

2010 EXTERNAL QUALITY REVIEW (EQR) PROTOCOLS

APPENDIX I: METHODOLOGY AND ORIGIN OF EXTERNAL QUALITY REVIEW (EQR) PROTOCOL DEVELOPMENT

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PURPOSE OF THE APPENDIX

The purpose of this Appendix is to describe how the protocols were developed and to document the references applied to them.

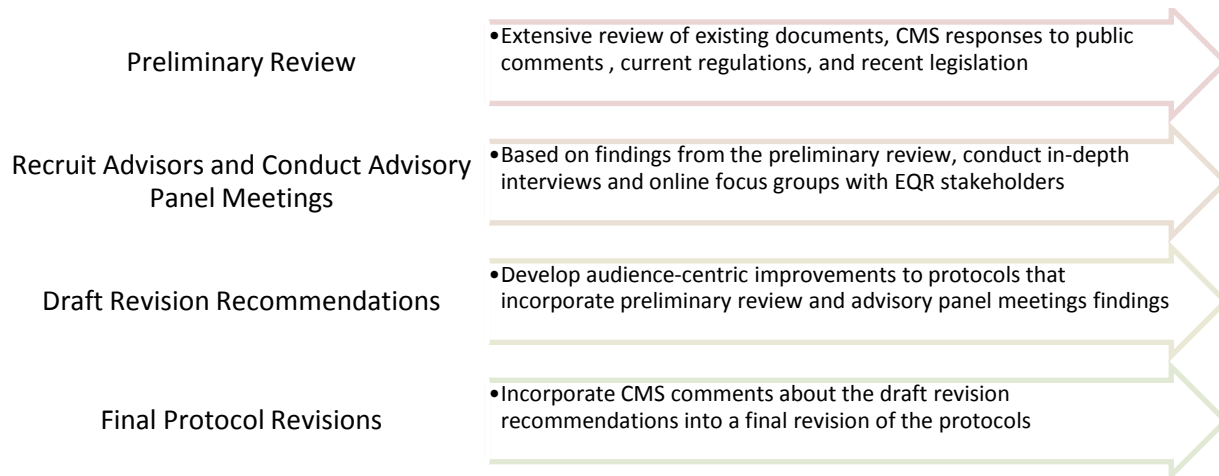
As described in the introduction to the protocols, the original protocols were developed in 2001 by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), working with consultants and representatives of private accrediting organizations, quality measurement experts, State Medicaid agencies, and advocates for Medicaid beneficiaries, under the direction of the Centers for Medicare & Medicaid Services (CMS).

In 2010, CMS contracted with 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 protocols by:

1. Aligning them with applicable federal legislation, including:
 - a. Health Insurance Portability and Accountability Act of 1996 (HIPAA);
 - b. Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA);
 - c. American Reinvestment and Recovery Act of 2009 (ARRA) / Health Information Technology for Economic and Clinical Health (HITECH); and
 - d. Affordable Care Act of 2010;
2. Updating them according to scientific and industry advances in performance improvement and measurement; and
3. Improving their utility for a broader audience in a more efficient manner.

The protocol revision process included four components as displayed in the diagram below:

Diagram 1: EQR Protocol 2010 Revision Process



PERFORMANCE IMPROVEMENT PROTOCOLS DEVELOPMENT

The Performance Improvement Project (PIP) Protocols include the following:

- Protocol 3: Validating PIPs (mandatory)
- Protocol 7: Conducting PIPs (optional)
- Protocol 8: Special Studies (optional)

The PIP protocols are three of nine EQR protocols developed during 1998-2001 from standards and guidelines used in the public and private sectors. The 2010 revisions updated the application of the references in accordance with industry advances, but the methodology remains unchanged.

PIP References

In addition to communications with stakeholders in the industry, the following resources were used in the development of the original protocols and/or the 2010 revisions:

1. NCQA's The Essential Guide to Health Care Quality, available at: <http://www.ncqa.org/tabid/460/Default.aspx>

2. The Agency for Healthcare Research and Quality's Child Health Care Quality Toolbox, available at: <http://www.ahrq.gov/chttoolbx/index.htm>

3. NCQA Volume 5. HEDIS[®] Compliance Audit. Standards, Policies and Procedures. 2010

This publication details the standards and guidelines used to evaluate a plan's ability to comply with HEDIS[®] specifications, assess information system capabilities, data collection programs, analysis and measure results

4. Quality Improvement System for Managed Care (QISMC)

QISMC was a CMS initiative that set forth standards and guidelines of healthcare quality for Medicaid and Medicare health plans (MCOs, PIHPs, and Medicare+Choice (now Medicare Advantage) plans) to address MCO and PIHP quality assessment and PIPs.

5. Health Care Quality Improvement Studies in Managed Care Settings: A Guide for State Medicaid Agencies (NCQA)

Produced under a contract from CMS, this guidebook identifies key concepts related to the conduct of QI studies and accepted principles of research design and statistical analysis as they apply to QI studies.

6. A Health Care Quality Improvement System for the Medicaid Managed Care, A Guide for States (Health Care Financing Administration (HCFA))

This guide for health care QI provides a framework for building QI systems within State Medicaid managed care initiatives. It offers guidelines for addressing quality assessment and improvement studies of MCOs and PIHPs. The 1993 guide was the result of the Quality Assurance Reform Initiative (QARI).

7. Framework for Improving Performance, From Principles to Practice (Joint Commission on Accreditation of Healthcare Organizations (JCAHO))

This publication describes the Joint Commission's theory-based, practical methodology for continuously improving the care practices of healthcare organization and defines the key characteristics and essential behaviors of healthcare organization striving to achieve high quality patient care.

8. 1990-2000 Standards for Health Care Networks (SHCN) (JCAHO)

The JCAHO 1990-2000 SHCN provides an evaluation process based on standards to assist the MCO in measuring, assessing, and improving its network's performance. It also helps the MCO focus on conducting performance improvement efforts in a multi disciplinary, system-wide manner. The 1990-2000 SHCN integrates information about the Joint Commission's healthcare network accreditation process.

9. Specifications Manual for Joint Commission National Quality Core Measures (version 2010B2)
This publication provides information describing the specifications of the Joint Commission's specifications and rationale for the organization's core quality measures.

10. NCQA 1997, 1998, and 1999 Standards for Accreditation of Managed Care Organizations and NCQA 1999 Standards for Accreditation of Managed Behavioral Healthcare Organizations (MBHO)

These documents include administrative policies and procedures for NCQA's MCO and MBHO accreditation programs using 1997, 1998, and 1999 standards, as well as the rationale for their use.

11. Quality Improvement Organizations (QIO) 9th Statement of Work (SOW) (CMS)

The ninth SOW documents outlined the requirements for PROs to adhere to while conducting health care quality and improvement activities for Medicare beneficiaries.

12. Peer Review Organizations (PRO) 4th and 5th Scope of Work (SOW) (CMS)

The fourth and fifth SOW documents outlined the requirements for PROs to adhere to while conducting health care quality and improvement activities for Medicare beneficiaries.

PIP Reference Analysis

An in-depth comparison of these documents identified common activities and features as well as features unique to individual protocols. The QISMC, JCAHO, and NCQA standards are written as guides for MCOs to follow in developing, conducting, and evaluating their PIPs. States or their agents (e.g., EQROs) may also use these guides to assess compliance with State-mandated guidelines and/or to facilitate overall plan-to-plan comparisons. QARI targeted States and EQROs to help them assure compliance with regulations and Medicaid program requirements, and promote consistency in the manner in which MCOs carry out activities related to PIPs.

PIP Components

The analysis revealed that all the documents identify common characteristics of effective PIPs. These include:

- **Selection of Topics:** All of the reference documents address the need for PIPs to clearly specify the topic to be addressed. They all acknowledge both clinical and non-clinical health service delivery issues as appropriate topics.
- **Means of Identifying Topics:** Continuous data collection and analysis is stressed throughout all documents as a means of identifying appropriate topics. Topics should be systematically selected and prioritized to achieve the greatest practical benefit for enrollees. A minimal set of criteria is suggested for selecting appropriate topics. These may include: the prevalence of a condition

among, or need for a service by, the MCO's enrollees; enrollee demographic characteristics and health risks; the likelihood that the study topic will result in improved health status among the enrollees; and the interest of consumers in the aspect of care or services to be addressed.

- Scope of project topics: The QISMC standards specify that PIPs should address the breadth of the MCO's or PIHP's services, such as whether they include physical health and mental/substance abuse health services. They also identify specific clinical and non-clinical focus areas that are applicable to all enrollees. The QISMC standards also specify that the scope of the health plans' improvement efforts are to include all enrollees.
- Stating the Study Question(s): The Healthcare Quality Information Systems (HCQIS) Guide discusses the importance of "stating the study question" after a study topic is identified. It asserts that stating a study question helps a project team avoid becoming sidetracked by data that is not central to the issue under study. For example, once a PIP has identified childhood immunizations as a study topic, it might specify a number of different study questions:
 - a. Have all children received all scheduled doses of one vaccine in particular?
 - b. Have all children of all ages received all recommended vaccines appropriate for their age?
 - c. Have all children of a particular age (e.g., at the age of one, two, six or other years) received all age-appropriate immunizations?

Alternatively, the purpose of the PIP might require more detailed information and specify the study questions as:

- d. What proportion of Medicaid enrollees who have reached two years of age have received:
 - All four recommended doses of DPT vaccine?
 - All three recommended doses of the Polio vaccine?
 - One recommended dose of the MMR vaccine?
 - At least one dose of Hib vaccine in the second year of life?

A PIP might further specify additional study questions to provide information to assist them in their QI efforts, such as:

- e. In what percent of cases were children not immunized for one of the following reasons?
 - Refusal by a parent or guardian?
 - Medical contraindications?
 - Member non-complaint with the recommended immunization regimen?

Incorporating the process of documenting a study question(s) into the project design can help ensure that the PIP used a systematic method of identifying appropriate indicators and data to be collected. In this protocol, "defining the study question(s)" is a key step in designing and implementing a PIP.

- Use of Quality Indicators: All reference documents address the need to specify well-defined indicators for monitoring and evaluation throughout the project. Quality indicators do not need to be outcome measures. Process measures are also appropriate, especially when there is strong clinical evidence that the process being measured has a meaningful association with outcomes. There are various ways to obtain appropriate indicators, such as using those dictated from outside sources (such as the State or CMS) or by an MCO developing them internally on the basis of clinical literature or findings of expert panels.

PIP Characteristics

In addition to these features found uniformly in all reference documents, other significant aspects of PIPs were identified by one or more of the reference documents. These include:

- “Significant” improvement: NCQA’s document, “Health Care Quality Improvement Studies in Managed Care Settings,” states that, “When presenting statistical results of any study, it is important to fully disclose ... the statistical significance of the estimates produced, as well as the statistical significance of any apparent differences between units of comparison.” Building on this, CMS’s QISMC document calls for specific amounts of measurable improvement to be demonstrated by the health plan. QISMC defines “demonstrable” improvement as either 1) benchmarks established by CMS (for national Medicare projects) or State agencies (for Statewide Medicaid QI projects) or by the health plans for individual (organizational) projects or 2) a 10 percent reduction in adverse outcomes. This protocol does not call for a specific level of statistical achievement but, consistent with the NCQA document, calls for disclosure and review of the statistical significance of any reported improvements in performance as one aspect of reviewing the overall success of a PIP.
- Phase-in or time frame requirements: QISMC delineates specific time frame requirements for MCOs to reach certain phases in a QI cycle. For example:
 - a. By the end of the first year, an MCO should have initiated at least two PIPs addressing two different focus areas;
 - b. By the end of the second review year, at least two additional projects addressing two different focus areas should be initiated.
 - c. By the end of the first year, after the 2- year phase-in period, and each subsequent year, at least two projects are to achieve demonstrable improvement in two of the focus areas.

The PIP protocols do not specify phase-in or time frame requirements, allowing States to specify any such requirements as they determine appropriate.

- Evaluation Tools: NCQA’s HCQIS guidebook includes study planning and summary worksheets to be used in the evaluation of an MCO’s PIP. This feature provides helpful in recording data during the evaluation process and promotes the collection of consistent information by all evaluators.

- Scoring system: NCQA accreditation provides a numerical scoring system to measure performance against standards and to promote consistency in the process used to evaluate MCOs. Although the scores do not dictate the final decision with respect to compliance with standards, they do serve as a guide for NCQA evaluators to recommend non-compliance. This scoring system includes an opportunity for the MCO to comment on the reviewer's scores before a final decision is rendered. It also promotes continuous improvement practices by securing "customer" input into a final product (i.e., evaluation decisions).

PERFORMANCE MEASUREMENT PROTOCOLS DEVELOPMENT

The Performance Measurement (PM) Protocols include the following:

- Protocol 2: Validating Performance Measures (mandatory)
- Protocol 4: Validating Encounter Data (optional)
- Protocol 6: Calculating Performance Measures (optional)

The PM protocols are three of nine EQR protocols developed during 1998-2001 from standards and guidelines used in the public and private sectors. They were originally derived from the following references:

1. HEDIS[®] Compliance Audit[™] Standards and Guidelines, 1999 National Committee for Quality Assurance (NCQA);
2. Tools used by the Island Peer Review Organization (IPRO) in their audits of HEDIS[®] measures for Medicare; and
3. Documents from the MEDSTAT Group, Inc., published in conjunction with work performed in 1997 and 1998 for CMS.

Since the time the PM protocols were originally developed, IPRO has abandoned the tools that were presented in the initial EQR protocols, and The MEDSTAT Group, Inc., no longer conducts performance measurement validation work. As of 2011, IPRO and much of the industry use NCQA's HEDIS[®] Compliance Audit – 40 States recognize NCQA MCO accreditation in whole or part in either their commercial market and/or their Medicaid managed care program.¹ CMS now mandates the use of the HEDIS[®] Compliance Audit for the validation of performance measures submitted by Medicare Advantage Plans. While the HEDIS[®] Compliance Audit is most often used to validate HEDIS[®] measures, it is frequently used to validate other performance measures, including those State-specific measures used in some Medicaid programs.

The 2010 revisions updated the application of the original references in accordance with industry advances, which are largely derived from HEDIS^{®2} 2011 Volumes 2 (Technical Specifications) and 5 (HEDIS[®] Compliance Audit: Standards, Policies and Procedures). Additional sources included:

1 NCQA website, <http://www.ncqa.org/tabid/135/Default.aspx>

2 HEDIS[®] is a registered trademark of the National Committee for Quality Assurance (NCQA).

- APCD Council, available at: <http://www.apcdouncil.org>;
- NCQA's Medicaid Deeming Toolkit, available at: www.ncqa.org; and
- CMS's Measures Management System Blueprint, available at: http://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp

INFORMATION SYSTEM CAPABILITIES ASSESSMENT DEVELOPMENT

Most of the EQR protocols include an assessment of the structure and integrity of the MCO's underlying information system, and of the MCO's ability to collect valid data from a variety of sources internal and external to the organization. Furthermore, the regulation at 42 C.F.R. § 438.242 requires 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.

The initial EQR protocol package included an Appendix Z, now referred to as Appendix V, for information system assessment. The 2010 revised information system assessment initiates stepwise modernization by updating the original references, applying more recent legislation (e.g., HITECH), and aligning it with current technology standards. Potential expansive revisions of the information system assessment may be anticipated in the future due to a host of emerging federal information technology initiatives and industry evolutions of standardized health information systems, their users, and purposes.

A number of public and private sector protocols and tools were examined during the development of both the original protocols and the 2010 revisions to promote consistency between this assessment and similar public and private sector activities. These include:

1. The National Committee for Quality Assurance's (NCQA) Volume 5, HEDIS[®] Compliance Audit Standards and Guidelines 2010;
2. Tools used by the Island Peer Review Organization (IPRO) in their audits of HEDIS[®] measures;
3. Documents from the MEDSTAT Group, Inc., published in conjunction with work performed for CMS in 1997 and 1998;
4. Stakeholder interviews with entities that perform external audits; and
5. Review of NCQA HEDIS[®] Compliance Audit[™] Volume 5 for auditing standards, policies, and procedures related to health information systems as a potential Protocol tool.

Existing regulations at 42 C.F.R. § 438.242 (Health information systems) and 42 C.F.R. § 438.352 (External quality review protocols), require the MCO to ensure its information system processes, utilities, and functional infrastructure have demonstrable capabilities for collecting valid, accurate data, and then calculating and reporting quality improvement data. This is important to emerging electronic health record and health information exchange technologies that States are using as part of quality improvement initiatives in their care delivery systems.,

However, the HIPAA security audit reporting capabilities assessment supports and focuses on improving information system integrity. HIPAA includes requirements for the assurance of information systems' administrative integrity and the integrity of information gathered, processed, and reported by those systems then used by covered entities, such as health plans.ⁱ Previous publications by HHS provide guidance and tools on key aspects of HIPAA Security Rule compliance.ⁱⁱ

ADDITIONAL REFERENCES

Brown, J. G. (September 1998). Lessons Learned from Medicaid's Use of External Quality Review Organizations. Office of the Inspector General, United States Department of Health and Human Services.

Ireys, H.T., Krissik, T., Verdier, J.M., Faux, M. (May 2005). Using External Quality Review Organizations to Improve the Quality of Preventive and Developmental Services to Children. Mathematica Policy Research, Inc., The Commonwealth Fund.

Krissik, T., Ireys, H.T., Markus, A., Rosenbaum, S. (July 2008). Monitoring and Assessing the Use of External Quality Review Organizations for Young Children: A Toolkit for State Medicaid Agencies. Mathematica Policy Research, Inc., The Commonwealth Fund, George Washington University.

Levinson, D. R. (June 2008). External Quality Reviews in Medicaid Managed Care. Office of the Inspector General, United States Department of Health and Human Services.

END OF DOCUMENT

ⁱⁱ See 45 C.F.R. §164.308 Administrative safeguards.

ⁱⁱ See Security Rule Educational Paper Series and the sublinks to Security 101, Administrative Safeguards, Physical Safeguards, Technical Safeguards, Organizational Policies and Procedures and Documentation Requirements, Basics of Risk Analysis and Risk Management, available at:
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html>