing a longer timeline for compliance.

Comments

CMS seeks comments on the proposal and alternatives.

III. Medical Loss Ratio (MLR) Standards

A. Standards for Provider Incentives (section 3.a pgs. 204-210)

Proposed Changes

CMS proposes the following changes to incorporate more clearly defined, measurable, and well documented clinical and quality improvement standards to receive a bonus or incentive payment:

- Amend § 438.3(i)(3) and (4) to require states to have specific provisions for incentive payments in their contracts with managed care organizations. Specifically, to require alignment of performance period and MLR reporting period and require providers and managed Medicaid plans to sign and date incentive contracts prior to commencement of the reporting period.
- In § 438.3(i)(3)(iii), make changes to require all incentive payment contracts to include well-defined quality improvement or performance metrics for providers to meet.
- Change § 438.3(i)(3)(iv) to require a specific dollar amount that is linked to the incentives.
- Require in § 438.3(i)(4)(i) that the contract between state and MCO must have documentation to support the arrangement.
- Change § 438.3(i)(4)(ii) to prohibit attestations from serving as adequate documentation to support provider incentive payments.
- Modify § 438.3(i)(4)(iii) to include provisions that managed Medicaid plans must provide the incentive payment contracts upon state request and at a frequency defined by state.
- States have to comply with § 438.3(i)(3) and (4) no later than the rating period for contracts with managed Medicaid plans, PIHPS and PAHPS beginning on or after 60 days following the effective date of the final rule.
- Amend § 438.608 to cross reference these requirements in program integrity contract requirements section.
- Change §438.8(e)(2)(iii)(A) to require that for the provider bonus or incentive to be included in the MLR numerator, the provider bonus or incentive to be clearly linked to an objectively measurable, well-defined, and documented clinical or quality improvement standards.

Medical loss ratio standards are effective 60 days after the effective date of the rule.

Background/Rationale

Managed Medicaid plans typically have MLR limits and remit revenues in excess of this limit to states. Incentive payments can help some managed Medicaid inflate their MLR, thereby reducing their remittance to states. High incentive payments also increase future capitation rates. CMS review of state contracts with managed Medicaid plans revealed that 1) some contracts do not have improvement requirements for incentives, 2) provider performance periods do not always align with MLR reporting

periods, 3) incentive expectations are not always established prospectively, 4) and that documentation practices are often inconsistent between managed Medicaid plans for development of incentive plans.

Regarding the requirements for the bonus to be included in the numerator, CMS notes that the change would improve the accuracy of their MLR, as well as other components of managed care programs that rely on reported MLRs, such as capitation rate development and remittances. Further, a consistent methodology across multiple markets would allow for administrative efficiency for the states as they monitor their Medicaid and CHIP programs, and for issuers and managed care plans to collect and measure data necessary to calculate an MLR and provide reports.

CMS notes that by requiring States' contracts with managed care plans to specify how provider bonus or incentive payment arrangements would be structured in managed care plans' provider contracts, transparency around these arrangements would improve. In addition, by requiring the contracts to include more specific documentation requirements, CMS and States would be better able to ensure that provider bonus or incentive payments are not being used either to inappropriately increase the MLR to avoid paying potential remittances, inflate future capitation rates, or to simply move funds from a Medicaid managed care plan to an affiliated company.

CMS proposes that States and managed care plans would be required to comply with these requirements 60 days after the effective date of this final rule.

Marketplace plans are already required to have incentive payments linked to measurable and objective outcomes. As managed Medicaid and Marketplace plans are often administered by same entities, such required alignment will lead to greater administrative efficiency.

Comments

CMS solicits comments on the proposal, including whether additional documentation should be required. CMS also seeks comment on the timing for compliance.

B. Prohibited Costs in Quality Improvement Activities (section 3.b pgs. 210-211)

Proposed Changes

CMS proposes to amend § 438.8(e)(3)(i) to add a reference to Marketplace regulation that prohibits inclusion of overhead or indirect expenditure that are not related to health care quality improvement in MLR calculation.

CMS proposes that these requirements would be effective 60 days after the effective date of this final rule as they believe these proposals are critical for fiscal integrity in Medicaid and CHIP.

Background/Rationale

There are large inconsistencies between managed Medicaid plans in what is included within the MLR calculations, which leads to discrepancies in financial reporting. In 2022, via regulation, Marketplace plans were prohibited from including overhead or indirect expenses in their MLR calculations. Requiring

exclusion of overhead and indirect expenses in MLR calculation in Medicaid will bring financial and quality reporting alignment across various plans and improve administrative efficiency for entities that administer both plan types.

Comments

CMS solicits comments on the applicability date of the proposal.

C. Additional Requirements for Expense Allocation Methodology (section 3.c pgs. 211-213)

Proposed Changes

CMS proposes to change § 438.8(k)(1)(vii) to require that Medicaid managed care plans provide a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes, licensing or regulatory fees, and other non-claims costs, as described in § 158.170(b).

Background/Rationale

Medicaid managed care plans are required to report how much of the expenses are attributed to Medicaid vs. other non-Medicaid plans but are not required to provide details on how such expenses were attributed to Medicaid. This prevents CMS from determining whether Medicaid MLR is being inflated. Currently, Marketplace plans are required to provide detailed allocation methodology for their expenses and this rule will bring Medicaid and CHIP in alignment with marketplace plans.

CMS proposes that these requirements would be effective 60 days after the effective date of this final rule.

Comments

CMS solicits comments on this proposal.

D. Credibility Factor Adjustment to Publication Frequency (section 3.d pgs. 213-214)

Proposed Changes

CMS proposes to change § 438.8(h)(4) to remove “on an annual basis”.

Background/Rationale

The statistical methodology used to develop the credibility factors for adjustments of MLR in smaller plans do not warrant annual updates or changes to these factors. Therefore, the annual frequency will be removed from the regulation and future updates will be made when necessary.

Comments

CMS solicits comments on this proposal.

E. MCO, PIHP, or PAHP MLR Reporting Resubmission Requirements (section 3.e pgs. 214-216)

Proposed Changes

CMS proposes to change § 438.8(m) to replace "payment" with "rate" and insert "retroactive rate" before the word "change". These changes will require managed Medicaid plans to resubmit their MLR reports to state only if the capitation rates are changed, not the payments.

Background/Rationale

Current language requires managed Medicaid plans to resubmit their MLR reports to the state if "capitation payments" change. Many states retroactively deem individuals eligible for Medicaid and this results in additional capitation payments to managed Medicaid plans. Because this increases total capitation payments to the plans, the plans resubmit their MLR reports to states. States must review multiple MLR reports from plans despite no changes to the capitation rates. Proposed adjustment in language will result in reduced unnecessary administrative burden for both plans and states.

Comments

CMS solicits comments on this proposal.

F. Level of MLR Data Aggregation (section 3.f pgs. 216-217)

Proposed Changes

CMS proposes changes to § 438.74(a)(1) to replace "the" with "each" before "report(s)" and § 438.74(a)(2) to add language which specifies that summary description must be provided for each MCO, PIHP or PAHP contracted with the state. These changes will clarify that summaries for MLR reports submitted by the state to CMS must be provided for each plan that the state contracts with.

CMS proposes that these requirements would be effective 60 days after the effective date of this final rule.

Background/Rationale

States are required to submit a summary of MLR reports which it receives from contracted plans. Several states have submitted these reports for statewide aggregated data across all contracted plans as the regulation does not currently specify that these summaries must be plan specific. The proposed rule attempts to clarify this part of the regulation.

Comments

CMS solicits comments on this proposal.

G. Contract Requirements for Overpayments (section 3.g pgs. 217-221)

Proposed Changes

CMS proposes to make following changes:

- Modify § 438.608(a)(2) to define the word "prompt" as within 10 business days of identifying or recovering overpayment.
- Revise § 438.608(d)(3) to specify that any identified or recovered overpayment must be reported by plans to the states.

Background/Rationale

CMS has previously not defined "prompt" in these regulations, and this has resulted in large inconsistencies in defining prompts by states and managed Medicaid plans in contracts. CMS previously did not include "identified" in § 438.608(d)(3) for overpayments. This resulted in plans reporting only recovered payments and created incentives for plans to not seek recovery of the entire overpayment from providers. Such practices lead to inclusion of overpayments in MLR and capitation rates.

Comments

CMS solicits comments on these proposals.

H. Reporting of SDPs in the Medical Loss Ratio (section 3.h pgs. 221-226)

Proposed Changes

CMS proposes to establish new reporting requirements for Medicaid state directed payments (SDP) in §§ 438.8 and 438.74 to align with Medicaid FFS supplemental payments. The proposal specifically includes:

- Modification of § 438.8(k) to require two additional line items for SDPs – first line item would require reporting of expenditure associated with SDPs to providers for managed Medicaid plans under § 438.6(c). The other line item would require reporting of revenue received by managed Medicaid plan from state to make SDPs to providers.
- Change of § 438.74 to require two additional line items for SDPs – the first would require states to report amount of payment made to providers that direct Medicaid plans, PIHP or PAHP

expenditures under § 438.6(c). The other line item would require reporting of payments by state to managed Medicaid plans, PIHPs or PAHPs for approved SDPs under § 438.6(c). § 438.74(a)(4) will be added to state that compliance with these changes would be effective at the end of the rating period for contracts with managed Medicaid plans, PIHPs and PAHPs.

- Amendment of § 438.8(e)(2)(iii)(C) to specify that SDPs expenditures, regardless of whether they require approval by CMS, must be included in the MLR numerator.
- Change of § 438.8(f)(2)(vii) to specify that SDPs made to managed Medicaid plans, PIHPs or PAHPS for approved arrangements under 438.6(c) must be included in the MLR denominator as premium revenue.
- Removal of references to SDPs for managed care MLR reporting from § 457.1203(f).

Background/Rationale

SDPs are being used by many states under authority outlined in § 438.6(c). SDPs have grown in numbers and complexity over time, but CMS continues to have limited oversight, and this has been identified as a risk by MACPAC, HHS, OIG and GAO. Currently, states provide SDP estimates to CMS, and CMS may review SDP expenditures in state specific MLR reports as part of financial management review. CMS believes that consistent and systematic reporting of SDPs will allow it to execute better oversight of the process.

Comments

CMS solicits comments on these proposals.

IV. In Lieu of Services and Settings (ILOS)

A. Overview of ILOS Requirements (section 4.a pgs. 226-231)

Proposed Changes

CMS proposes to revise the regulatory requirements for ILOSs to specify the nature of the ILOSs that can be offered, effective the first rating period beginning on or after 60 days following the effective date of the final rule.

- CMS proposes to add a definition in § 438.2 for Medicaid 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) and acknowledge that 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 State plan-covered service or setting.
- CMS proposes to align the ILOS definition for CHIP by adding the definition provided in § 438.2 to § 457.10.

- CMS proposes to make several conforming changes in § 438.3(e)(2) to align the language with the proposed definition in § 438.2. CMS proposes to make the same conforming changes to the CHIP managed care plan contract requirements through the existing cross-reference at § 457.1201(e).
- CMS proposes to create a new section § 438.16 titled *ILOS requirements for Medicaid*, and the agency proposes to amend § 457.1201(c) and (e) to include cross-references to § 438.16 to adopt for separate CHIP.
- CMS proposes to add § 438.3(e)(2)(v) to explicitly provide an exception from the applicability of § 438.16 for short term stays, as specified in § 438.6(e), for inpatient mental health or substance use disorder treatment in an institution for mental diseases (IMD). CMS does not propose to adopt the IMD exclusion for separate CHIP.

Background/Rationale

In the 2016 final rule, CMS finalized that managed care plans have the flexibility under risk contracts to provide a substitute service or setting for a service or setting covered under the State plan when medically appropriate and cost effective. ILOSs are utilized by states and their managed care plans to strengthen access to services. CMS expects that States' and managed care plans' use of ILOSs, as well as associated Federal expenditures for these services and settings, will continue to increase. CMS' rationale for the proposed changes is that it is necessary to ensure adequate assessment of these substitute services and ongoing monitoring for appropriate utilization of ILOSs and beneficiary protections.

B. ILOS General Parameters (section 4.b pgs. 231-243)

Proposed Changes

CMS proposes to add several requirements in § 438.16 that ILOSs would have to meet, effective the first rating period beginning on or after 60 days following the effective date of the final rule.

- CMS proposes, in § 438.16(b), that an ILOS must be approvable as a service or setting through a State plan amendment or a waiver under section 1915(c) of the Act. Similarly for CHIP, CMS proposes that ILOSs must be consistent with services and settings approvable under sections 2103(a) through (c), 2105(a)(1)(D)(ii), and 2110(a) of the Act as well as the services and settings identified in § 438.16(b).

- CMS proposes to establish an ILOS cost percentage to limit allowable ILOS costs to a portion of the total costs for each managed care program that includes ILOS(s). Specifically, CMS proposes in § 438.16(c), that the ILOS cost percentage must be calculated based on capitation rates and capitation payments. Further, CMS proposes to define both a "projected ILOS cost percentage" and "final ILOS cost percentage" in § 438.16(a) as the amounts for each managed care program that includes ILOS(s) using the calculations proposed in § 438.16(c)(2) and (3), respectively. In § 438.16(c)(2), CMS proposes that the projected ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that would be attributable to all ILOSs, excluding short term stays in an IMD, for each managed care program (numerator) by the

projected total capitation payments for each managed care program and the projected total State directed payments that are paid as a separate payment term (denominator). In § 438.16(c)(3), CMS proposes that the final ILOS cost percentage would have to be calculated by dividing the portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD, for each managed care program (numerator) by the actual total capitation payments for each managed care program and the actual total State directed payments that are paid as a separate payment term (denominator). For CHIP, CMS proposes to align with the projected and final ILOS cost percentage calculations by amending § 457.1201(c) to include cross-references to § 438.16(c)(2) through (3). However, since pass-through payments and State directed payments are not applicable to separate CHIP, CMS propose to exclude all references to passthrough payments and State directed payments at § 457.1201(c).

- CMS proposes, at § 438.16(c)(1)(i), to require that the projected ILOS cost percentage could not exceed 5 percent and the final ILOS cost percentage could not exceed 5 percent. For CHIP, CMS proposes to amend § 457.1203(b) to adopt 5 percent ILOS cost percentage limits by amending § 457.1201(c) to include a new cross-reference to § 438.16(c)(1).

- CMS proposes, in § 438.16(c)(1)(ii), that the State's actuary would have to calculate the projected ILOS cost percentage and final ILOS cost percentage on an annual basis and recalculate these projections annually. CMS proposes at § 438.16(c)(1)(iii) to require that the projected ILOS cost percentage and the final ILOS cost percentage would have to be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices. For CHIP, CMS proposes to amend § 457.1201(c) to exclude requirements for certification by an actuary.

- CMS proposes to require, at § 438.16(c)(5)(i), that States annually submit to CMS for review the projected ILOS cost percentage for each managed care program as part of the Medicaid rate certification required in § 438.7(a). CMS proposes, at § 438.16(c)(5)(ii), to require that States must submit the final ILOS cost percentage report to CMS with the rate certification for the rating period beginning 2 years after the completion of each 12-month rating period that included an ILOS(s). CMS proposes, in § 438.16(c)(4), that States provide to CMS a summary report of the actual managed care plan costs for delivering ILOSs based on claims and encounter data provided by the managed care plans to States.

- CMS proposes that the ILOS documentation States would have to submit to CMS, as well as an evaluation States would have to complete, would vary based on a State's projected ILOS cost percentage for each managed care program. CMS proposes that documentation requirements for States with a projected ILOS cost percentage that is less than or equal to 1.5 percent would undergo a streamlined review, while States with a higher projected ILOS cost percentage would have more robust documentation requirements. Additionally, it proposes States with a higher final ILOS cost percentage would be required to submit an evaluation of ILOSs to CMS.

Background/Rationale

CMS proposes to make these changes because it believes that it is necessary to implement appropriate Federal protections to ensure the effective use of Medicaid and CHIP resources. CMS explains that ILOSs

can give States and managed care plans the opportunity to strengthen access to care and address unmet needs. Specifically, CMS explains that a limitation on the types of substitute services or settings that can be offered as an ILOS would help ensure effective use of Medicaid and CHIP resources. To increase accountability, CMS states that there should be a limit on the amount of expenditures for ILOSs. Limiting the expenditures can also help reduce inequities in the services and settings available to beneficiaries across delivery systems and ensure enrollees receive State plan-covered settings and services.

In terms of establishing the ILOS expenditure limit, CMS explains that the cost percentage and expenditure limit should be measured on a projected basis when capitation rates are developed and on a final basis after capitation payments are made by States to the managed care plans because capitation rates are developed prospectively based on historical utilization and cost experience. The cost percentage would also be based on each managed care program. CMS provides that rationale that the 5 percent is a reasonable limit on ILOS expenditures because it is high enough to ensure that ILOSs would be used effectively to achieve their intended purpose, but still low enough to ensure appropriate fiscal safeguards. CMS explains that regularly calculated the projected and final ILOS cost percentages ensures consistent application across all States and managed care programs. CMS also proved the rationale that including this percentage within the rate certification would reduce administrative burden for States and actuaries.

For documentation requirements, CMS explains that it would be appropriate to use a risk-based approach for States' documentation and evaluation requirements to balance States' administrative burden with ensuring fiscal safeguards and enrollee protections related to ILOSs. CMS proposes 1.5 percent for this risk-based approach in § 438.16(d)(2) because 5 percent is the proposed limit for the projected and final ILOS cost percentages, and CMS states that a greater degree of State documentation and CMS oversight is necessary for States that offer ILOSs that represent a higher share of overall managed care program costs.

Comments

CMS requests comment on whether 1 year after the completion of the rating period that included ILOS(s) is an insufficient amount of time for the final ILOS cost percentage be submitted to CMS.

C. Enrollee Rights and Protections (section 4.c pgs. 243-245)

Proposed Changes

- CMS proposes to specify, in § 438.3(e)(2)(ii)(A), that an enrollee who is offered or utilizes an ILOS would retain all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they would retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option.
- CMS also proposes to revise § 438.10(g)(2)(ix) to explicitly require that the rights and protections in § 438.3(e)(2)(ii) be included in enrollee handbooks if ILOSs are added to a managed care plan's contract. For separate CHIP, CMS proposes to amend § 457.1207, (which includes an existing cross-reference to § 438.10) to reference instead to the separate CHIP enrollee rights and protections under subparts K and L of part 457.

- CMS proposes to add § 438.3(e)(2)(ii)(B) to ensure that an ILOS would not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and a managed care plan may not deny an enrollee access to a service or setting covered under the State plan on the basis that an enrollee has been offered an ILOS as a substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past. For separate CHIP, CMS proposes to adopt the enrollee rights and protections at § 438.3(e)(2)(ii)(A) and (B) through an existing cross-reference at § 457.1201(e) and to amend § 457.1201(e) to acknowledge that the CHIP enrollee rights and protections are unique from those offered to Medicaid enrollees and are instead located under subparts K and L of part 457.
- CMS proposes requiring clear documentation of enrollee rights and protections in States' managed care plan contracts in § 438.16(d)(1)(v). For separate CHIP, CMS proposes to adopt this requirement in managed care plan contracts by amending § 457.1201(e) to include a cross-reference to § 438.16(d)(1)(v).

Background/Rationale

Since ILOSs can be offered as substitutes for covered State plan services and settings, CMS provides the rationale that it is important to identify the enrollee rights and managed care protections for individuals who are offered or opt to use an ILOS instead of receiving State plan-covered service or setting. CMS explains that these rights and protections are not explicitly stated in part 438. CMS explains that safeguards and protections are necessary to make clear that the provision or offer of an ILOS may not be used coercively or with the intent to interfere with the provision or availability of State plan-covered service and setting that an enrollee would otherwise be eligible to receive. CMS also states that these enrollee rights and protections must be clearly documented in States' managed care plan contracts.

D. Medically Appropriate and Cost Effective (section 4.d pgs. 246-251)

Proposed Changes

CMS proposes to expand the documentation requirements for ILOSs through the addition of requirements in § 438.16. Specifically, CMS proposes at § 438.16(d)(1), elements that must be included in any managed care plan contract that includes ILOS(s) to receive CMS approval.

CMS proposes § 438.16(d)(1)(i) and (ii) to require that States would include within each managed care plan contract that includes ILOS(s), the name and definition for each ILOS and clearly identify the State plan-covered service or setting for which each ILOS has been determined to be a medically appropriate and cost-effective substitute by the State. For separate CHIP, CMS proposes to adopt these requirements at § 438.16(d)(1)(i) and (ii) by amending § 457.1201(e) to include the cross-reference.

CMS proposes a new requirement at § 438.16(d)(1)(iii) to require States to document within each managed care plan contract the clinically defined target population(s) for which each ILOS has been determined to be a medically appropriate and cost effective substitute. For separate CHIP, CMS proposes

to adopt the new documentation requirements at § 438.16(d)(1)(iii) by amending § 457.1201(e) to include the cross-reference. CMS proposes using the phrase "clinically defined target populations".

CMS proposes, at § 438.16(d)(1)(iv), to require that the managed care plan contract document a process by which a licensed network or managed care plan staff provider would have to determine that an ILOS is medically appropriate for a specific enrollee. Under this proposal, this determination and documentation could be done by either a licensed network provider or a managed care plan staff provider. For separate CHIP, CMS proposes to adopt these requirements at § 438.16(d)(1)(iv) by amending § 457.1201(e) to include the cross-reference.

To specify the proposed additional documentation requirements for a State with a projected ILOS cost percentage that exceeds 1.5 percent, CMS proposes, at § 438.16(d)(2), the documentation requirements in paragraphs § 438.16(d)(2)(i) and (ii), and that this documentation would be submitted to CMS concurrent with the managed care plan contract that includes the ILOS(s). CMS proposes that the State submit a description of the process and supporting evidence the State used to determine that each ILOS would be a medically appropriate service or setting for the clinically defined target population(s). In § 438.16(d)(2)(ii), CMS proposes that the State provide a description of the process and supporting data that the State used to determine that each ILOS is a cost effective substitute for a State plan-covered service or setting for the defined target population(s). For separate CHIP, CMS proposes to adopt the new requirements at § 438.16(d)(2) by amending § 457.1201(e) to include the cross-reference.

CMS proposes to require at § 438.16(d)(3) that any State must provide additional documentation if CMS determines that the requested information would be pertinent to the review and approval of a contract that includes ILOS(s). For separate CHIP, CMS proposes to adopt the new requirements at § 438.16(d)(3) by amending § 457.1201(e) to include the cross-reference, except that references to rate certifications do not apply.

Background/Rationale

CMS provides that rationale that States are already required to authorize and identify ILOSs in each managed care plan contract, and as a result, it reasonable to require States to provide sufficient detail regarding any ILOSs covered under the contract and accounted for in the capitation rates. CMS states that it is important to ensure appropriate documentation to support a State's determination that an ILOS is a medically appropriate and cost effective substitute, and adequate ILOS documentation requirements for States would permit CMS and the State to better monitor the use of ILOSs, safeguard enrollee rights, facilitate fiscal accountability, and promote transparency to ensure the efficient and appropriate use of Medicaid and CHIP resources. CMS explains States do not always provided sufficient detail in their managed care plan contracts for Federal review, necessitating clear guidelines for documentation. CMS also provides the rationale that prospective identification of the target population for an ILOS is necessary to ensure capitation rates are developed in an actuarially sound manner. Although states may establish target population(s) for which an ILOS is medically appropriate, CMS asserts that the actual determination of medical appropriateness should be completed by a provider.

E. Payment and Rate Development (section 4.e pgs. 251-253)

Proposed Changes

CMS proposes to revise § 438.3(c)(1)(ii) to include "ILOS" to clearly acknowledge the inclusion of ILOSs in the final capitation rates and related capitation payments. CMS proposes including this technical change in separate CHIP regulations through an existing cross-reference at § 457.1201(c). CMS also proposes to revise § 438.7(b)(6) and the proposed § 438.7(c)(4) (see section I.B.2.l. of this proposed rule) to add "ILOS in § 438.3(e)(2)" to ensure any contract provision related to ILOSs must be documented in all rate certifications submitted to CMS for review and approval.

Background/Rationale

CMS provides the rationale that while ILOS utilization and actual costs, when allowed, are included in rate development, the existing regulations at § 438.3(c)(1)(ii) do not clearly acknowledge the inclusion of ILOSs in the final capitation rates and related capitation payments. CMS states that this proposed change is necessary to ensure compliance with proposed new regulatory requirements in § 438.16(c)(1)(i) and (c)(4)(i). CMS also states that it intends to issue additional guidance in the Medicaid Managed Care Rate Development Guide on the Federal standards and documentation requirements for adequately addressing ILOSs in all rate certifications.

F. State Monitoring (section 4.f pgs. 253-256)

Proposed Changes

CMS proposes in § 438.16(d)(1)(vi), to require that States include a contractual requirement that managed care plans utilize the specific codes established by the State to identify each ILOS in enrollee encounter data. States could require the use of specific HCPCS or CPT codes and modifiers, if needed, that identify each ILOS. For separate CHIP, while the provisions at § 438.66 are not applicable, CMS proposes to adopt the new coding requirements at § 438.16(d)(1)(vi) by amending § 457.1201(c) to include the cross-reference.

States are required to submit an annual performance report to CMS for each Medicaid managed care program administered by the State, known as the MCPAR. CMS proposes a minor revision to § 438.66(e)(2)(vi) to add the phrase "including any ILOS." CMS also intends to update the MCPAR report template to enable States to easily and clearly include ILOS data throughout the report.

Background/Rationale

CMS explains that it aims to continue to strengthen State and CMS oversight of each Medicaid managed care program with the addition of proposed text to explicitly address States' monitoring of ILOSs. In the 2015 notice of proposed rulemaking, CMS proposed expanded State monitoring requirements in § 438.66 because strong State management and oversight of managed care is important throughout a program's evolution, but is particularly critical when States transition large numbers of beneficiaries from FFS to

managed care or when new managed care plans are contracted. CMS provides the rationale that this logic is also applicable when a State expands the use of ILOSs as States have in recent years.

Supporting the use of specific codes, CMS explains that because ILOSs may not be easily identifiable in CPT and HCPCS, it is imperative that States identify specific codes and modifiers, if needed, for each ILOS and provide that information to its managed care plans to ensure consistent use of the codes. CMS also encourages States to work towards the development of standard CPT and HCPCS codes for ILOSs.

G. Retrospective Evaluation (section 4.g pgs. 256-266)

Proposed Changes

CMS proposes the following in § 438.16(e) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for CHIP:

- Require States to submit a retrospective evaluation to CMS of ILOSs, if the final ILOS cost percentage exceeds 1.5 percent. CMS strongly encourages all States that include ILOSs in their managed care plan contracts to conduct a retrospective evaluation of all ILOSs.
- An evaluation must be completed separately for each managed care program that includes an ILOS.
- A State's retrospective evaluation would have to use the 5 most recent years of accurate and validated data for the ILOSs. CMS proposes that States' evaluations should be retroactive to the first complete rating period following the effective date of this provision in which the ILOS was included in the managed care plan contracts and capitation rates.
- Require that States must utilize data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS.
- Require States to evaluate the impact each ILOS had on utilization of State plan-covered services and settings, including any associated savings.
- Require that States evaluate trends in managed care plan and enrollee use of each ILOS.
- Require that States use encounter data to evaluate if each ILOS is a cost effective and medically appropriate substitute for the identified covered service or setting under the State plan or a cost effective measure to reduce or prevent the future need to utilize the identified covered service or setting under the State plan.
- States must evaluate the impact of each ILOS on quality of care. CMS proposes that States provide the final ILOS cost percentage for each year in their retrospective evaluation, consistent with the report proposed in § 438.16(c)(5) with a declaration of compliance with the allowable 5 percent threshold proposed in § 438.16(c)(1)(i).
- Require States to evaluate the impact of each ILOS on health equity efforts undertaken by the State to mitigate health disparities. To do this, managed care plans should submit enrollee encounter data, to the extent possible, that includes comprehensive data on sex (including sexual orientation and gender identity), race, ethnicity, disability status, rurality and language spoken.
- To explicitly assert the agency's right to require States to provide additional 5-year retrospective evaluations.

Background/Rationale

CMS provides the rationale that States should evaluate and demonstrate that ILOSs are cost effective, medically appropriate, and an appropriate and efficient use of Medicaid and CHIP resources. CMS explains that it requires states to include separate data for each managed care program because a State with multiple managed care programs (for example, behavioral health, physical health, etc.) could have differing enrollee eligibility criteria, populations, covered benefits, managed care plan types, delivery models, geographic regions, or rating periods among the separate managed care programs. Including more than one managed care program in an evaluation would likely impact evaluation rigor and could dilute or even alter evaluation results due to the variability among managed care programs. For the 5-year evaluation period, CMS explains that this timeframe would provide sufficient time to collect complete data and allow managed care plans and enrollees to become comfortable with the available ILOSs and opt to provide or receive them, thus generating the necessary data for the evaluation.

CMS highlights that its proposed approach is aligned with identified best practices for evaluation. CMS provides the rationale that it is necessary to understand actual utilization of each ILOS to evaluate enrollee access to ILOSs and related trends that occur over time. As ILOSs are services and settings provided to Medicaid and CHIP managed care enrollees in lieu of State plan-covered services and settings it is important for States to evaluate the quality of care provided to enrollees who utilized ILOSs to ensure that the ILOS(s) are held to the same quality standards as the State plan services and settings enrollees would otherwise receive. CMS notes that it considered requiring states to conduct an independent evaluation; however, the agency is concerned that it would be overly burdensome for States to procure independent evaluators for ILOSs. CMS explains that States should use validated measure sets, when possible, to evaluate the quality of care of ILOSs, though it does not want to stifle State innovation in this area, so CMS is not proposing to require it.

For the evaluation of the impact of ILOSs on health equity, CMS explains that it is a critical component to measure enrollee experience, health outcomes, and whether ILOSs are an appropriate and efficient use of Medicaid and CHIP resources. As ILOSs can be an innovative option States may consider employing in Medicaid and CHIP managed care programs to address SDOH and HRSNs, and CMS expresses that it is critical to measure their impact on improving population health and reducing health disparities.

Comments

CMS seeks comment on whether the evaluation should be completed for each managed care program, across multiple managed care programs, each managed care plan contract, or at a level selected by the State.

CMS requests comments on the appropriate length of the evaluation period. CMS proposed that a State's retrospective evaluation would have to use the 5 most recent years of accurate and validated data for the ILOSs.

CMS seeks comments on the appropriate timing of an ILOS evaluation period.

CMS solicits comments on whether it should consider a requirement that States use an independent evaluator for ILOS evaluations.

CMS seeks public comment on whether or not the proposed retrospective evaluation should be incorporated into the CHIP Annual Report Template System (CARTS) for CHIP ILOSs.

H. State and CMS Oversight (section 4.h pgs. 266-270)

Proposed Changes

CMS proposes, in § 438.16(e)(3) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to establish processes and timelines for State and CMS oversight of ILOSs. CMS proposes to require that States notify CMS within 30 calendar days if the State determines that an ILOS is no longer a medically appropriate or cost-effective substitute for a State plan-covered service or setting, or the State identifies another area of noncompliance.

CMS proposes a Federal oversight process at § 438.16(e)(2)(ii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, which would permit CMS to terminate the use of an ILOS if there is noncompliance. In § 438.16(e)(2)(iii) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, CMS proposes a process for termination of an ILOS that would apply when a State terminates an ILOS, a managed care plan elects to no longer offer an ILOS to its enrollees, or CMS notifies the State that it must terminate an ILOS. In any of these events, CMS proposes that the State would be required to submit an ILOS transition plan to CMS for review and approval within 15 calendar days of the decision by the State to terminate an ILOS, a managed care plan notifying the State it will no longer offer an ILOS, or receipt of notice from CMS to terminate.

CMS proposes in § 438.16(e)(2)(iii)(A) through (D) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, the elements States should include in the transition plan for the ILOS. CMS proposes to require that States establish a process to notify enrollees that the ILOS they are currently receiving will be terminated as expeditiously as the enrollee's health condition requires. CMS also proposes, in § 438.16(e)(2)(iii)(B) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, to require that States create and make publicly available a transition of care policy to arrange for State plan services and settings to be provided timely and with minimal disruption to the care for any enrollees receiving an ILOS at the time of termination.

CMS proposes, in § 438.16(e)(2)(iii)(C) for Medicaid, and through a proposed cross-reference at § 457.1201(e) for separate CHIP, that the transition plan also include administrative actions that States would take to remove a terminated ILOS from the applicable managed care plan contract(s) and capitation rates. CMS proposes to direct States to remove the ILOS from the applicable managed care plan contracts and submit a modified contract to CMS for review and approval. CMS also proposes in § 438.16(e)(2)(iii)(D) to direct States to adjust the actuarially sound capitation rate(s), as needed, to remove utilization and cost of the ILOS from Medicaid capitation rates as required.

CMS proposes to adopt § 438.16(e)(2)(iii)(D) for separate CHIP through a new cross-reference at § 457.1201(e) to direct a State to evaluate if an adjustment to the capitation rate is needed to account for the removal of ILOS utilization and cost from the managed care plan contract in the event of the termination of a CHIP ILOS.

Background/Rationale

CMS provides the rationale 30 days is a reasonable period of time for a State to identify and confirm an area of noncompliance, and it is necessary that States notify CMS quickly so that CMS may assess and remediate issues of noncompliance that might cause harm to enrollees. Issues of noncompliance that would require State notification to CMS include, but are not limited to, contravening statutory requirements (for example, the provision of room and board), failure to safeguard the enrollee rights and protections enumerated under part 438, or the absence of the proposed provider documentation necessary to establish that an ILOS is medically appropriate for a specific enrollee.

For the 15 day window for submission of an ILOS transition plan following termination of an ILOS, CMS explains that a transition plan would need to be implemented immediately following an ILOS termination to safeguard enrollee health and safety, and to maintain the integrity and efficient operation of the Medicaid program Given the submission timeline and that ILOSs are provided at the option of the managed care plan, CMS explains that States should prepare an ILOS transition plan as part of the implementation process for any new ILOSs.

Comments

CMS solicits comments on whether the 30-day time period is reasonable and appropriate for a State to identify and confirm an area of noncompliance.

I. Applicability Dates (section 4.i pgs. 270)

Proposed Changes

CMS proposes that States and managed care plans would be required to comply with the provisions outlined in §§ 438.2, 438.3(c)(1)(ii) and (e)(2)(i) through (iv), 438.10(g)(2)(ix), 438.66(e)(2)(vi) and applicable cross-references for separate CHIP at §§ 457.10, 457.1201(c) and (e), and 457.1207 no later than the effective date of the final rule. Additionally, CMS proposes that States and managed care plans would have to comply with §§ 438.3(e)(2)(v), 438.16, 438.7(b)(6) no later than the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following the effective date of the final rule. For separate CHIP, CMS proposes to adopt the applicability date by adding § 457.1200(d).

Background/Rationale

CMS provides the rationale that the proposed applicability dates are appropriate because these proposals are technical corrections or clarifications of existing requirements.

Comments

CMS is not soliciting comment on these proposed changes.

V. Quality Assessment and Performance Improvement Program, State Quality Strategies and External Quality Review

A. Quality Assessment and Performance Improvement Program (section 5.a pgs. 270-272)

Proposed Changes

CMS proposes to change § 438.330(d)(4) by replacing reference to § 422.152(d) with § 422.152(c). This change would allow managed Medicaid plans who only serve dually eligible individuals to meet requirements for one or more of their Performance Improvement Projects (PIP) by using a Chronic Care Improvement Program (CCIP) in Medicare instead. The effective date is the end of the rating period for contracts beginning after the effective date of the final rule.

Background/Rationale

Existing regulations allow plans exclusively serving dually eligible beneficiaries to meet their PIP requirements by using a Quality Improvement Project (QIP). Both CCIP and QIP were part of the quality improvement requirements for Medicare Advantage (MA) plans. Allowing managed Medicaid plans to fulfill their quality improvement requirements by using CCIP or QIP was thought to reduce duplication and improve administrative efficiency. Subsequently, CMS eliminated requirements for QIP for MA plans. CMS wants to update § 438.330(d)(4) by removing reference to QIP, while allowing managed Medicaid plans who serve dually eligible beneficiaries to use CCIP to meet their PIP requirements.

B. Managed Care State Quality Strategies (section 5.b pgs. 272-275)

Proposed Changes

CMS proposes to make several changes in managed care plan quality strategies in § 438.340. Adoption of these strategies must be within 1 year after the final rule per § 438.310(d)(2).

- Revise § 438.340(c)(1) to require states to make quality strategy available to public comment at each 3-year renewal, even in absence of any significant changes.
- Modify § 438.340(c)(2)(ii) to clarify that the entire evaluation report of quality strategy must be posted on state's website.
- Change § 438.340(c)(3)(ii) to require that state submit their quality strategy to CMS every 3 years, even in absence of any significant changes.

Background/Rationale

CMS requires states to have a quality strategy and evaluate it at least every 3 years. Both the initial quality strategy, as well as any significant changes to the strategy must be posted for public comment and

submitted to CMS. CMS's proposal will require states to post quality strategy for public comment and submit it to CMS every 3 years, even when there are no significant changes. States will also be required to post the evaluation report of their quality strategy every three years on their website. CMS believes these changes will strengthen the quality strategy improvement process and allow CMS to provide regular feedback to states on their quality strategy.

C. External Quality Review (section 5.c pgs. 275-289)

1. Removal of PCCM (Primary Care Case Management) entities from scope of mandatory External Quality Review (pgs. 276-278)

Proposed Changes

Effective the date of the final rule, CMS proposes to change to § 438.310(c)(2) to remove PCCM from the managed care entities under § 438.350. This would remove PCCM entities from the scope of mandatory External Quality Reviews (EQR). CMS also proposes to remove reference to PCCM from §§ 438.310(b)(5), 438.358(a)(1), 438.364(a)(3) through (6), and 438.364(c)(2)(ii), and to remove the reference to § 438.350 from § 438.310(c)(2). Another included proposal is to modify § 438.354(c)(2)(iii) to provide clarification that if states require EQR organizations (EQRO) to review PCCM entities, the EQROs must be independent of the PCCMs. This proposal will also remove all references to PCCMs and relevant cross-references for separate CHIP.

Background/Rationale

PCCM entities may contract with managed Medicaid plans to provide case management to beneficiaries. In 2016, a final rule passed by CMS added PCCM to managed care entities subject to EQR. CMS has since learned that PCCMs can often be small entities, including an independent physician and an EQR will not result in meaningful findings or reporting for such entities. Further, EQR requirements may discourage small providers from contracting with managed Medicaid plans as PCCM. CMS hopes to remove such disincentives by eliminating EQR requirements for PCCMs. States will continue to have authority to subject PCCMs to EQR by EQROs. In such cases, CMS wants to ensure that EQROs are independent of the PCCMs that they review.

2. EQR Review Period (pgs. 278-281)

Proposed Changes

CMS proposes to add a new paragraph "(a)3" under § 438.358 which clarifies that a 12-month review period for applicable EQR activities beings on first day of the most recently concluded contract year or

calendar year, whichever is nearest to the date of EQR-related activity. CMS is proposing compliance with this proposed rule by December 31, 2025, and codifying this date in § 438.310(d)(3).

Background/Rationale

Three mandatory and one optional EQR activities refer to "preceding 12 months" for information collection and calculation. Confusion about what the preceding 12 months refer to led to inconsistencies in reporting.

3. **Using an Optional EQR Activity to Support Current and Proposed Managed Care Evaluation Requirements (pgs. 281-282)**

Proposed Changes

CMS proposes to add a new optional EQR activity at § 438.358(c)(7) to assist with evaluations of quality strategies, state directed payments (SDPs) and In-lieu of service settings (ILOS) that pertain to outcomes, quality or access to health care services.

Background/Rationale

In this draft rule, CMS has introduced additional reporting and monitoring requirements for quality strategy, SDPs and ILOSs. Using an optional EQR activities, EQROs can help managed Medicaid plans and states fulfil the newly proposed requirements. This optional activity will also provide EQROs guidance by CMS on how to perform these evaluations.

4. **Non-duplication of Mandatory EQR Activities with Medicare or Accreditation Review (pgs. 282-284)**

Proposed Changes

Effective date of the final rule, CMS proposes to remove the requirement for private, national accreditation organizations (PAOs) to apply for Medicare Advantage deeming authority from CMS (§ 438.360(a)(1)) in order for states to rely on PAO accreditation reviews in lieu of EQR.

Background/Rationale

CMS believes that the requirement for PAOs to receive MA deeming authority from CMS was too burdensome and unnecessary for both PAOs and CMS.

5. **External Quality Review Results (pgs. 284-289)**

Proposed Changes

CMS proposes to make 4 changes to the EQR technical reports:

1. Change § 438.364(a)(2)(iii) to require inclusion of any outcomes data and results from quantitative assessments for the applicable EQR activity and network adequacy mandatory validation activities to the EQR technical report.
2. Revise § 438.364(c)(1) and (c)(2)(i) to change the EQR technical report due date from April 30th to December 31st.
3. Modify § 438.364(c)(2)(i) to require that states notify CMS of when the EQR technical reports have been posted on their website within 14 calendar days of posting via a method of CMS preference.
4. Add requirements for EQR technical report retention in § 438.364(c)(2) for five years.

Background/Rationale

Currently, the EQR technical reports are required to include data on validation of the performance measures. However, other data which may help measure outcomes of PIPs are not currently required in the technical reports. This has resulted in EQROs not including any data about beneficiary participation, patient satisfaction and other measures which may provide insights into success of these measures. CMS believes that these additional data will help present a more complete picture of the success of quality measures. States are currently required to post the EQR technical reports on their website by April 30th. Most EQR measures are HEDIS measures, and HEDIS data audit and finalization concludes in June each year. CMS believes that change of technical report posting date will allow states to evaluate their HEDIS data and incorporate it into their EQR technical report.

Requiring states to communicate links to their EQR technical reports to CMS will ensure timeliness and inclusion of data in the CMS annual report. Retention of these reports for 5 years will be helpful for CMS in evaluating historical data for managed care and align the data retention timeframe with current duration of 1915(b) and 1115 waivers.

Comments

CMS is seeking comments on the EQR technical report posting date for states, and whether change of date to December 31st is sufficient. CMS is also seeking comments on best methods of communicating the link to EQR technical report to CMS.

VI. Medicaid Managed Care Quality Rating System

A. Definitions (section 6.c pg. 295-296)

Proposed Changes

CMS proposes the following definitions at § 438.500(a) for Medicaid and at § 457.1240(d) for CHIP:

- Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.
- Measurement year means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.
- Medicaid managed care quality rating system framework (QRS framework) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.
- Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system) means the rating system described in subpart D of parts 422 and 423 of this chapter.
- Qualified health plan rating system (QHP quality rating system) means the health plan quality rating system developed in accordance with 45 CFR 156.1120.
- Quality rating means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.
- Technical resource manual means the guidance described in § 438.530.
- Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

Background/Rationale

These definitions are relevant to the proposed regulations regarding implementation of the MAC QRS.

B. General Rule and Applicability (section 6.d pgs. 296-300)

Proposed Changes

CMS proposes to require states to implement their MAC QRS (or alternative QRS) by the end of the fourth calendar year following the effective date of the final rule (meaning the fourth calendar year following issuance of the final rule).

CMS also proposes that states provide a support system for beneficiaries or users of a state's MAC QRS, leveraging existing state resources. States would be required to use the beneficiary support system implemented under current § 438.71 to provide choice counseling to all beneficiaries, and assistance for enrollees on understanding how to use the managed care quality rating system to select a managed care plan, including the receipt of long-term services and supports.

CMS also proposes to revise the applicability of the QRS provisions to certain managed care plans. Specifically CMS specifies that the provisions apply to MCOs PIHPs, and PAHPs for delivery of services covered under Medicaid. Notably this excludes PCCM entities, non-emergency medical transport PAHPs, and D-SNP contracts where the D-SNP is only required to provide Medicaid coverage of Medicare cost-sharing.

Background/Rationale

This proposed change from the current 3-year implementation date under § 438.344(a) would provide States more time to make the operational and contractual changes needed to meet the requirements in this proposed rule and also give states flexibility to determine what time of year to publish their quality ratings.

Regarding the support system, CMS believes that states could leverage existing resources by developing new scripts and training existing staff.

C. Establishing and Modifying a Mandatory Measure Set for MAC QRS (section 6.e pgs. 300-326)

1. Future updates to the Mandatory Measure List Criteria (pgs. 302-307)

Proposed Changes

CMS proposes inclusion criteria for determining the initial set of measures and inclusion of future measures. A measure is only included in the proposed initial mandatory measure set and would only be added in the future if (1) it meets five of the six measure inclusion criteria proposed; (2) it would contribute to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas (for example, preventive health, long term services and supports, etc.) within a concise set of mandatory measures; and (3) the burdens associated with including the measure do not outweigh the benefits to the overall quality rating system framework of including the new measure based on the measure inclusion criteria. Six inclusion criteria include:

1. Usefulness to beneficiaries: is the measure meaningful and useful for beneficiaries and their caregivers when choosing a managed care plan;
2. Alignment: does the measure align with other CMS rating programs described in § 438.505(c) of this chapter;
3. Relevance: does the measure assess health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity;
4. Actionability: does the measure provide an opportunity for managed care plans to influence their performance on the measure;
5. Feasibility: is the measure based on data that are readily available, or available without undue burden on States and plans, such that it is feasible to report by most States and managed care plans; and
6. Scientific Acceptability: does the measure demonstrate scientific acceptability, meaning that the measure, as specified, produces consistent and credible results

Background/Rationale

CMS notes that while each of the six criteria is important to consider, it would be difficult for a measure to meet all six criteria.

However, CMS also found that many measures meet at least five of the six measure inclusion criteria, and without the additional guardrails in place, the set would quickly expand and become burdensome to states and plans. States and managed care plans interviewed generally recommended limiting the mandatory set to between 10 and 30 measures to ensure plans' ability to improve on selected measures and States' capacity to succeed in reporting, and to limit the impact of implementing a QRS on State and plan resources. Furthermore, MAC QRS website prototype user testing showed that beneficiaries were evenly split between those with high informational needs who preferred detailed information from a lot of measures and those who valued clear, concise information on the big picture using fewer measures. Thus, CMS incorporated the second and third inclusion standards to reflect this reasoning.

Comments

CMS seeks comment on the six criteria they are proposing to evaluate prospective measures for the mandatory measure set, and whether there are additional objective measure inclusion criteria that they should use to evaluate quality measures for inclusion as mandatory measures. Additionally, they seek comment on the proposal to require measures to meet five out of the six proposed criteria, and whether that threshold produces a sufficient number of measures to consider for the MAC QRS. Finally, they seek comment on the extent to which the measures in their proposed measure set meet the proposed measure inclusion criteria, including the reasons and/or supporting data for why the measure meets or does not meet the criteria.

CMS seeks comment on the standards proposed and how measures should be assessed using these standards. In particular, they seek comment on the appropriate balance of representation (of populations and performance areas) in the mandatory measure set and any additional considerations that may be missing. Further, they seek comment on whether there are additional considerations for the weighing of burdens and benefits of a measure.

2. Mandatory Measure Set (pgs. 307-314)

Proposed Changes

Using the criteria in the preceding section, CMS proposes the initial quality measure set of 18 measures below.

Background/Rationale

CMS received input through consultations with interested parties, on how to construct a mandatory measure set for the MAC QRS, including the number of measures, measure inclusion criteria, and performance areas and populations represented by the measures. After considering the priorities and other information gleaned through the several years of consultations, and applying the standards discussed CMS proposed an initial set of 18 mandatory measures that represents the collective input CMS received

during those consultations. These proposed mandatory measures reflect a wide range of preventive and chronic care measures representative of Medicaid and CHIP beneficiaries.

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
2801	NCQA	Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics (APP-CH)	The percentage of members who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment. Ages: 1 to 17	Administrative**
0004	NCQA	Initiation and Engagement of Substance Use Disorder (SUD) Treatment	The percentage of new SUD episodes for members that result in the following: • Initiation of SUD Treatment. Percentage of new SUD episodes for members that result in treatment initiation through an inpatient SUD admission, outpatient visit, intensive outpatient encounter or partial hospitalization, telehealth, or medication treatment within 14 days of the diagnosis • Engagement of SUD Treatment. The percentage of new SUD episodes for members that have evidence of treatment engagement within 34 days of the initiation visit. Ages: 13 – 17 | 18 to 64 | 65 and older	Administrative or EHR
0418* **	CMS	Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF)	The percentage of members screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool, and if positive, a follow-up plan is documented on the date of the eligible encounter. Ages: 12 to 17 | 18 to 64 | 65 and older	Administrative or EHR
3489	NCQA	Follow-Up After Hospitalization for Mental Illness (FUH)	The percentage of emergency department (ED) visits for members with a principal diagnosis of mental illness or intentional self-harm and who had a follow-up visit for mental illness. The following rates are reported: • The percentage of ED visits for mental illness for which the member received follow-up within 30 days of the ED visit (31 total days) • The percentage of ED visits for mental illness for which the beneficiary received follow-up within 7 days of the ED visit (8 total days). Ages: 6 to 17 | 18 to 64	Administrative
1392	NCQA	Well-Child Visits in the First 30 Months of Life (W30)	The percentage of members who had the following number of well-child visits with a primary care practitioner (PCP) during the last 15 months. The following rates are reported: • Well-Child Visits in the First 15 Months. Children who turned age 15 months during the measurement year: Six or more well-child visits. • Well-Child Visits for Age 15 Months to 30 Months. Children who turned age 30 months during the measurement year: Two or more well-child visits.	Administrative

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			Ages: 0 to 15 months | 15 to 30 months	
1516	NCQA	Child and Adolescent Well-Care Visits (WCV)	The percentage of members who had at least one comprehensive well-care visit with a primary care practitioner (PCP) or an obstetrician/gynecologist (OB/GYN) during the measurement year. Ages: 3 to 21	Administrative
2372	NCQA	Breast Cancer Screening (BCS)	The percentage of women who had a mammogram to screen for breast cancer. Ages: 50 to 74	Administrative, EHR, or Electronic Clinical Data System (ECDS)♦
0032	NCQA	Cervical Cancer Screening (CCS)	The percentage of women who were screened for cervical cancer using either of the following criteria: • Women ages 21 to 64 who had cervical cytology performed within the last 3 years • Women ages 30 to 64 who had cervical high-risk human papillomavirus (hrHPV) testing performed within the last 5 years • Women ages 30 to 64 who had cervical cytology/high-risk human papillomavirus (hrHPV) co-testing within the last 5 years Ages: 21 to 64	Administrative, hybrid, or EHR
0034	NCQA	Colorectal Cancer Screening (COL)	The percentage of members who had appropriate screening for colorectal cancer. Ages: 50 to 75	Administrative, hybrid, or ECDS
2517	DQA	Oral Evaluation, Dental Services (OEV)	The percentage of members who received a comprehensive or periodic oral evaluation within the reporting year. Ages: 0 to 20	Administrative
2902	OPA	Contraceptive Care - Postpartum Women (CCP)	Among women who had a live birth, the percentage that: 1. Were provided a most effective or moderately effective method of contraception within 3 and 60 days of delivery. 2. Were provided a long-acting reversible method of contraception (LARC) within 3 and 60 days of delivery. Ages: 15 to 20 | 21 to 44	Administrative
1517**	NCQA	Prenatal and Postpartum Care (PPC)	Percentage of deliveries of live births on or between October 8 of the year prior to the measurement year and October 7 of the measurement year that: 1. Received a prenatal care visit in the first trimester, on or before the enrollment start date or within 42 days of enrollment in Medicaid/CHIP (Timeliness of Prenatal Care Rate). 2. That had a postpartum visit on or between 7 and 84 days after delivery (Postpartum Care Rate). Ages: All Ages	Administrative or hybrid
0575/0059	NCQA	Hemoglobin A1c Control for Patients with Diabetes (HBD)	The percentage of members with diabetes (types 1 and 2) whose hemoglobin A1c (HbA1c) was at the following levels during the measurement year: • HbA1c control (<8.0%).	Administrative or hybrid

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• HbA1c poor control (>9.0%). Ages: 18 to 75	
1800	NCQA	Asthma Medication Ratio (AMR)	The percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. Ages: 5 to 18 | 19 to 64	Administrative
0018	NCQA	Controlling High Blood Pressure (CBP)	The percentage of members who had a diagnosis of hypertension and whose blood pressure (BP) was adequately controlled (< 140/90 mm Hg) during the measurement year. Ages: 18 to 85	Administrative, hybrid, or EHR
0006	AHRQ❖	CAHPS – How people rated their health plan	The percentage of members who rated their health plan a 9 or 10, where 0 is the worst health plan possible and 10 is the best health plan possible. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Getting care quickly	Composite of the following items: • The percentage of members who indicated that they always got care for illness, injury, or condition as soon as they needed, in the last six months. • The percentage of members who indicated they always got check-up or routine care as soon as they needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Getting needed care	Composite of the following items: • The percentage of members who indicated that it was always easy to get necessary care, tests, or treatment, in the last six months. • The percentage of members who indicated that they always got an appointment with a specialist as soon as needed, in the last six months. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – How well doctors communicate	Composite of the following items: • The percentage of members who indicated that their doctor always explained things in a way that was easy to understand. • The percentage of members who indicated that their doctor always listened carefully to enrollee. • The percentage of members who indicated that their doctor always showed respect for what enrollee had to say. • The percentage of members who indicated that their doctor always spent enough time with enrollee. Ages: 0 to 17 | 18 and older	Consumer Survey
0006	AHRQ❖	CAHPS – Health plan customer service	Composite of the following items:	Consumer Survey

NQF #*	Measure Steward	Measure Name	Measure Description	Data Collection Method
			• The percentage of members who indicated that customer service always gave necessary information or help, in the last six months. • The percentage of members who indicated that customer service always was courteous and respectful, in the last six months. Ages: 1 to 17 | 18 and older	
Not endorsed	CMS	MLTSS-1 LTSS Comprehensive Assessment and Update	The percentage of Medicaid MLTSS plan participants who have documentation of a comprehensive assessment in a specified timeframe that includes documentation of core elements. Two performance rates and two exclusions rates are reported for this measure: • Assessment of Core Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) • Assessment of Supplemental Elements. Medicaid MLTSS plan participants who had a long-term services and supports comprehensive assessment with nine core elements and at least 12 supplemental elements documented within 90 days of enrollment (for new participants) or during the measurement year (for established participants) Ages: 18 and older	Case Management Record Review
3547	CMS	MLTSS-7: LTSS Minimizing Institutional Length of Stay	The proportion of admissions to an institutional facility (for example, nursing facility, intermediate care facility for individuals with intellectual disabilities (ICF/IID)) for managed long-term services and support (MLTSS) plan enrollees that result in successful discharge to the community (community residence for 60 or more days) within 100 days of admission. This measure is reported as an observed rate and a risk-adjusted rate. Ages: 18 and older	Claims, Enrollment Data

* Refers to National Qualify Forum number. Measure endorsed by NQF can be found at NQF: Quality Positioning System ™ (qualityforum.org)
** Examples of administrative data collection methods are claims, encounters, vital records, and registries.
*** This measure is no longer endorsed by NQF.
♦ The HEDIS® Electronic Clinical Data System (ECDS) reporting standard defines data sources and types of structured data acceptable for use for a measure. The measures are provided as digital quality measures.
❖AHRQ is the measure steward for the survey instrument (NQF #0006) and NCQA is the developer of the survey administration protocol.

Comments

CMS welcomes comments on the proposed measure set.

3. Sub Regulatory Process to Update Mandatory Measure Set (pgs. 314-317)

Proposed Changes

CMS proposes to revise § 438.334(b)(2), redesignated at new proposed § 438.510(b) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS undergoes a subregulatory process to engage with States and other interested parties, to obtain expert and public input and recommendations prior to modifying the mandatory measure set. CMS proposes for these modifications to occur at least every other year.

CMS would engage in a two-step subregulatory process to obtain input and recommendations from States and other interested parties prior to finalizing certain types of changes to the mandatory measure set in the future. As a first step in the process, CMS would engage with States and interested parties (such as State officials, measure experts, health plans, beneficiaries and beneficiary advocates or organizations, tribal organizations, health plan associations, health care providers, external quality review organizations and other organizations that assist States with MAC QRS ratings) to evaluate the current mandatory measure set and make recommendations to add, remove, or update existing measures. The purpose of this evaluation would be to ensure the mandatory measures continue to meet the standards proposed in § 438.510(c).

The second step would be for CMS to provide public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) that includes the mandatory measures identified for addition, removal or updating through the public engagement step. Following the public notice and opportunity for public comments, CMS would publish the modifications to the mandatory measure set in the technical resource manual proposed at § 438.530.

If the proposed rule is finalized in 2024, the implementation deadline for each State's MAC QRS per proposed § 438.505(b) (which provides for such implementation to be no later than the fourth calendar year following publication of the final rule) would be December 31, 2028, and the first measurement year would be 2026.

CMS would initiate the proposed subregulatory process for the second display year (for example, 2029 if the rule is finalized in 2024) because the mandatory measure list would be 5 years old by then, and at least biennially thereafter.

Background/Rationale

CMS believes that requiring rulemaking to add new measures that may better meet beneficiaries' and States' needs or to remove measures whose utility has been surpassed by other measures would be overly restrictive and would undermine their ability to adapt the mandatory set to keep pace with changes in the quality field and user preferences. They also believe that a robust subregulatory process in which they interpret and apply substantive regulatory standards governing the measures to be included in the

mandatory measure set can ensure that any changes reflect the extensive input from interested parties that is needed.

The subregulatory process shares similarities with the QHP quality rating system, which uses a call letter process to gather feedback on measure updates. It also aligns with how the Core Sets are updated annually.

Comments

CMS seeks comment on whether they should instead initiate the subregulatory process to update the mandatory measure list for the third display year (for example, 2030 if the rule is finalized in 2024).

CMS also seeks comment on the types of engagement that would be important under this proposed subregulatory process (for example, workgroups, smaller meetings, requests for information), the types of experts that CMS should include in the engagement, and the use of a call letter or similar guidance to obtain public input.

CMS seeks comment on whether they should consider implementing the process on an annual basis, or another frequency, and why.

4. **Adding Mandatory Measures (pgs. 317-320)**

Proposed Changes

CMS clarifies that at its proposal at § 438.510(c), CMS would add a measure to the mandatory measure set when all three standards proposed at § 438.510(c)(1)-(3) are met, based on available information, including input from the subregulatory process. Under the proposal, at least biennially, CMS would use the subregulatory process proposed in § 438.510(b) to gather input that would be used to determine if a measure meets the proposed standards to be added to the mandatory measure set.

5. **Removing Existing Mandatory Measures (pgs. 320-321)**

Proposed Changes

CMS proposes at § 438.510(d)(1) that they may remove existing mandatory measures from the mandatory measure set if, after following the subregulatory process proposed at §438.510(b), they determine that the measure no longer meets the standards for the mandatory measure set proposed at 438.510(c).

CMS also proposes at § 438.510(d)(2) through (4) to provide CMS the authority to remove mandatory measures outside of the subregulatory process proposed in § 438.510(b) in three circumstances: when the measure steward (other than CMS) retires or stops maintaining a measure (proposed at § 438.510(d)(2)), if CMS determines that the clinical guidelines associated with the specifications of the measure change

such that the specifications no longer align with positive health outcomes (proposed at § 438.510(d)(3)), or if CMS determines that a measure shows low statistical reliability under the standard identified in § 422.164(e) of this chapter (proposed at § 438.510(d)(4)).

Background/Rationale

CMS notes that these proposed criteria for removing measures outside the subregulatory process align with the current regulations governing the MA and Part D quality rating system.

The proposal to allow CMS to remove a measure if an external measure steward retires or stops maintaining a mandatory measure would allow flexibility to ensure that measures included in the QRS mandatory measure set are maintained by the measure steward and consistent with the measure steward's underlying standards of clinical meaningfulness, reliability, and appropriateness for measures. Additionally, when there is a change in clinical guidelines such that measure specifications no longer align with or promote positive health outcomes, CMS believes it would be appropriate to remove the measure. Finally, CMS is proposing that CMS would have the authority to remove measures that show low statistical reliability (that is, how much variation between measure values that is due to real differences in quality versus random variation), using the same standard that is applied to the MA and Part D quality rating system.

CMS believes these criteria will allow CMS to swiftly remove measures that are no longer appropriate quality indicators of health plan performance.

Comments

CMS seeks comments on whether there are additional circumstances in which we should be able to remove a mandatory measure without engaging in the subregulatory process proposed at § 438.510(b).

6. Updating Mandatory Measure Technical Specifications (pgs. 321-324)

Proposed Changes

CMS proposes rules at § 438.510(e) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), address how CMS would handle updates to mandatory measures in the MAC QRS that are a result of changes made by a measure steward other than CMS to an existing mandatory measure's technical specifications.

First, CMS proposes that they would update the technical resource manual to revise descriptions of the existing mandatory measures that undergo non substantive measure technical specification changes. CMS then proposes codifying examples of the types of updates that are non-substantive under the proposal. Examples include but are not limited to:

- If the change narrows the denominator or population covered by the measure with no other changes
- If the change does not meaningfully impact the numerator or denominator of the measure

- If revisions are made to the clinical codes without change in the target population or the intent of the measure and the target population
- If the measure specification change provides additional clarifications for reporting, without changing the intent of the measure

Second, CMS proposes that they may update an existing mandatory measure that has undergone a substantive measure specification update only after completing the subregulatory process proposed in 438.510(b).

Background/Rationale

In alignment with current practices in the MA and Part D quality rating system and the Core Sets, CMS is not proposing to use the subregulatory process proposed in § 438.510(b) for non-substantive changes because they believe they reflect routine measure maintenance by measures stewards that do not significantly affect the measure and would not need additional review by the workgroup and CMS.

Comments

CMS seeks comment on their proposal to incorporate substantive measure specification updates to existing mandatory measures only after consultation with States, other interested parties, and the public, or whether they should consider a separate process for these types of updates.

7. Finalization and Display of Mandatory Measures and Updates (pgs. 324-326)

Proposed Changes

In new paragraph § 438.510(f) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), CMS proposes that it would communicate modifications to the mandatory measure set and the timeline States would be given to implement modifications to the mandatory measure set in the annual technical resource manual. CMS proposes to use the technical resource manual described in proposed § 438.530 to communicate the final updates.

CMS proposes that states would be given at least 2 calendar years from the start of the measurement year immediately following the technical resource manual in which the mandatory measure addition or substantive update was finalized to display the measurement results and ratings using the new or updated measure(s).

CMS proposes the same implementation timeline for substantive updates to existing mandatory measures, since they believe these should be treated in the same manner as new measures.

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 measures removed from the mandatory set as additional measures.

Background/Rationale

CMS believes that giving States at least 2 years would allow for contract and systems updates when new measures are added or substantive updates are made to the mandatory measure set.

Comments

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.

CMS seeks comment on the flexibility for lack of specific deadline for states to stop display of a measure considering the criteria under which measures can be removed at proposed § 438.510(d).

CMS seeks comment on whether their timeframes are appropriate for updates to the mandatory measure set or whether they should consider allowing for more or less time, and why.

D. MAC QRS Methodology (section 6.f pgs. 326-338)

Proposed Changes

CMS proposes, at § 438.515(a)(1) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d)), that States must collect the data necessary to calculate quality ratings for mandatory measures from their contracted managed care plans and, as applicable and available without undue burden, the State's Medicaid fee-for-service program and Medicare. Specifically, they propose that data be collected from managed care plans that meet a minimum enrollment threshold of 500 or more enrollees on July 1 of the measurement year. This enrollment threshold is the same as the enrollment threshold for the QHP quality rating system requirement at section 1311(c)(4) of the Patient Protection and Affordable Care Act.

CMS proposes at 438.515(a)(1)(ii) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that States would also be required to collect available data from the State's Medicaid fee-for-service (FFS) program, Medicare (including Medicare Advantage plans), or both if all necessary data cannot be provided by the managed care plans for the measures and collection of these data 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 need to collect both managed care and FFS data to calculate quality ratings for the managed care plans participating in its behavioral health managed care program for many of CMS' proposed behavioral health mandatory measures. Similarly, if a managed care plan provides services to enrollees who are dually eligible for Medicare and Medicaid services, it would be necessary for the State to collect data about services provided by Medicare to such enrollees to calculate quality ratings for some measures included on the proposed mandatory set.

CMS proposes in § 438.515(a)(3) that States use the validated data to calculate performance rates for managed care plans. Under this proposal, States would calculate, for each mandatory measure, a measure performance rate for each managed care plan whose contract includes a service or action being assessed by the measure, as determined by the State. Under this proposal, the mandatory measures would be

assigned to the plan(s) based on whether the plan's contract covers the service or action being assessed by the measure, as identified by the State.

As proposed at § 438.515(a)(4) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), States would be required to issue quality ratings as measure performance rates (that is, the individual percentage rates calculated under § 438.515(a)(3)). For example, a managed care plan that furnishes behavioral health services would likely be issued a measure performance rate for each of the proposed behavioral health mandatory measures, depending on the availability of data. This replaces the current regulation requiring states to issue an annual single quality rating to each managed care plan.

CMS has not yet tested domain level quality ratings with beneficiaries, and thus is proposing that it will engage with states, beneficiaries, and other interested parties before proposing to implement domain-level quality ratings for managed care plans.

To ensure that services provided to all Medicaid beneficiaries are reflected in each managed care plan's quality ratings, CMS proposes at § 438.515(b)(1) that States must ensure that the quality ratings issued under proposed § 438.515(a)(4) include data for all beneficiaries who receive coverage from the managed care plan for a service or action for which data are required to calculate the quality rating. This includes beneficiaries who are dually eligible for Medicare and Medicaid and receive services through the Medicaid managed care plan, subject to the availability of data about the services received by dually eligible individuals.

In § 438.515(b)(2) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), CMS proposes that States would be required to calculate quality ratings at the plan level by program. States that offer multiple managed care programs would calculate plan level ratings for each managed care plan participating in a single managed care program using only the service data described in § 438.515(b)(1) of beneficiaries enrolled in that managed care plan under that managed care program. A managed care plan that participates in multiple managed care programs would receive a distinct rating for each of these programs.

Background/Rationale

CMS believes that requiring States to calculate quality ratings for plans with fewer than 500 enrollees would be overly burdensome, as these plans may have limited resources for collecting and reporting data, and are more likely than plans with higher enrollment to have small denominator sizes that would make it inappropriate to issue and display quality ratings for some measures due to privacy or validity concerns. Further, through an analysis of 2019 Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files (which are research-optimized files of T-MSIS data), they determined that neither the number of managed care plans nor the percentage of beneficiaries reported in the MAC QRS would be significantly reduced by excluding plans with enrollment below 500.

CMS considered requiring States to collect data only from their contracted managed care plans and then only when a plan is able to provide all data necessary to calculate and issue a quality rating for a given performance measure, which is a common practice among measure stewards. However, they are concerned that there would be instances where there is no single plan from which a State could collect all data necessary to calculate one or more of the measures on the mandatory measure list. For example, of

the 18 measures on the proposed mandatory measure set, four require data from more than one setting, including three of our proposed behavioral health mandatory measures.

CMS believes that their proposal is aligned with ongoing efforts to expand access to health plan data at both the State and Federal level.

CMS' user testing suggests that displaying managed care plan quality ratings both at the individual measure and the domain level would be most desirable to beneficiaries. However, CMS did not significantly test domain level quality ratings and believe that additional engagement with interested parties and beneficiary testing would be necessary before requiring States to calculate and issue domain-level ratings.

The proposed plan level ratings for each managed care program would produce quality ratings that are most representative of the care beneficiaries can expect to experience because each rating would be calculated only from data for beneficiaries enrolled in the same managed care plan under the same program. CMS believe that this approach best balances the need for representative ratings with the level of effort States must employ to calculate quality ratings for the MAC QRS, while also accommodating the current way that States structure their overall Medicaid and CHIP program and the need for comparable quality ratings both within and among States.

Comments

CMS seeks comment on the proposed requirement that States collect available data from multiple sources on the mandatory measures. In addition, we request comment on the type of technical assistance that would be most helpful in assisting States in obtaining and using data from the sources specified in the proposed regulation.

CMS seeks comment on their proposal to issue individual performance rates and seek additional input on our decision not to require additional percentage ratings to reflect a national baseline for each mandatory measure.

CMS seeks feedback on our proposal to include individual percent scores, intended approach to domain-level ratings, and potential MAC QRS care domains.

CMS seeks comment on how its proposed policy to calculate plan level ratings for each managed care program would interact with their proposed minimum enrollment threshold, such as an analysis that assesses the extent to which a state's smaller plans may report missing data messages.

E. MAC QRS Website Display (section 6.g pgs. 338-354)

1. Introduction (pgs. 339-341)

Proposed Changes

CMS proposes at § 438.520 that States display a MAC QRS website that includes: (1) clear information that is understandable and usable for navigating a MAC QRS website; (2) interactive features that allows users to tailor specific information, such as formulary, provider directory, and quality ratings based on their entered data; (3) standardized information so that users can compare managed care programs and plans, based on our identified information; (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.

CMS will implement the website display in two phases. The first phase, implemented at the end of the fourth year, would encompass the state developing the MAC QRS website, displaying quality ratings, and ensuring that users can access information on plan providers, drug coverage, and viewing quality ratings by sex, race, ethnicity and dual eligibility status from the MAC QRS website.

In the second phase, required at least two years after the first phase, States would be required to modify the website to provide a more interactive user experience with more information readily available to users on the MAC QRS website.

Background/Rationale

Based on feedback CMS received during protype testing, CMS believes that these components are critically important to ensuring quality rating information can be readily understood by beneficiaries.

Comments

CMS seeks comment on which requirements should be phased in as well as how much time would be needed.

2. Navigational and Orienting Information (pgs. 342-344)

Proposed Changes

CMS proposes certain navigational requirements for the MAC QRS website display requirements in proposed § 438.520(a)(1). Specifically:

- In § 438.520(a)(1)(i) that States must provide users with information necessary to understand and navigate the MAC QRS display, including a requirement to provide users with information on the MAC QRS purpose, relevant information on dual eligibility and enrollment through Medicare, Medicaid, and CHIP, and an overview of how the MAC QRS website can be used to select a managed care plan.
- In § 438.520(a)(1)(ii) that States must provide information on how to access the beneficiary support system required under existing § 438.71 to answer questions related to the MAC QRS Since beneficiary support systems are not required for separate CHIP, our proposed amendment to § 457.1240(d) excludes references to this requirement.
- Require states to inform users of how any information they provide would be used.

- Require states to provide users with information or hyperlinks that direct users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan. This requirement ensures that users can easily navigate to the next steps in the plan selection process after reviewing the MAC QRS website.

CMS believe that States can implement these features by relying on existing public information or expanding current requirements.

Background/Rationale

In its user testing, CMS found that providing upfront clear information about what the MAC QRS is (a State run, unbiased source of information on managed care plans and their performance) and is not (a sales funnel for a particular managed care plan) and what it can do (help compare available managed care plans and their quality and performance) and what it cannot do (determine eligibility for Medicaid and CHIP or enroll beneficiaries in a health plan) allowed participants to quickly determine the purpose of the MAC QRS and whether the information available would be a useful tool for them when selecting a managed care plan. They also found that some beneficiaries initially needed additional background on relevant programs such as Medicaid, CHIP, and Medicare to understand if they were eligible for, or enrolled in, a plan or program with ratings or information available through the MAC QRS.

Comments

CMS seeks comment on whether beneficiary supports similar to those proposed for Medicaid should be required for States for separate CHIP in connection with the MAC QRS information or on a broader basis through future rulemaking.

3. Tailoring of MAC QRS Display Content (pgs. 344-349)

Proposed Changes

CMS proposes at § 438.520(a)(2)(i) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that each State's website must allow users to view available plans for which the user may be eligible based on users' age, geographic location, and dual eligibility status, as well as other demographic data identified by us in display guidance. States would retain the flexibility to allow users to use additional information or eligibility criteria to further narrow down available managed care plans, such as searching by health condition like pregnancy or diabetes.

States would be given at least two additional years after a State's initial implementation of their MAC QRS (that is, two additional years after the date proposed at § 438.505(a)(2) for initial implementation) to display provider directory and drug coverage information for each managed care plan through an integrated, interactive search feature that allows users to identify plans that cover certain providers and prescriptions.

In § 438.520(a)(2)(v) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), CMS proposes a first phase of implementation for this information that

would require States to display quality ratings for mandatory measures stratified by factors including dual eligibility status, race and ethnicity, and sex. To reduce burden on States, CMS would permit States to report, if finalized, the same measurement and stratification methodologies and classifications as those proposed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule and the Access proposed rule.

In the first phase of implementation, a State's website would need to provide access to quality ratings that reflect the quality of care furnished to all of a plan's enrollees, as well as quality ratings that reflect the quality of care furnished to these subpopulations of a plan's enrollees. Furthermore, many testing participants shared their concern that health outcomes and customer experience may vary when stratified by race, ethnicity, or sex. CMS also believes that those who are dually eligible to receive Medicare and full Medicaid benefits would find it particularly useful to see quality ratings that focus specifically on the experience of such dually eligible beneficiaries. They believe that such ratings would allow beneficiaries who are dually eligible for Medicare and Medicaid to best identify a high-quality health plan, given the unique access considerations among this population. States would be required to display this information by the general MAC QRS implementation date proposed under § 438.505(a)(2).

Background/Rationale

Measuring and making available performance reports on a stratified basis will assist in identifying health disparities. Driving improvements in quality is a cornerstone of the CMS approach to advancing health equity and also align with the CMS Strategic Priorities. CMS believes that its selection of initial stratification factors is mostly likely to be collected compared to their other proposed stratification factors.

Comments

CMS seeks comment on its phased-in approach and a reasonable timeline for the second phase. In addition, they seek comment on the display requirements and technical assistance needs.

CMS seeks comment on the proposal including the timeline for implementation, technical assistance that may be necessary for States to implement the proposed feature, and the proposed factors by which such quality ratings would be stratified.

4. **Plan Comparison Information (pgs. 349-351)**

Proposed Changes

CMS proposes in § 438.520(a)(3) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), to require States to display, for each managed care plan, standardized information identified by CMS that allows users to compare available managed care plans and programs, including the name, website, and customer service telephone hot line of each managed care plan; premium and cost sharing information; a summary of covered benefits; certain metrics of managed care plan access and performance; and whether the managed care plan offers an integrated Medicare-

Medicaid plan. States would be required to identify comparative information about plans, specifically differences in premiums, cost-sharing, and benefits among managed care plans, to help users quickly identify where managed care plans do and do not differ.

Under proposed § 438.520(a)(3)(v), States would also be required to provide on the QRS website certain metrics of managed care plan performance that States must make available to the public under Part 438, subparts B and D regulations, including certain data most recently reported to CMS on each managed care program under § 438.66(e) (Medicaid only) and the results of secret shopper survey proposed at § 438.68(f) in this proposed rule. Proposed paragraph (a)(3)(v) authorizes CMS to specify the metrics that are required to be displayed this way.

Lastly, at § 438.530(a)(3)(vi), CMS is proposing to require States to indicate when a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D-SNP and to provide a link to the integrated plan's rating under the MA and Part D quality rating system.

Background/Rationale

States already report information related to grievances, appeals, availability and accessibility of covered services under § 438.66(e) and CMS believes that displaying some of this information would be responsive to input received from r testing participants and improve transparency for beneficiaries without imposing significant burden on States since the information is already reported to CMS. States could choose to integrate these metrics into the display of MAC QRS measures on the MAC QRS website. These proposed requirements also support CMS' goal for the MAC QRS to be a one-stop-shop where beneficiaries can access a wide variety of information on plan quality and performance in a user-friendly format to help inform their decision making.

Comments

CMS seeks comment on the inclusion of these metrics, and whether we should consider phasing in certain metrics first before others.

CMS seeks comment on their proposal to require States to provide standardized information that users may rely on to compare managed care plans and request feedback on the feasibility of providing this information by the initial implementation date.

5. Information on Quality Ratings (pgs. 351-353)

Proposed Changes

CMS proposes in § 438.520 for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.124, that States would provide plain language descriptions of the importance and impact of each quality measure.

CMS also proposes states be required to indicate the measurement period during which data were produced to calculate the displayed quality ratings. CMS also proposes that States must provide on the

MAC QRS website when, how, and by whom quality ratings have been validated. This information would be provided in plain language and convey the role of parties (other than the rated plans) in validating data used to calculate the quality ratings, which will promote transparency and trustworthiness in the data. CMS notes that states may use the External Quality Review optional activity described at § 438.358(c)(6) for EQRO assistance with quality ratings and link to the validated data included in the EQR technical reports.

CMS also proposes to periodically consult with interested parties, including MAC QRS users such as Medicaid and CHIP beneficiaries and their caregivers, to maintain and update the website display requirements for the information required.

Background/Rationale

CMS found that a simple explanation of what a quality measure is assessing, as well as how the measure relates to a beneficiary's health and well-being, were most helpful to users in understanding displayed quality ratings.

CMS also believes that user preferences for how information should be displayed may change over time as the available data and the technology that enables website display of available data evolves. To ensure that the MAC QRS website continues to be a useful tool, they intend to periodically engage in additional consultations with MAC QRS users as part of a continuous improvement approach.

Comments

CMS seeks comment on the display requirement proposed in § 438.520(a)(4) and request feedback on the feasibility of implementing these requirements by the initial implementation date proposed at§ 438.505(a)(2).

6. **Display of Additional Measures Not on the Mandatory Measure Set (pgs. 353-354)**

Proposed Changes

CMS proposes to require States to obtain input from prospective MAC QRS users, including beneficiaries, their caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy. States could meet this requirement by ensuring that beneficiary members of the MCAC are present when obtaining input from the State's MCAC, or may engage in direct beneficiary interviews, focus groups, or prototype testing.

CMS also proposes that States must document the input received from prospective MAC QRS users on such additional measures, the modifications made to the proposed additional measures in response to the input, and rationale for not accepting input. CMS is also proposing this documentation to be reported as part of the MAC QRS annual report for States that currently publish a QRS-like website, measures that are not in the mandatory measure set would be considered additional measures and would be subject to

this process prior to display. If a State obtained user input for the additional measure prior to displaying the measure on its current website, the State may use this input to meet this requirement.

Background/Rationale

In this proposed rule, CMS has extensively noted the importance of the prospective user testing they engaged in and the extent to which this feedback directed their design of the MAC QRS framework and selection of the preliminary mandatory measure set. Just as beneficiary participation was, and will continue to be, critical in design of the MAC QRS, they believe beneficiary participation is critical in the identification of any additional measures included in a State's MAC QRS.

F. Alternative Quality Rating System (section 6.h pgs. 354-356)

Proposed Changes

First, CMS proposes to remove the language in current § 438.334(c)(1) that includes the use of "different performance measures" being subject to their review and approval as part of an alternative QRS. Current regulations at § 438.334(c)(1) require States to submit for review and approval an alternative QRS request to include measures different than those included in the mandatory measure set identified by CMS. Instead of requiring approval of different measures, CMS is proposing that States would have the flexibility to add measures that are not mandatory measures without prior approval from CMS.

Second, CMS proposes to further define the criteria and process for determining if an alternative QRS system is substantially comparable to the MAC QRS methodology described in proposed § 438.515. The current regulations at § 438.334(c)(4) provide that CMS will issue guidance on the criteria and process for determining if an alternative QRS meets the substantial comparability standard in current § 438.334(c)(1)(ii), redesignated at § 438.525(a)(2). CMS proposes to eliminate § 438.334(c)(4) and redesignate as proposed § 438.525(c)(2)(i) through (iii) and specify in proposed § 438.525(c)(2)(iv) that States will be responsible for submitting documents and evidence that demonstrates compliance with the substantial comparability standards.

CMS proposes to redesignate § 438.334(c)(2), with revisions, at § 438.525(c)(2)(iv) to allow States to provide additional supporting documents and evidence that they believe demonstrates that a proposed alternative QRS would yield information regarding managed care plan performance that is substantially comparable to that yielded by the MAC QRS methodology described in § 438.515. Examples of such additional supporting documents could include a summary of the results of a quantitative or qualitative analysis of why the proposed alternative methodology is substantially comparable or calculations of mandatory measures with the alternative methodology and with the methodology required under § 438.515.

Background/Rationale

CMS believes requiring States to obtain approval to include measures not required by CMS creates unnecessary administrative burden for both States and CMS. CMS believes that their proposed policy

provides flexibility to States while ensuring that the results on the mandatory measures remain comparable among States.

CMS believes that eliminating § 438.334(c)(4) is appropriate as this rulemaking provides an opportunity for States and other interested parties to submit comments on how CMS should evaluate alternative quality rating systems for substantial comparability.

Comments

CMS seeks comment on these proposals, in particular, the described process and documentation for assessing whether a proposed alternative QRS framework is substantially comparable, by when States would need alternative QRS guidance, and by when States would need to receive approval of an alternative QRS request to implement the alternative by the implementation date specified in proposed § 438.505(a)(2).

G. Annual Technical Resource Manual (section 6.i pgs. 356-359)

Proposed Changes

CMS proposes at § 438.530(a) for Medicaid, and for separate CHIP by cross-reference through a proposed amendment at § 457.1240(d), that CMS will develop and update annually a Medicaid managed care quality rating system technical resource manual no later than August 1, 2025, and update it annually thereafter. Required contents of the technical manual include:

- The mandatory measure set
- The specific MAC QRS measures newly added to or removed from the prior year's mandatory set as well as a summary of the engagement and public comments received during the engagement process
- The subset of mandatory measures that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by CMS
- How to use the methodology described in § 438.515 to calculate quality ratings for managed care plans.
- Technical specifications for mandatory measures produced by measures stewards as part of the proposed annual technical resource manual

CMS is proposing the general rule that CMS take into account stratification guidance issued by the measure steward and other CMS reporting programs when identifying which measures, and by which factors, States must stratify mandatory measures.

CMS is considering releasing an updated technical resource manual at least five months prior to the measurement period for which the technical resource manual will apply. This is in alignment with the proposed date for the first technical resource manual of August 1, 2025 for a 2026 measurement year, and would ensure that States have enough time to implement any necessary changes before the measurement period and, if necessary, submit and receive approval for an alternative QRS request.

Background/Rationale

CMS believes providing clear and detailed information for reporting on MAC QRS measures not only supports States in implementing their MAC QRS but is also essential for consistent reporting and comparable quality ratings across States and managed care plans. This manual would include information needed by States and managed care plans to calculate and issue quality ratings for all mandatory measures that States would be required to report under this proposed rule.

Comments

CMS seeks comment on whether this timing is appropriate for States to implement any changes included in the reporting and technical guidance for the initial measurement year as well as subsequent measurement years.

H. Reporting (section 6.j pgs. 359-361)

Proposed Changes

CMS proposes requirements at § 438.535 for States to submit to CMS, upon request, information on their MAC QRS to support oversight of Medicaid and CHIP and compliance with MAC QRS requirements. The report would include:

- A list of all measures included in the state's MAC QRS, including the list of mandatory measures reported and any additional measures
- An attestation that the displayed quality ratings for all mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate any additional measures when it deviates from the methodology proposed in § 438.515
- If a State chooses to display additional quality measures, a description of and the required documentation for the process required under § 438.520(b)
- The date on which the State publishes or updates their quality ratings for the State's managed care plans
- The link to the State's MAC QRS website to enable CMS to ensure the MAC QRS ratings are current
- The use of any technical specification adjustments to MAC QRS mandatory measures
- A summary of each alternative QRS approved by CMS, including effective dates.

Background/Rationale

CMS notes that this ensures beneficiaries can meaningfully compare ratings between plans, and to help CMS monitor trends in additional measures and use of permissible modifications to measure specifications used among States, which could inform future additions to the mandatory measures and modifications of our methodology.

Comments

CMS seeks comment on whether states prefer one annual reporting date or a date that is relative to their MAC QRS updates.