

EQR PROTOCOLS INTRODUCTION

An Introduction to the External Quality Review (EQR) Protocols

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Introduction
Version 1.0

September 2012

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0786. The time required to complete this information collection is estimated to average 1,591 hours per response for all activities, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850

Table of Contents

EXTERNAL QUALITY REVIEW (EQR) BACKGROUND	4
PURPOSE OF THE EQR PROTOCOLS	6
Protocol 1 – Assessment of Compliance with Medicaid Managed Care Regulations	8
Protocol 2 – Validation of Measures Reported by the MCO	8
Protocol 3 – Validation of Performance Improvement Projects (PIPs)	8
Protocol 4 – Validation of Encounter Data Reported by the MCO	9
Protocol 5 – Validation and Implementation of Surveys	9
Protocol 6 – Calculation of Measures	9
Protocol 7 – Implementation of Performance Improvement Projects (PIPs).....	10
Protocol 8 – Focused Studies	10
Appendices	11
CONDUCTING EXTERNAL QUALITY REVIEW.....	11

EXTERNAL QUALITY REVIEW (EQR) BACKGROUND

The Balanced Budget Act of 1997 (BBA) requires State Medicaid agencies that contract with Medicaid managed care organizations (MCOs) to develop a State quality assessment and improvement strategy that is consistent with standards established by the Department of Health and Human Services (HHS).¹ The BBA also requires HHS to develop protocols for use in the performance of independent, external reviews of the quality and timeliness of, and access to, care and services provided to Medicaid beneficiaries by Medicaid MCOs and prepaid inpatient health plans (PIHPs).

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) requires that Children's Health Insurance Program (CHIP) managed care plans also participate in external quality review (EQR). CHIPRA Section 403, adds managed care requirements applicable to Medicaid under §§1932(a)(4), (a)(5), (b), (c), (d), and (e), to States contracting with MCOs for the delivery of care under separate CHIP programs. These provisions apply to contract years for managed care plans beginning on or after July 1, 2009. Section 401(c)(1) of CHIPRA requires each State to annually report on its child health quality measures and other State-specific information, including information collected through EQRs. CMS strongly encourages States to have final EQR Technical Reports available to CMS and the public by April of each year, for data collected within the prior 15 months. This submission timeframe will align with the collection and annual reporting on managed care data by the Secretary each September 30th, which is also required under the Affordable Care Act [Sec. 2701 (d)(2)]. In 2010, the Secretary began an analysis and publication of information obtained from this annual data.

For the purposes of these protocols, "MCO" will include all managed care organizations subject to EQR. As of December 31, 2010, "MCO" includes all Medicaid and CHIP MCOs and PIHPs.

A State Medicaid agency may choose an External Quality Review Organization (EQRO) as defined in Federal regulation or a non-EQRO organization to conduct MCO reviews, assessments, studies, or validations. For convenience, in these protocols, an "EQRO" refers to any organization that conducts an EQR of a State Medicaid or CHIP MCO.

The regulations at 42 C.F.R. § 438, subpart E—External Quality Review mandate States to perform three activities:

1. A review conducted within the previous 3-year period that determines the MCO's compliance with standards established by the State to comply with the requirements of 42 C.F.R. § 438.204(g), (except standards under 42 C.F.R. §§ 438.240(b)(1) and (b)(2), for the conduct of performance improvement projects and calculation of performance measures respectively), as well as applicable elements of the MCO's State contract (Protocol 1). It is important to note, however, that the MCO is responsible for addressing any recommendations by the EQRO for that review in the following year, as part of the Annual EQRO Technical Report process (per 42 C.F.R. § 438.364);

¹ See Section 1932(c)(1)(B) of the Social Security Act.

2. Validation during the preceding 12 months, to determine the accuracy of the performance measures reported by the MCO and the MCO's compliance with rules outlined by the State as set forth in 42 C.F.R. § 438.240(b)(2) for calculating the performance measures (Protocol 2); and
3. Validation of performance improvement projects (PIPs) required by the State to comply with requirements set forth in 42 C.F.R. § 438.240(b)(1) and that were underway during the preceding 12 months (Protocol 3).

In addition, a State may use five additional EQR activities to assess the performance of its MCOs:

4. Validation of encounter data reported by the MCO (Protocol 4);
5. Design and administration of a survey or validation of the results of a previously administered survey (Protocol 5);
6. Calculation of performance measures for a State based on data reported by the MCO and validation of the accuracy of the calculations of the performance measures made by the MCO's information system (Protocol 6);
7. Implementation of PIPs required by the State in addition to those conducted by the MCO (Protocol 7); and
8. Implementation of focused, one-time studies of the MCO's clinical and/ or non-clinical services as directed by the State (Protocol 8).

Under the direction of the Centers for Medicare & Medicaid Services (CMS), The Joint Commission worked with several consultants and an expert panel, composed of representatives of private accrediting organizations, quality measurement experts, State Medicaid agencies, and advocates for Medicaid beneficiaries, to develop an initial set of nine EQR protocols in 2001. The initial set of protocols included one for each of the eight EQR activities listed above and one for an information system assessment applicable to the EQR activities. HHS published its final rule on EQR of Medicaid MCOs on January 24, 2003. The regulations at 42 C.F.R. § 438 require that State Medicaid programs use Protocols 1, 2, and 3 (mandatory EQR activities) to complete their review of MCOs.

Significant changes in health care policy occurred in 2009 and 2010 that offer new opportunities in quality improvement of health care, including CHIPRA, the American Recovery and Reinvestment Act (ARRA), and the Affordable Care Act. In 2010, CMS contracted Provider Resources, Inc. (PRI) and their subcontractor, the National Committee for Quality Assurance (NCQA), to work with EQR stakeholders, including States, EQROs, and MCOs, to modernize the initial EQR protocols. Substantial updates for both content and structure are included in the revised protocols provided in this package. Appendix A provides methodology for the development of the initial EQR protocols and the methodology used for the revisions in 2010. In addition to the Protocol revisions, CMS is considering changes in regulatory requirements to address the duplication of effort that occurs when States seek to fulfill both EQR and accreditation requirements.

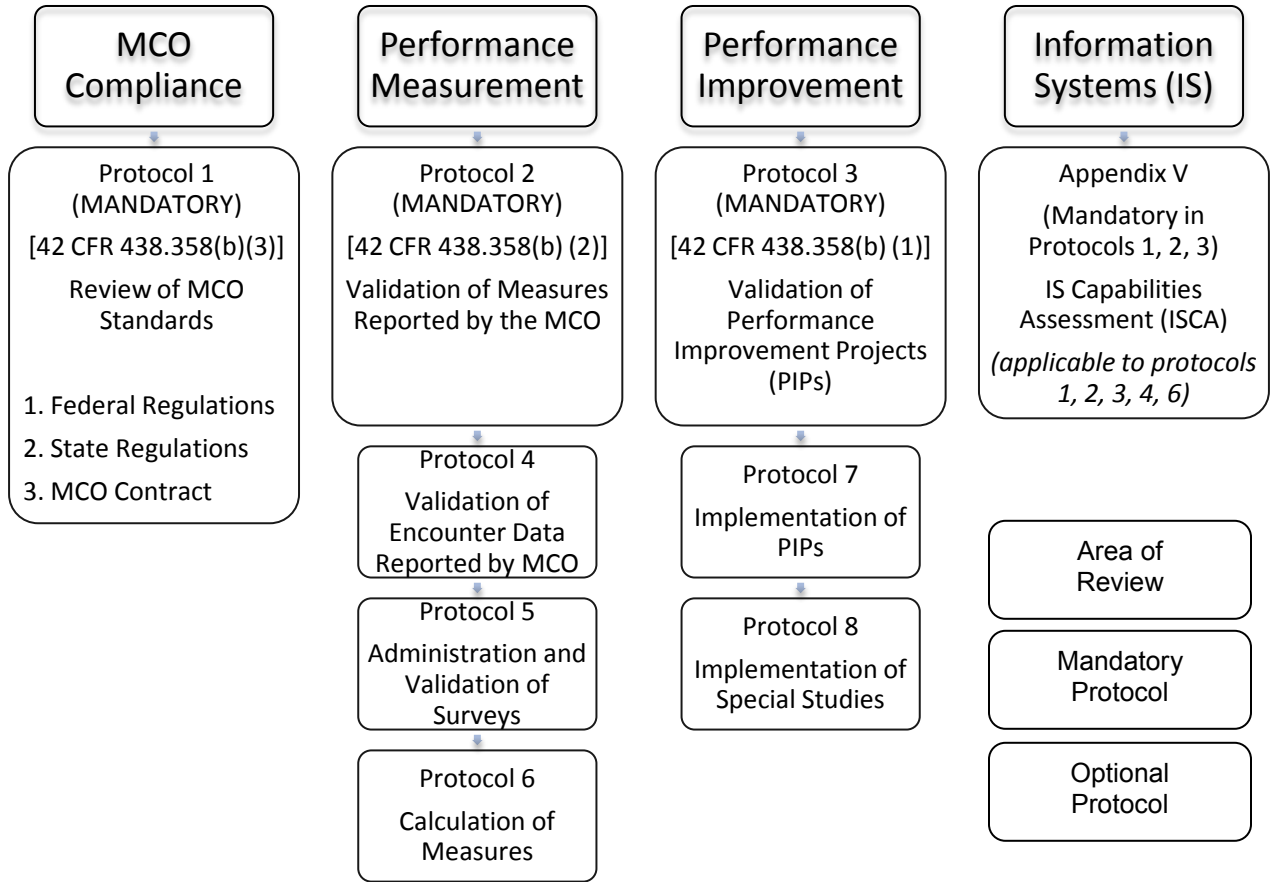
PURPOSE OF THE EQR PROTOCOLS

The purpose of the EQR protocols is to provide States, their Medicaid and CHIP MCOs, and EQROs with instructions for performing EQR. They fulfill the requirement found in 1932(c)(2)(a)(iii) of the Social Security Act for a governing protocol for EQROs to use for EQR of MCOs. Nine protocols guide EQR activities. The first three protocols mirror 42 C.F.R. §438, subpart E specifications for the three mandated EQR activities. Protocols 4 through 8 guide additional voluntary EQR activities and Appendix V guides an MCO information system assessment that is necessary for the completion of several other protocols. The protocol map on the next page illustrates how the EQR protocols and activities relate to one another, as well as source regulation information.

Each protocol describes why the activity is important to EQR, what the activity accomplishes, and how to conduct the activity. Specifically, each protocol includes:

- Data to be gathered;
- Sources of the data;
- Activities and steps to collecting the data to promote its accuracy, validity, and reliability;
- Proposed method or methods for validly analyzing and interpreting the data once obtained; and
- Instructions, guidelines, worksheets, and other documents or tools that may be used, but are not required, for implementing the protocol.

Figure 1: CMS External Quality Review Protocols



Throughout the protocols, the following definitions apply:

- Quality means the degree to which the MCO increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge in at least one of the six domains of quality as specified by the Institute of Medicine (IOM) – efficiency, effectiveness, equity, patient-centeredness, patient safety, and timeliness.¹
- 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; and
- MCO means all managed care organizations, including PIHPs under a Medicaid and/or CHIP program.

¹ This is the definition of quality in the context of Medicaid/CHIP MCOs, and was adapted from the IOM definition of quality.

Protocol 1 – Assessment of Compliance with Medicaid Managed Care Regulations

States are required to perform a compliance review of each MCO once in a 3-year period. Protocol 1 is mandatory and specifies procedures to determine the extent to which MCOs comply with Federal regulatory provisions, State standards, and MCO contract requirements. Protocol 1 includes five activities:

1. Establish Compliance Thresholds;
2. Perform Preliminary Review;
3. Conduct MCO Site Visit;
4. Compile and Analyze Findings; and
5. Report Results to the State.

In addition, Protocol 1 includes four attachments:

- A. Compliance Review Worksheet
- B. Compliance Definitions
- C. Sample Site Visit Agenda
- D. Compliance Interview Questions

While a full compliance review is only required once every 3 years, States must address any EQR findings in the next reporting year.

Protocol 2 – Validation of Measures Reported by the MCO

States must provide to the EQRO and the MCO the performances measures to be calculated, the specifications for the measures, and State reporting requirements. Protocol 2 is mandatory and tells the EQRO how to:

1. Evaluate the accuracy of the Medicaid/ CHIP MCO reported performance measures based on the measure specifications and State reporting requirements; and
2. Evaluate if the MCO followed the rules outlined by the State Agency for calculating the measures.

Protocol 2, Attachment A, provides 14 different worksheets for validating performance measures.

Protocol 3 – Validation of Performance Improvement Projects (PIPs)

MCOs are required to implement a performance improvement project (PIP). Protocol 3 is mandatory and specifies procedures for EQROs to use in assessing the validity and reliability of a PIP. Protocol 3 includes three activities:

1. Assess the Study Methodology;
2. Verify PIP Study Findings (Optional); and
3. Assess Overall Validity and Reliability of PIP Results.

Protocol 3, Attachment A, provides a PIP Review Worksheet.

Protocol 4 – Validation of Encounter Data Reported by the MCO

States use encounter data, which are data about a distinct service provided to an enrollee, to assess and review quality, monitor program integrity, and determine capitation payment rates. Protocol 4 is voluntary and specifies procedures for assessing the completeness and accuracy of encounter data submitted by MCOs to the State. It also assists in the improvement of processes associated with the collection and submission of encounter data. Protocol 4 includes five activities:

1. Review State requirements for collecting and submitting encounter data;
2. Review the MCO's capability to produce accurate and complete encounter data;
3. Analyze MCO electronic encounter data for accuracy and completeness;
4. Review medical records for additional confirmation of findings; and
5. Submit findings.

Protocol 4, Attachment A, provides Encounter Data Validation Tables and Attachment B provides a Medical Record Review Worksheet.

While Protocol 4 is voluntary, the significance of encounter data in payment reform continues to become increasingly important. CMS strongly encourages States to incorporate the validation of encounter data as part of the responsibilities in the State's EQR contract.

Protocol 5 – Validation and Implementation of Surveys

Healthcare surveys are a common method of measuring healthcare quality. Protocol 5 is voluntary and specifies procedures for conducting various types of surveys and validating those surveys. Protocol 5 includes eight activities:

1. Identify Survey Purpose(s), Objective(s) and Intended Use;
2. Select the Survey Instrument;
3. Develop the Sampling Plan;
4. Develop a Strategy to Maximize the Response Rate;
5. Develop a Quality Assurance Plan;
6. Implement the Survey;
7. Prepare and Analyze the Data Obtained from the Survey; and
8. Document the Survey Process and Results.

Protocol 5, Attachment A, provides a Survey Validation Worksheet.

Protocol 6 – Calculation of Measures

States use performance measures to monitor the performance of MCOs over time, to compare the performance of different MCOs, and to inform the selection and evaluation of quality improvement activities. Protocol 6 is voluntary, and specifies procedures for calculating MCO performance measures in accordance with State specifications. It also supplies information to the State on the extent to which the MCO's information system provides accurate and complete information necessary for the calculation of performance measures. Protocol 6 includes three activities and eleven different steps:

1. Prepare for Measurement
 - 1.1. Review State Requirements
 - 1.2. Prepare for Data Collection
 - 1.3. Review MCO's Information System Capabilities Assessment (ISCA)
2. Calculate Measures
 - 2.1. Collect Performance Measure Data
 - 2.2. Clean Data
 - 2.3. Integrate Data into Repository
 - 2.4. Conduct Preliminary Analyses
 - 2.5. Calculate Denominators, Numerators, and Performance Measure Rates
3. Report Results
 - 3.1. Report Preliminary Performance Measurement Rates to MCOs
 - 3.2. Analyze the Data Using Prescribed Benchmarks and Performance Standards
 - 3.3. Submit a Final Report to State

Protocol 6, Attachment A, provides Performance Measure Calculation Tables.

Protocol 7 – Implementation of Performance Improvement Projects (PIPs)

States may request an EQRO conduct a statewide PIP. Protocol 7 is voluntary and specifies procedures for implementing voluntary PIPs. It includes ten activities:

1. Select the Study Topic(s);
2. Define the Study Question(s);
3. Select the Study Variables(s);
4. Use a Representative and Generalizable Sample;
5. Use Sound Sampling Techniques (if sampling is used);
6. Reliably Collect Data;
7. Implement Intervention and Improvement Strategies;
8. Analyze Data and Interpret Study Results;
9. Plan for “Real” Improvement; and
10. Achieve Sustained Improvement.

Protocol 8 – Focused Studies

States may choose to conduct a focused study of healthcare provided by its MCOs. Protocol 8 specifies procedures to do so and includes seven activities:

1. Select the Study Topic(s);
2. Define the Study Question(s);
3. Select the Study Measures(s);
4. Study the whole population or use a representative sample;
5. Use Sound Sampling Techniques;
6. Reliably Collect Data; and
7. Analyze Data and Interpret Study Results.

Appendices

The revised EQR protocol package includes five Appendices that are applicable to all of the protocols:

- I. Methodology and Origin of EQR Protocol Development
- II. Sampling Approaches
- III. EQR Glossary
- IV. EQR Acronyms
- V. Information Systems Capabilities Assessment

Protocols 1, 2, 3, 4 and 6 mandate that States assess their MCOs' information system capabilities. The regulations at 42 C.F.R. § 438.242 also require the State to ensure that each MCO maintains a health information system that collects, analyzes, integrates, and reports data for areas including, but not limited to, utilization, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility. Portions of Appendix V are voluntary; however, there are components that relate directly to the three mandatory protocols. It defines the desired capabilities of an MCO's information system as well as how to assess the strength of the MCO's information system capabilities. It includes a basic overview of the processes of collecting, processing, and reporting data, four activities to performing the assessment, and information about the future of information system assessments, and four activities:

1. Completion of the Information System Capabilities Assessment (ISCA);
2. Review of ISCA and Accompanying Documents;
3. Interview MCO Staff; and
4. Analyze ISCA Findings.

Appendix V, Attachment A, provides an ISCA Template and Attachment B provides an Information System Review Worksheet and Interview Guide.

CONDUCTING EXTERNAL QUALITY REVIEW

The protocols assist States in meeting the requirement to conduct an EQR of its MCOs. The regulations require a State/ EQRO to use methodologies that are consistent with the Protocols; therefore, States/ EQROs have the option of using other methods and/or tools than those provided in these Protocols if the alternative methods are equivalent to the EQR Protocols. States are encouraged to discuss any potential alternative methods to EQR methods with CMS prior to implementation to assure they meet regulatory compliance.

While most States hire an EQRO or other appropriately qualified and independent organization to fulfill the EQR requirements, a State may designate a State department other than the Medicaid agency to perform the EQR. However, per regulation, an independent organization (e.g., an EQRO) must draft the final EQR report.

Preparation for an EQR begins with a clear, written understanding of the parameters of the EQR, including a list of the MCOs for review, selection of applicable protocols (the three mandatory protocols and any additional that the State chooses), and a review of all applicable Federal regulations, State regulations or standards, and MCO State contracts. States will determine

which protocols to apply during established timeframes and for which of their MCOs. States must also take into consideration the CMS Medicaid and CHIPRA core sets of quality measures and the annual Secretary's Reports, published at the end of each September. Prior to conducting individual protocols, the State and EQRO should confirm with all EQR participants the understanding of:

1. Each organization's responsibilities in collecting, reporting, and/ or analyzing data applicable to selected protocols;
2. Which regulations and/or contracts and/or initiatives will be evaluated;
3. Which reviews will be performed and the tools that will be used; and
4. The scheduled commencement and completion of each protocol.

The State may decide that immediate corrective action is required during any part of an EQR. At the conclusion of the EQR, the EQRO must prepare a detailed technical report for the State that includes the following for each activity conducted in accordance with 42 C.F.R. § 438.358:

- An assessment of each MCO's strengths and weaknesses with respect to the quality, timeliness, and access to healthcare services furnished to Medicaid recipients;
- Recommendations for improving the quality of healthcare services furnished by each MCO; and
- An assessment of the degree to which each MCO has effectively addressed the recommendations for quality improvement made by the EQRO during the previous year's EQR.

The report must also document procedures used by the EQRO to analyze the data collected and how they reached their conclusions regarding the quality, timeliness, and access to care furnished by the MCO. This report must be available to the public and must assure the privacy of patient information. The State may request methodologically appropriate, comparative information about all MCOs. At the State's discretion, the State may request the EQRO assess how each MCO contribute toward the State's overall Quality Strategy or objectives.

END OF PROTOCOL