CLIENT ALERT: EXTERNAL QUALITY REVIEW

CMS Final Rule: Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS-2439-F)

On May 10, 2024, the Centers for Medicare & Medicaid Services (CMS) published a final rule titled: Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality (CMS-2439-F) in the Federal Register. Myers and Stauffer is providing this client alert to states to make them aware of several notable provisions specific to the external quality review (EQR) standards and to help inform each state's evaluation of the final rule language and potential concerns.

For the full rule text, see: https://www.federalregister.gov/public-inspection/2024-08085/medicaid-program-medicaid-and-childrens-health-insurance-program-managed-care-access-finance-and

EQR protocols are part of the tools available to states to monitor their managed care delivery systems. Some of the protocols are required, while others are voluntary. In this final rule, CMS is requiring several changes to the EQR regulations that seek to accomplish two overarching goals: (1) eliminate unnecessary burdensome requirements; and (2) make EQR more meaningful for driving quality improvement. Increased transparency of the data and results are part of this goal so that states can use the results of the protocols to make informed decisions about the Medicaid program.

The current standards (§§ 438.350, 438.354, 438.358, 438.360, 438.364, 457.1201, 457.1240, and 457.1250) provide requirements for annual reporting related to Medicaid managed care programs on quality, timeliness, and access to health care services. The activities are performed by states or a qualified EQR organization (EQRO), and a technical report is submitted to CMS, which describes the data and results.

The final rule, aimed to strengthen the standards and monitoring applicable to EQR requirements in the Medicaid managed care environment, will do the following:

- Remove certain primary care case management organizations (PCCMs) described in § 438.310(c)(2) from the mandatory review set forth in the 2016 Medicaid Managed Care Final Rule.
- Define the 12-month EQR review period for all but one of the EQR-related activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c). States must comply with these updates to § 438.358 no later than April 30.

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- Provide optional protocols with enhanced matching funds (up to 75 percent), including a new optional protocol to evaluate in lieu of services (ILOSs) and state-directed payments (SDPs).
- Use Medicare or accreditation reviews for EQR.
- Require enhanced reporting of EQR results §§ 438.364 and 457.1250(a).
  - Data included in EQR Technical Reports.
  - Notifying CMS when annual EQR Technical Reports are posted.
  - Revising website requirements for historical EQR Technical Reports.

Additional discussion for each of these elements is included below.

1. Removal of PCCM Entities from Scope of Mandatory External Quality Review (§ 438.310(c)(2)).
2. EQR Review Period (§ 438.358).
3. Using an Optional EQR Activity to Support Current Managed Care Evaluation Requirements (§ 438.358(c)(7)).
4. Non-Duplication of Mandatory EQR Activities with Medicare or Accreditation Review (§ 438.360).
5. External Quality Review Results (§§ 438.364 and 457.1250(a)).

1. Removal of PCCM Entities from Scope of Mandatory External Quality Review (§ 438.310(c)(2))

PCCMs, described in § 438.310(c)(2), will be removed from the mandatory EQR activities set forth in the 2016 Medicaid Managed Care Final Rule. A PCCM is recognized as a physician or a physician group practice or, at the state option, a physician assistant, nurse practitioner, or certified nurse-midwife that contracts with the state to furnish case management services to Medicaid beneficiaries. The 2016 final rule added "PCCM entity," as defined in §§ 438.2 and 457.10 as an organization that provides one or more additional functions to the case management services, such as development of care plans. Based on contract reviews and other information, CMS is removing PCCM entities from the managed care entities subject to EQR. Other risk-bearing PCCM requirements are not impacted the final rule.

States may perform EQR-related activities and additional oversight activities that may be similar to EQR; however, these activities will not be subject to the EQR regulations.

Applicability date: The revision becomes effective as of the effective date of the final rule.

2. EQR Review Period (§ 438.358)

The current regulations refer to most EQR activities as performed using information from the preceding 12 months; however, it is not clearly defined as to which 12-month period. This has resulted in a lack of uniformity in the review periods in the annual reports. To support the use of the reports for quality improvement and oversight, CMS is modifying the regulation to ensure consistency and to align data reported with the most recently available information.

The final rule will add a new paragraph (a)(3) in § 438.358 to define the 12-month review period for all but one the EQR-related activities described in § 438.358(b)(1) and the optional activities described in § 438.358(c). The one exception is the activity described in § 438.350(b)(1)(iii), which requires a review within the previous three years.

- Under the revised § 438.358(a)(3), the 12-month review period for the applicable EQR activities begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity.
- The 12-month period for the EQR activities does not have to be same. For example, performance measurement validation can be performed with a different 12-month period than the performance improvement project (PIP).
- At § 438.358(b)(1) and (c), CMS is also requiring that the EQR-related activities must be performed in the 12 months preceding the finalization and publication of the annual report.
- These modifications are designed to allow for more recent data being publicly posted in the annual technical report, and work towards the consistency that will make the annual technical report more meaningful.

Applicability date: States are required to comply with these updates to § 438.358 no later than **April 30**.

3. Using an Optional EQR Activity to Support Current Managed Care Evaluation Requirements (§ 438.358(c)(7))

CMS is adding a new optional protocol to evaluate the quality strategies, in lieu of services or settings (ILOSs), and state directed payments (SDPs). CMS' reviews of states' quality strategies indicate the need for more technical assistance for the states. CMS will develop this new optional EQR activity, in coordination with the National Governors Association, to assist with the evaluation activities of quality strategies, SDPs and ILOSs, that pertain to outcomes, quality, or access to health care services. CMS also clarified that states are allowed to evaluate the quality strategy, SDPs, and ILOSs themselves. CMS intends to provide guidance and once published, states can claim FFP match for this activity.

The final rule will not include separate CHIP evaluations of SDPs; however, retrospective evaluations of ILOSs will be required.

Applicability date: This optional activity is available to states as of the effective date of the final rule.

4. Non-Duplication of Mandatory EQR Activities with Medicare or Accreditation Review (§ 438.360)

Section 438.360 has provided an option for states to exempt MCOs from EQR activities that would be duplicated as part of either a Medicare review of a Medicare Advantage plan or a private accreditation review. To exercise that option, the private accreditation organization (PAO) must be recognized by CMS as applying standards at least as stringent as Medicare under the procedures in § 422.158. PAOs must therefore obtain deeming authority from CMS before a state could use the PAO's accreditation review of the health plan.

CMS believes this causes an administrative burden and may restrict the use of the EQR non-duplication option, so the final rule removes the requirement that PAOs must apply for deeming authority for states to rely on PAO accreditation reviews in lieu of EQR activities.

States will still be required to ensure the review standards are in compliance and will need to explain the rationale of the state's determination that the activity is comparable.

Applicability date: This revision becomes effective as of the effective date of the final rule.

5. External Quality Review Results (§§ 438.364 and 457.1250(a))

A. Data included in EQR Technical Reports

The current regulations describe the information to be included in the annual technical report and the public availability of the reports; however, the regulations limit the data included in the reports to performance measurement data. Other types of data, including data from the network adequacy validation activity, are not required in the report.

CMS is requiring that the Technical Reports include any outcomes data and results from quantitative assessments, whether the data was validated, and requiring similar data and results from the network adequacy validation activity. This change intends to make the annual technical report a more meaningful and effective tool to drive quality improvement and oversight activities.

CMS is adding guidance related to stratification of performance measures, which would allow states to monitor disparities and address equity gaps. CMS is intending to release future guidance within the EQR protocols.

Applicability date: States are required to comply with updates to the type of data in the EQR technical report no later than one year from the issuance of the associated protocol.

B. Revising the date annual EQR Technical Reports must be finalized and posted

Currently, the annual Technical Reports are to be completed, available on the state's website, and submitted to CMS by April 30. Most states use Healthcare Effectiveness Data and Information Set (HEDIS) measures, which use the previous calendar year's data and are audited and finalized in June each year. CMS had proposed to change the April 30 date to following December 31; however, this proposed change will not be part of the final rule. April 30 will remain the Technical Report due date, going forward.

C. Notifying CMS when annual EQR Technical Reports are posted.

States are not currently required to notify CMS when EQR Technical Reports are completed and posted to the state's website. CMS is revising § 438.364(c)(2)(i) to require that states notify CMS within 14 calendar days of posting their EQR Technical Reports on their website.

Applicability date: This revision becomes effective as of the effective date of the final rule.

D. Revising website requirements for historical EQR Technical Reports

States are currently encouraged to keep previous EQR Technical Reports on their website. The rule will require states to maintain at least the previous five years of EQR Technical Reports on their website.

Applicability date: States are required to comply no later than December 31, 2025.

Next Steps:

- Assess contractual requirements in the managed care organizations, EQROs, and other entities that may have EQR responsibilities. The contractual requirements may need to be amended to address the rule requirements, as finalized.
- Timelines for EQR activities may affect other requirements for reporting and auditing the MCOs may have that could be adjusted to accommodate the new rules.

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