

Responses to Comments Received after Federal Register Notice on Revised External Quality Review Protocols

CMS received four formal sets of comments in response to the February 17, 2012 notice on the proposed revisions to the External Quality Review Protocols. One informal comment was emailed from a State Medicaid agency directly to a CMS representative. The commenters were the Tennessee Medicaid Director, Health Services Advisory Group (HSAG), the Association for Community Affiliated Plans (ACAP), and Delmarva. HSAG and Delmarva are both External Quality Review Organizations (EQRO). ACAP is an association for Medicaid managed care organizations (MCOs). As the comments differed, we will address each in turn.

Comments on Protocol 1 - Tennessee Medicaid

A commenter from Tennessee Medicaid noted that Protocol 1, the compliance protocol, was too prescriptive in its listing of MCO staff required, particularly MCO leaders, at the EQRO on site interviews (also see Protocol 1 Attachment D). The commenter suggested that CMS allow the EQRO discretion to invite fewer people so long as it felt that it could obtain the required information without all of the listed MCO staff members.

CMS Response

CMS agrees with the comment and has included language in Protocol 1 to indicate that the EQRO has discretion to meet with less than the full list of MCO employees in situations where the EQRO can obtain the required information without the attendance of all MCO employees listed in the Protocol.

Justification

It may be difficult to assemble all of the listed MCO staff during the short period that an EQRO surveyor is reviewing the MCO. The revised language will allow the EQRO to excuse the attendance of MCO staff members that may be unavailable.

Comments on Protocol 3 – New Jersey Medicaid informal comment via email

A commenter from New Jersey noted that in Protocol 3, Step 8, in the section for “Assessment” on page 16, language on validation of performance improvement projects (PIPs) was unclear where the text reads “realistic and unambitious.”

CMS Response

The intended language was “realistic and unambiguous.” This error has been corrected and the language now reads “realistic and unambiguous.”

Justification

This corrects the terminology to language that was intended.

Comments on Protocol 3 from HSAG External Quality Review Organization

- 1) The change from use of the word indicator to variable is inconsistent throughout the protocol. In most instances in Steps 8, 9, and 10, the protocols refer to “indicator.” We suggest using the word “indicator” to describe the measure. The word “variable” implies that it will or have the potential to change from measurement to measurement.
- 2) Pages 6-7: Please consider switching the order of Steps 3 and 4. The study population should be identified and defined (Step 4) prior to selecting the study indicators (Step 3) used to measure and track performance where the denominator is derived directly from the study population identified.
- 3) Pages 14-15: Please consider switching Steps 7 and 8. In order for a MCO to identify the specific improvement strategies it will implement to improve performance (Step 7), the MCO should first conduct data analyses and interpret the results associated with baseline or remeasurement data (Step 8).
- 4) Page 17, Step 9, bullets B. and C. appear to ask the same thing. Should these bullets be consolidated into one bullet?

CMS Responses

- 1) Where the word “variable” is used with the same meaning as indicator, we will uniformly use the word “indicator.” “Indicator” is also listed in Appendix III – Glossary.
- 2) CMS agrees to switch the order of Steps 3 and 4
- 3) CMS agrees to switch the order of Steps 7 and 8
- 4) CMS agrees that question B and C are redundant and will eliminate question B.

Justification

CMS concurs with the commenter recommendations. The requested changes will provide clarification to the language in Protocol 3.

Comments from Association for Community Affiliated Plans (ACAP)

ACAP recommends several changes to the protocols. ACAP’s first request is for the protocols to address unnecessary duplication of costs in requiring an EQRO to revalidate performance measures where an approved HEDIS auditor has already validated the HEDIS measures.

Specifically ACAP recommends that the protocols require deeming for validation of performance measures. Secondly, ACAP suggests that states be flexible and engage the MCOs early on decisions related to State mandated PIPs. Thirdly, it requests that MCOs be allowed to append their response to an EQRO review to assure that the MCOs view is reflected in the final EQR report. Finally, ACAP notes that the EQR review process takes so long that that it delays timely action and asks for federal timeframes to speed up the process.

CMS Response

CMS agrees with many of the points raised by ACAP, but has limited authority as to what can be required in the protocols under 42 CFR 438, subpart E. The first concern regarding duplication of costs for validation of performance measures that are validated through the HEDIS process arises because the approved HEDIS auditor is paid by the MCO and, therefore, not considered “independent” under 42 CFR 438.354. Lack of “independence” means the original auditor’s work may not be used to meet the EQR validation requirement. CMS does not have the regulatory authority to change the protocols to include deeming of validation of performance measures.

Second, the present regulatory language on PIPs does not allow CMS to require that States consult MCOs prior to implementation. However, CMS can encourage States to include MCOs in the identification of PIP topics and methodologies so that relevant clinical, administrative, and population-based improvement efforts are addressed as part of the State’s overall strategy to improve health care delivery and outcomes of the people it serves. CMS has included language in the Protocols that encourage States to consider use of the voluntary CHIPRA child core performance measures, as well as nationally recognized performance improvement initiatives such the HHS Partnership for Patients and Million Hearts Campaign.

Third, CMS does not have the authority to require or preclude States from appending MCO responses to the EQRO technical report. However, to ensure that there is no violation of the “independence” requirement under 42 C.F.R. § 438.354, it must be clearly identified in the EQRO technical report that the MCO response is separate and distinct from the EQRO’s assessment.

Fourth, CMS agrees the timeframe for issuing the EQRO report varies by State, and therefore, usefulness of the data for implementing meaningful quality improvement efforts can also vary. CMS does not have the authority to specify a timeframe for issuing EQR reports. However, CMS strongly encourages States to make available final EQR Technical Reports by April of each year, for data no older than 15 months. This submission timeframe will align with the collection and annual reporting on managed care data by the Secretary each September 30th, as required under the Children’s Health Insurance Program Reauthorization Act (CHIPRA) [Sec. 401 (c)(2)] and the Affordable Care Act [Sec. 2701 (d)(2)].

Justification

The EQR protocols are technical manuals which must be consistent with existing regulations. CMS thanks the commenter for raising these significant issues, which will be considered in any future revisions to the managed care regulations. For revisions to the EQR Protocols, CMS has

provided enhanced guidance to States and EQROs with suggestions on areas of opportunity to improve the timeliness and meaningfulness of the information reported in the final EQR technical reports so that State managed care program performance information can accurately be reported in the Annual Secretary's Report on Quality of Care each year. These edits were included in the EQR Background section and Protocol 1.

Comments on Protocol 5 – Delmarva External Quality Review Organization

A commenter from Delmarva noted that, while Protocol 5 describes eight activities, only three of the eight are covered in the Worksheet Attachment to the Protocol.

CMS Response

The worksheet does not address all eight activities, only the first three, which were thought to require a more detailed explanation. The other five activities are explained in the main text. Clarification will be noted in the Protocol as to why the worksheet only covers the first three activities. Additionally, CMS will change the title of Protocol 5, Attachment A from "Survey Validation Worksheet" to "Survey Validation Worksheet for the Initial Three Activities" to avoid concern that the final five activities were inadvertently omitted.

Justification

The modification of language in the Protocol will clarify that the Appendix was only intended for the first three activities.

Additional Comments from Delmarva External Quality Review Organization

1) Appendix III-EQRP Glossary of Terms

The HEDIS® acronym is defined as Health Effectiveness Data Information Set. The correct acronym description is *Healthcare* Effectiveness Data and Information Set.

2) Protocol 1- (Mandatory Activity) Assessment of Compliance with Medicare Regulations
With the changes brought about by the Affordable Care Act (ACA), do you anticipate this protocol being applicable to other populations/organizations such as Accountable Care Organizations? In the protocols for state compliance, it notes that states must include HITEC review, but there are no guidelines. Can CMS provide guidelines on how to effectively evaluate an HIT plan and meaningful use? In order to eliminate redundancy, is CMS looking to mandate accreditation?

3) Protocol 2- (Mandatory Activity) Validation of Measures Reported by the MCO
Should there be guidance on the number of performance measures a state should mandate for review?

4) Protocol 3- (Mandatory Activity) Validation of Performance Improvement Projects (PIPs)
Is CMS considering providing guidance on the number of PIPs?

Does CMS want to promulgate PIP topics and number or variables/indicators required per PIP? In Step 1, there is a new question, “Did the MCO obtain input from enrollees with special health needs, especially those with mental health and substance abuse problems?”

Can you provide guidance on how EQROs are to assess this?

In Step 7, how do we determine if interventions are culturally and linguistically appropriate? Can CMS provide guidance on how to assess appropriateness? For example, must at least 10% of the population speak a specific non-English language? Further, MCO distributed materials are assessed for appropriateness as part of the compliance review. Is it necessary to duplicate this effort?

5) Protocol 4- (Voluntary Activity) Validation of Encounter data Reported by the MCO

A comment was added about 75% federal matching funds to help states with the transparency of reporting. Why is the 75% match noted here and not anywhere else? Does this apply only to encounter data validation?

6) Protocol 7 (Voluntary Activity) Implementation of Performance Improvement Projects

The comment notes that each activity 1 through 10 in Protocol 7 refers back to Protocol 3 on Validation of Performance Improvement Projects, and requests Protocol 7 to be eliminated

7) Protocol 8 (Voluntary Activity) Special Studies

If CMS mandates deeming, will CMS provide the crosswalk?

CMS Responses

1) Appendix III-EQRP Glossary of Terms - The commenter is correct. The glossary has been changed to use the word “healthcare” instead of “health.”

2) Protocol 1 - CMS does not have the authority to apply the managed care requirements for EQR to ACOs or other emerging entities under the Affordable Care Act. Under 42 CFR 438, the protocols are specified for use with MCOs and PIHPs participating in managed care. Similarly, CMS does not have authority under current regulation to mandate accreditation for Medicaid MCOs. However, States do retain the flexibility to require accreditation.

CMS considered the inclusion of guidelines regarding the review of State HIT plans and meaningful use. However, because these topics are covered elsewhere in regulations not tied to EQR, the Protocols are not the proper forum for extensive technical guidance in this area. Information is, however, provided in Appendix V on the importance of how emerging information system capabilities are assessed (page 4). Attachment B to Appendix V, under section E starting on page 29, addresses Meaningful Use of Electronic Health Records and the assessment by the EQRO in how MCO systems and processes address EHR in collection and/or reporting of performance information.

3) Protocol 2 - States vary in the number of performance measures required for the annual validation process and there is no authority for CMS to require a minimum or maximum number of measures. CMS does recommend that States consider the collection and validation of performance measures from the CMS adult and CHIPRA child core measure sets, particularly as they relate to efforts to improve care under the State’s Managed Care Quality Strategy.

4) Protocol 3 - CMS does not have the authority to require a minimum or maximum number of PIPs, however, CMS does recommend that States and MCOs consider performing at least one clinical and one administrative PIP. CMS recommends that States implement PIPs that align with CMS priorities, as set forth in Protocol 3 and Protocol 7 (i.e., Partnership for Patients). To determine whether an MCO has considered input from enrollees who are users of, or concerned with specific areas such as mental health or substance abuse, the EQRO may look to materials such as surveys, focus groups, enrollee representation on MCO quality committees, etc. Protocol 3 has been edited to reflect these recommended sources of supporting documentation. Protocol 3 has also been edited to clarify that more information on culturally and linguistically appropriate services may be found at the following website:

<http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15>. CMS is aware that some written materials are assessed for compliance under Protocol 1. However, the EQRO must ensure that any materials related to all PIPs are assessed for cultural and linguistic appropriateness.

5) Protocol 4 - The fact that the 75% EQR enhanced federal match is mentioned only in Protocol 4 does not mean that it is only available for Protocol 4 activities. All EQR authorized activities may receive enhanced 75% match. CMS has highlighted Protocol 4 as an important voluntary activity for States to consider including as part of the EQR process – to demonstrate the appropriate and accurate use of enrollment data in quality improvement initiatives. CMS has added this clarification to the language in Protocol 4.

6) Protocol 7 – The difference between Protocol 3 and Protocol 7 is that the EQRO *validates* the PIP in Protocol 3, whereas the EQRO *conducts* the PIP in Protocol 7 for the purpose of assessing and improving processes and outcomes of care provided by MCOs in the State. While this is an optional activity for implementing PIPs and has many similarities to steps addressed in Protocol 3 for validation of PIPs, CMS is required to still issue guidance for this optional activity. Therefore, the protocol cannot be eliminated. CMS frequently refers to Protocol 3 to minimize redundancy and duplication of information that still applies to Protocol 7, but would only lengthen the protocols if also included here. The Protocol has been revised, however, to clarify why States may consider using this voluntary Protocol, and to reflect the reordering of activities recommended for Protocol 3.

7) Protocol 8 – CMS does not have the authority to mandate deeming.

Justification

The EQR Protocols are drafted to provide guidance on implementation of the EQR regulations. In some cases, as noted above, the EQR regulations define the limits of the CMS Protocols. Where there is opportunity to encourage States to consider options in EQR contracting that align with CMS or HHS priorities, CMS has noted that.