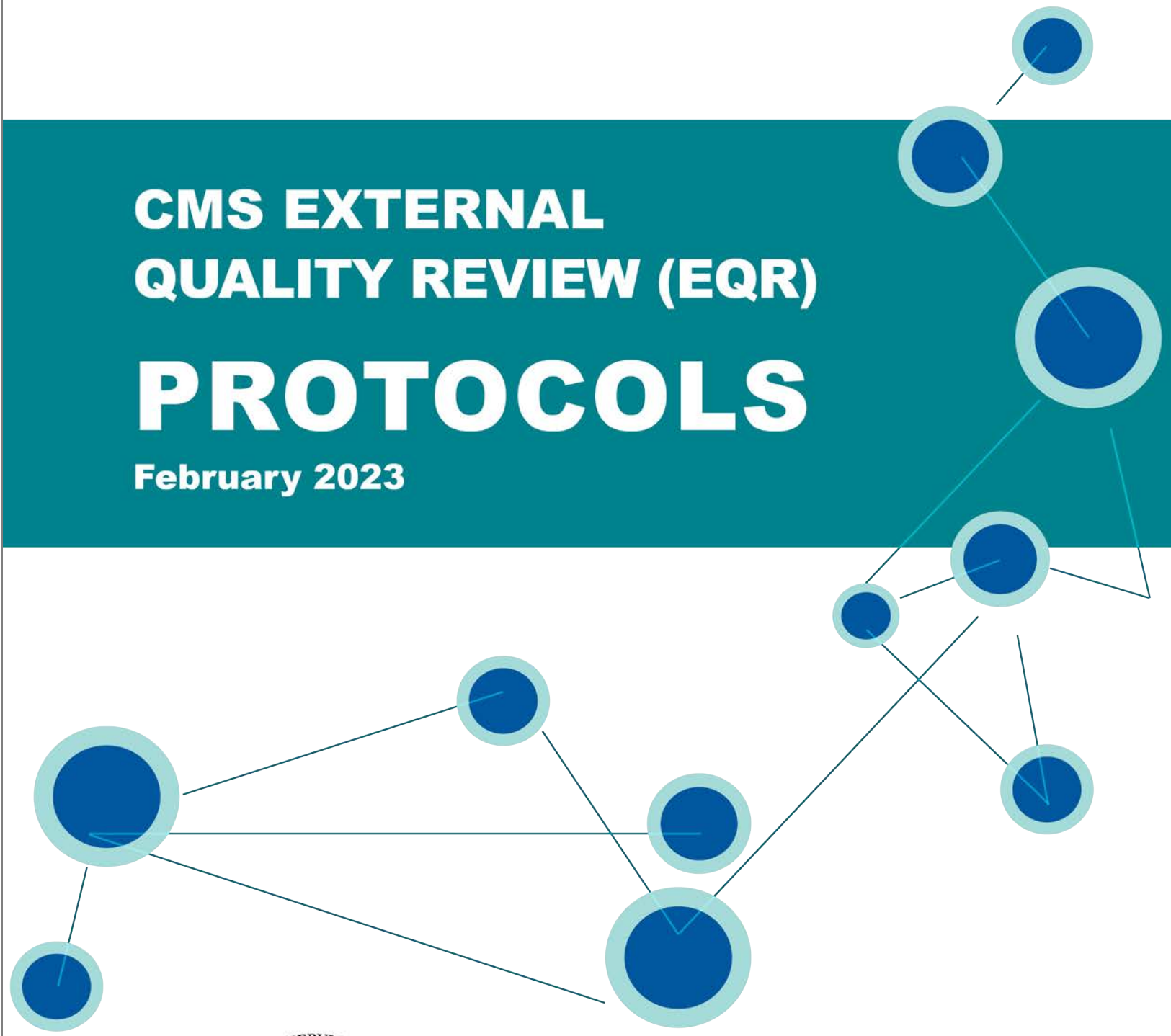
OMB Control No. 0938-0786
Expires: December 31, 2025

CMS EXTERNAL QUALITY REVIEW (EQR) PROTOCOLS

February 2023



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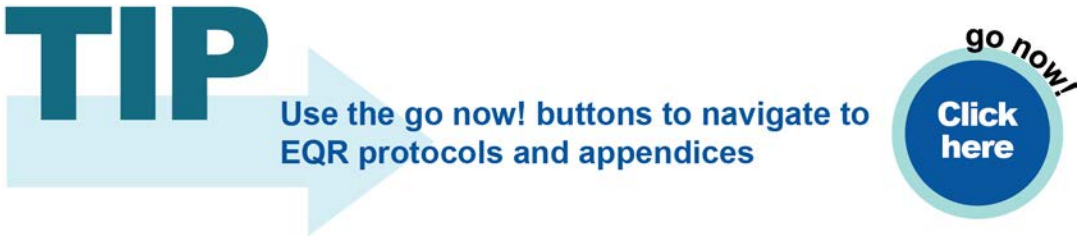

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Introduction

Background

Together, Medicaid and the Children's Health Insurance Program (CHIP) cover more than 83 million people,[1] representing about 1 in 4 people in the United States, and covering 42 percent of all births.[2] Nationally, 69 percent of adults and children enrolled in Medicaid and CHIP obtain their care through managed care plans (MCPs), although the rate of managed care enrollment in states using a managed care delivery system varies widely.[3] The federal requirements related to Medicaid managed care quality, including the external quality review (EQR) process, were established in statute at section 1932(c) of the Social Security Act (the Act) and are set forth in 42 CFR 438(c). The same statutory federal requirements were made applicable to CHIP managed care quality through section 2103(f)(3) of the Act and are set forth in 42 CFR 457.1240 and 1250. Box 1 defines key terms related to the EQR process.

Box 1. Key Definitions Related to the External Quality Review Process

- **Managed care plan (MCP).** Encompasses managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and primary care case management (PCCM) entities described in 42 CFR 438.310(c)(2).
- **External quality review (EQR)**. EQR is the analysis and evaluation of aggregated information on quality, timeliness, and access to the health services that an MCP or its contractors furnish to Medicaid beneficiaries [see 42 CFR 438.320]. EQR can only be conducted by a qualified EQRO.
- **External quality review organization (EQRO)**. An EQRO is an organization that meets the competence and independence requirements set forth in 42 CFR 438.354, and performs EQR, EQR-related activities, or both.
- **EQR-related activities**. The activities addressed in these protocols. EQR-related activities produce the data used by an EQRO to complete the annual EQR. EQR-related activities may be conducted by the state, its agent that is not an MCP, or an EQRO [see 42 CFR 438.358]..

The Centers for Medicare & Medicaid Services (CMS) published the Medicaid and CHIP managed care final rule in May 2016, which aligns key rules with those of other health insurance coverage programs, modernizes how states purchase managed care for beneficiaries, and strengthens the consumer experience and key consumer protections.[4] The rule also updated and expanded EQR in the following ways:

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[1] Estimates are for July 2021. July 2021 Medicaid and CHIP Enrollment Data Highlights. Available at https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.

[2] Data on births covered by Medicaid and CHIP in 2019 is available at https://www.cdc.gov/nchs/data/nvsr/nvsr70/nvsr70-02-508.pdf.

[3] Data on the percentage of Medicaid beneficiaries in comprehensive managed care, by state, is available at https://www.medicaid.gov/medicaid/quality-of-care/downloads/beneficiary-profile-2021.pdf.

[4] More information about the Medicaid and CHIP managed care final rule is available at https://www.medicaid.gov/medicaid/managed-care/guidance/final-rule/index.html and the Federal Register at https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf.

- Clarified that the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) applied EQR (including EQR-related activities) to both separate CHIP MCPs and Medicaid Expansion CHIP MCPs. A state that uses MCPs to provide CHIP benefits must develop and implement a managed care quality strategy and must require CHIP MCPs to operate quality assessment and performance improvement (QAPI) programs
- Applied EQR to a broader range of Medicaid MCPs, that is, beyond managed care organizations (MCOs) and prepaid inpatient health plans (PIHPs) to also include prepaid ambulatory health plans (PAHPs) and primary care case management (PCCM) entities whose contracts with the state provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes[5]
- Added two EQR-related activities: (1) a mandatory EQR-related activity, validation of network adequacy (effective no later than one year from the issuance of the associated EQR protocol) and (2) an optional EQR-related activity, assistance with the quality rating of MCOs, PIHPs, and PAHPs required under a Medicaid and CHIP quality rating system (effective no earlier than the issuance of the associated EQR protocol)[6]

In November 2020, CMS released revisions to the 2016 final rule. The 2020 rule updated the following EQR provisions:

- Required states to identify MCOs exempt from EQR annually on its website in the same location where EQR technical reports are posted. State must include the name(s) of the MCO(s) exempt from EQR, including the beginning date of the current exemption period, or that no MCOs are exempt from EQR.
- Clarified standards for the EQR compliance review activity in 42 CFR 438.358(b)(1)(iii) by referencing the full set of subpart B, C, and D standards that comprise the compliance review. The rule made further modifications to the standards subject to EQR in each of these subparts, and CMS encourages states and EQROs to familiarize themselves with these changes.
- Inserted several technical revisions to CHIP regulations that cross-reference Medicaid EQR standards to align CHIP and Medicaid EQR standards, and those quality standards relevant to EQR reporting requirements.

The timeline in Figure 1 chronicles the evolution of the scope of EQR in Medicaid and CHIP. These updated protocols reflect changes included in the 2020 rule.

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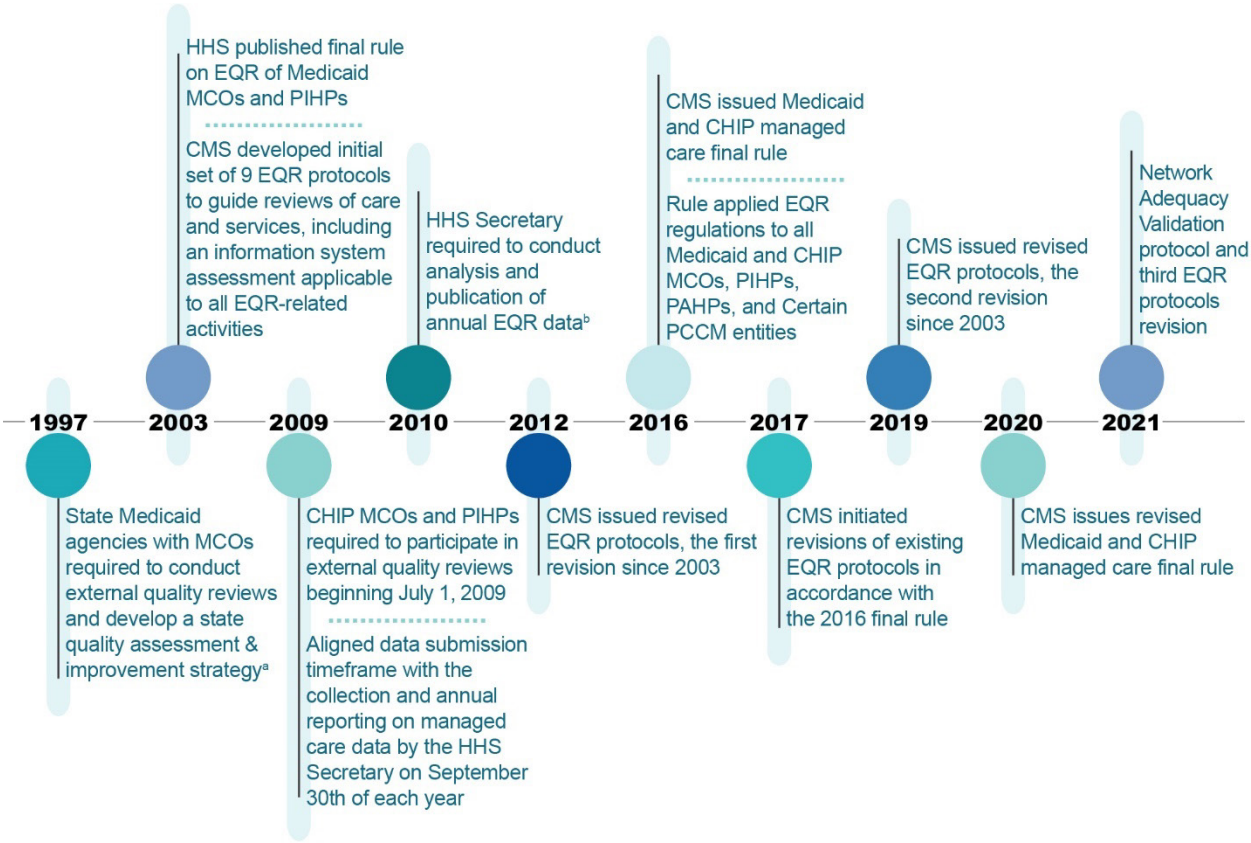
[5] For the purposes of the EQR protocols, all references to PCCM entities should be assumed to refer to the applicable subset of PCCM entities described at 42 CFR 438.310(c)(2), and 457.1240(f).

[6] Page 27499 of the 2016 final rule includes effective dates for the additional EQR-related activities: "States must begin conducting the EQR-related activity described in 438.358(b)(1)(iv) (relating to the mandatory-EQR-related activity of the validation of network adequacy) no later than one year from the issuance of the associated EQR-protocol. States may begin conducting the EQR-related activity described in 438.358(c)(6) (relating to the optional EQR-related activity of plan rating) no later than the issuance of the associated EQR protocol."

Figure 1. Evolution of EQR in Medicaid and CHIP



[a] Balanced Budget Act of 1997 amending section 1932(c)(1)(B) of the Social Security Act.

[b] Section 1139A(c)(2) of the Social Security Act, as amended by section 401(a) of CHIPRA, requires the U.S. Department of Health & Human Services (HHS) Secretary to summarize State-specific information on the quality of health care furnished to children under titles XIX (Medicaid) and XXI (CHIP). Section 1139A(c)(1)(B) of the Act specifically requests information gathered from the external quality reviews of managed care organizations (MCOs) and benchmark plans.

Managed Care Quality Tools and the EQR Process

EQR is one part of a multipronged approach to Medicaid and CHIP managed care quality. These managed care quality tools are interrelated, with each informing and reinforcing the others (Figure 2). For example, state quality strategies articulate managed care priorities, including goals and objectives for quality improvement. QAPI programs should reflect the priorities articulated in the quality strategy and include specific measures and targets from the quality strategy, with performance improvement projects (PIPs) aimed at driving improvement on the measures. The performance measures and PIPs are then validated during the annual EQR, with results included in the EQR technical report. The EQR technical report also includes recommendations from the EQRO on how states can target quality strategy goals and objectives to support improvements in quality of care, as well as reviews the standards in 42 CFR 438.56, 438.110, 438.114, 42 CFR subpart D, and 42 CFR 438.330. Additionally, in the 2022 revision of the EQR protocols, Validation of Network Adequacy is being added as an essential oversight component for managed care plans. By thinking holistically about these managed care quality

components (see Figure 2 for the interrelationships among QS, QAPI, and EQR), states can maximize the impact of their managed care quality initiatives.

Figure 2. Relationship between State Medicaid and CHIP Managed Care Quality Initiatives

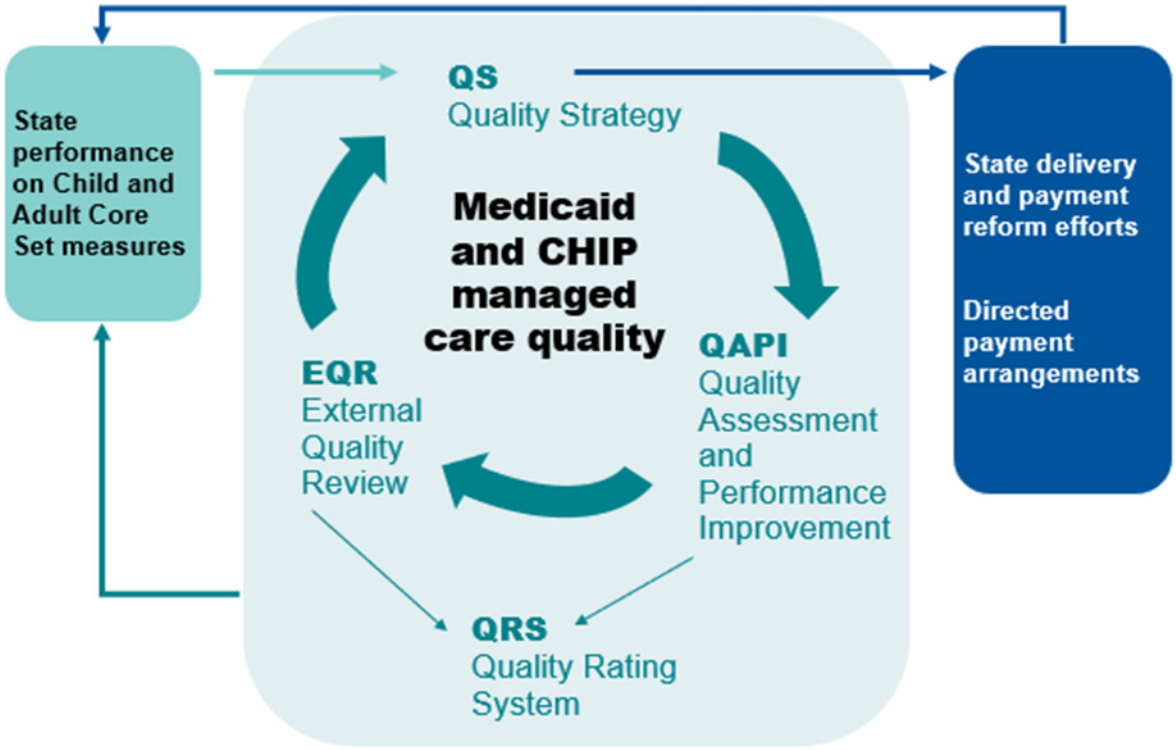
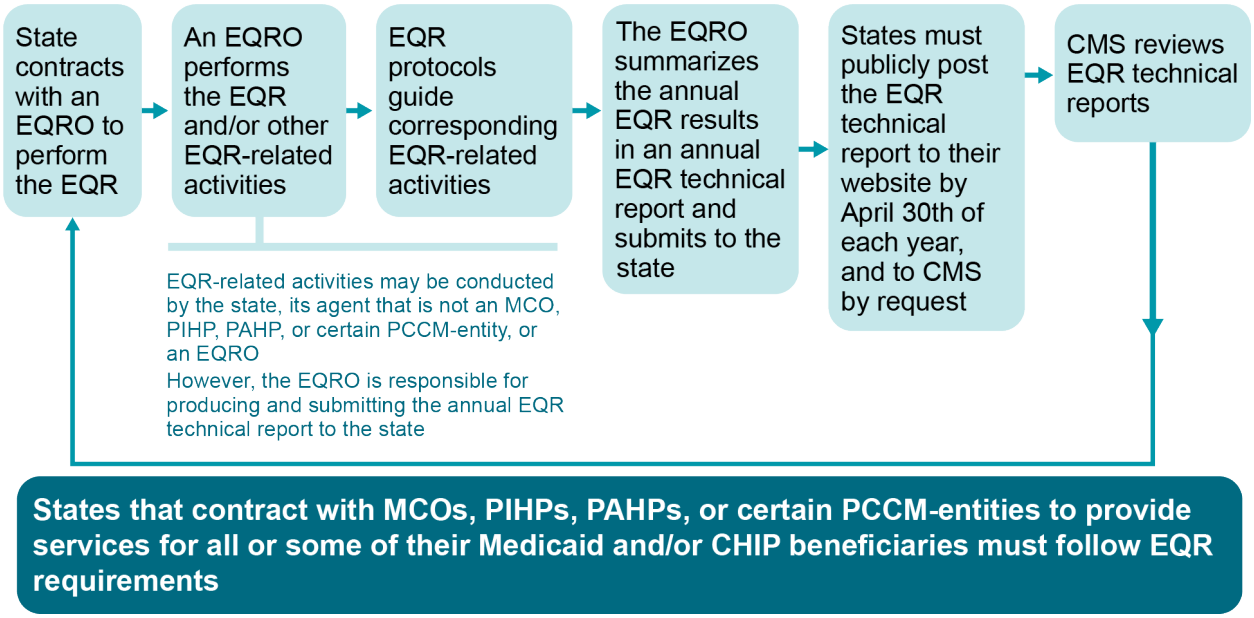


Figure 3 outlines the EQR process. States using a managed care delivery system for all or some of their Medicaid and/or CHIP beneficiaries are required to contract with a qualified independent EQRO to conduct an annual EQR to assess and monitor the quality of care provided to Medicaid and CHIP beneficiaries enrolled in MCPs and to identify opportunities for quality improvement.[7] To simplify the narrative of these protocols, the term "EQRO" is used to refer to the entity which conducts the EQR-related activities that generate the information for the annual EQR. An EQRO is the only entity which may conduct the annual EQR, that is, the analysis and evaluation of information generated by the EQR-related activities (or via nonduplication, if applicable) regarding the quality, timeliness, and access to the health care services that an MCP, or its contractors, furnish to beneficiaries. States with both Medicaid and CHIP managed care programs may elect to contract with a single EQRO to conduct EQR of both Medicaid and CHIP or may contract with different EQROs for EQR of Medicaid and CHIP. Many states choose to utilize the same EQRO for EQR of both Medicaid and CHIP.

[7] CHIP regulations at 42 CFR 457.1250 cross-reference to the Medicaid managed care EQR requirements at 42 CFR 438.356.

The end product of the EQR is an annual EQR technical report, which summarizes findings on access and quality of care, and must be drafted by said EQRO.[8]

Figure 3. The EQR Process



The EQR process also includes a series of mandatory and optional EQR-related activities designed to provide a sound understanding of the strengths and weaknesses of Medicaid and CHIP MCP performance related to quality, timeliness, and access to care (see Box 2). The EQR-related activities are intended to (1) improve states' ability to oversee and manage the MCPs they contract with for services, and (2) help MCPs improve their performance with respect to quality, timeliness, and access to care. Effective implementation of the EQR-related activities will facilitate state efforts to purchase high-value care (rather than volume) and to achieve higher performing health care delivery systems for their Medicaid and CHIP beneficiaries. States have flexibility regarding who will conduct the EQR-related activities; they may be conducted by the state, its agent that is not a managed care plan, or an EQRO. If the state elects to contract with an EQRO to conduct the EQR-related activities, this can be the same EQRO that conducts the EQR for the state, or one or more additional EQROs.[9]

[8] CHIP regulations at 42 CFR 457.1250 cross-reference to Medicaid managed care EQR requirements at 42 CFR 438.364.

[9] States may choose to contract with different entities, including more than one EQRO, for different EQR-related activities. For example, the state might validate performance improvement projects (see Protocol 1) itself, contract with EQRO A for the validation of performance measures (see Protocol 2), and contract with EQRO B for the compliance review (see Protocol 3). Said state could then contract with EQRO A, B, or a third EQRO (C) to conduct the EQR and produce the EQR technical report. For information on state contracting options for EQR, see 42 CFR 438.356 (as cross referenced at 457.1250 for CHIP.

Box 2. Mandatory and Optional EQR-Related Activities

Mandatory EQR-Related Activities

- Validate performance improvement projects (PIPs)
- Validate performance measures
- Review compliance with Medicaid and CHIP managed care regulations
- Validate network adequacy (Reserved)

Optional EQR-Related Activities

- Validate encounter data reported by MCPs
- Administer or validate quality of care surveys
- Calculate additional performance measures
- Conduct additional PIPs
- Conduct focus studies of health care quality
- Assist with quality rating of MCPs (Reserved)

Medicaid and CHIP MCOs, PIHPs, and PAHPs are subject to all four mandatory EQR-related activities;[10] PCCM entities are subject to two of the mandatory EQR-related activities (a compliance review and validation of performance measures).[11] See Table 1 for additional information about the application of EQR-related activities to MCPs.

Table 1. Application of Mandatory and Optional EQR-related Activities by MCP Type

	MCP Type			
EQR-Related Activity	**MCO**	**PIHP**	**PAHP**	**PCCM Entity**
Validation of Performance Improvement Projects	Required	Required	Required	State Discretion
Validation of Performance Measures	Required	Required	Required	Required
Review of Compliance with Medicaid Managed Care Regulations	Required	Required	Required	Required
Validation of Network Adequacy[a]	Required	Required	Required	N/A
Validation of Encounter Data Reported by the MCP	State Discretion	State Discretion	State Discretion	State Discretion
Administration or Validation of Quality of Care Surveys	State Discretion	State Discretion	State Discretion	State Discretion

[10] The network adequacy validation requirement will go into effect one year after the release of the network adequacy validation protocol. Until then, MCOs, PIHPs, and PAHPs will be subject to three mandatory EQR-related activities: Protocol 1 (Validation of PIPs), Protocol 2 (Validation of Performance Measures), and Protocol 3 (Review of Compliance with Medicaid Managed Care Regulations) (Figure 4).

[11] While regulations do not require PCCM entities to conduct PIPs as a part of their QAPI programs, states may choose to require their PCCM entities to do so. States that require PCCM entities to conduct PIPs should consider validating those PIPs.

	MCP Type			
EQR-Related Activity	**MCO**	**PIHP**	**PAHP**	**PCCM Entity**
Calculation of Additional Performance Measures	State Discretion	State Discretion	State Discretion	State Discretion
Implementation of Additional Performance Improvement Projects	State Discretion	State Discretion	State Discretion	State Discretion
Conducting Focus Studies of Health Care Quality	State Discretion	State Discretion	State Discretion	State Discretion
Assist with Quality Rating of Medicaid and CHIP MCOs, PIHPs, and PAHPs[a]	State Discretion	State Discretion	State Discretion	N/A

[a] States may not claim for these EQR-related activities until the EQR protocol is issued.

Federal Financial Participation for EQR

For Medicaid programs, EQR (including the production of the EQR technical report) and EQR-related activities performed on MCOs, as well as the production of the EQR technical report are eligible for Federal financial participation (FFP) at a ***75 percent match rate*** (1) when conducted by a qualified EQRO, (2) when the EQR-related activities are completed using methodologies consistent with the protocols contained within this document, and (3) when the state receives approval of its EQRO contract from CMS.[12,13] The EQRO's analysis is eligible for the 75 percent match rate when the information from a Medicare or private accreditation review of an MCO is used for the mandatory EQR-related activities. However, the accreditation activities that produce the information cannot receive the match.

Medicaid programs are eligible for the ***50 percent match rate*** if an agency other than a qualified EQRO conducted the EQR-related activities.[14] EQR (including the production of the EQR technical report) and EQR-related activities conducted on PIHPs, PAHPs and PCCM entities are eligible for the 50 percent match rate.[15] For CHIP, EQR and EQR-related activities are subject to the ***10 percent administrative cap*** as required by section 2105(c)(2)(A) of the Act; a state is

[12] See 42 CFR 433.15 and 438.370(a) and the July 10, 2016 CMCS Informational Bulletin (CIB), Federal Financial Participation for Managed Care External Quality Review, available at https://www.medicaid.gov/federal-policy-guidance/downloads/cib061016.pdf.

[13] If the state or the state's agent that is not an MCP conducts the EQR-related activity on an MCO, it would be eligible for the 50 percent match rate. See 42 CFR 438.370(a)–(b). When information from a Medicare or private accreditation review of an MCO is used to support one or more mandatory EQR-related activities in place of a Medicaid review, the EQRO's analysis of the MCO data as part of the EQR is eligible for FFP at the 75 percent rate. The accreditation activities that produce the information are not eligible for the FFP.

[14] See 42 CFR 433.15 and 438.370(b).

[15] See 42 CFR 438.370(b). Note that this is a change from the previous regulation, under which the enhanced match was available for EQR of PIHPs to the same extent as MCOs. For further explanation of the change, see discussion in the Medicaid and CHIP Managed Care 2016 final rule at 81 CFR 27498, 27715-27716.

eligible to receive the state's enhanced CHIP FFP match rate for these activities, regardless of which entity completes the activity.

Overview of the EQR Protocols

CMS is required to develop EQR protocols to guide and support the annual EQR process.[16] The first set of protocols was issued in 2003, updated in 2012 (recall Figure 1), and updated again in 2019 to incorporate regulatory changes contained in the May 2016 Medicaid and CHIP managed care final rule. The 2019 revised protocols were also designed to improve the user experience navigating through the components, provide new tools to drive improvement using current industry methodologies (such as rapid cycle evaluation approaches), and offer practical tips and best practices for reporting.

CMS is required to review the protocols and make necessary revisions every three years. In 2022, CMS issued the third revision to the EQR Protocols to incorporate regulatory changes contained in the 2020 final rule, clarify federal requirements for the EQR process to promote compliance, respond to state and EQRO feedback about the protocols, and include the network adequacy validation protocol.

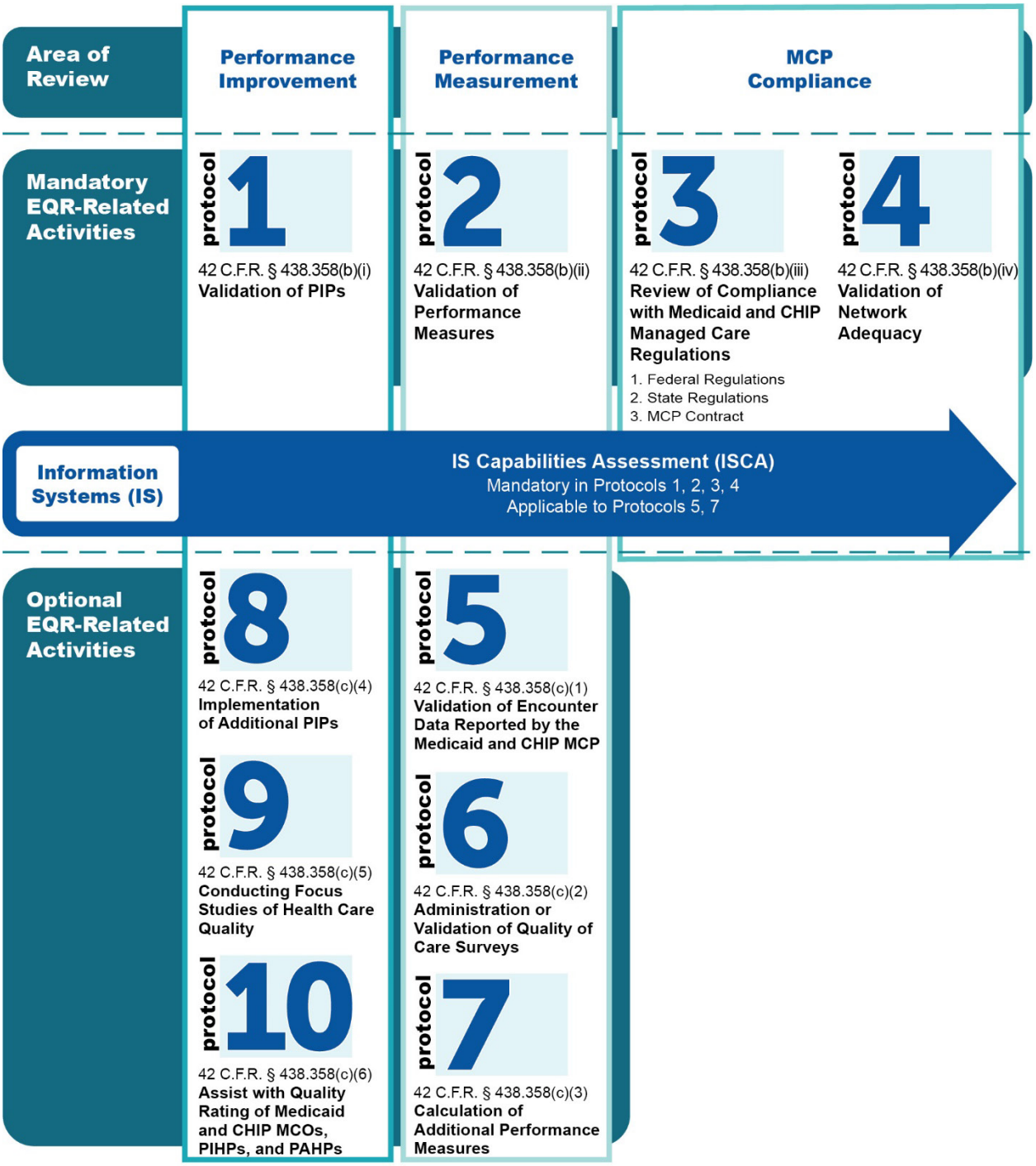
Figure 4 (next page) identifies the EQR protocols linked to each of the mandatory and optional EQR-related activities, as well as the source of the regulations that guide the protocols. In addition, an Information Systems Capabilities Assessment (ISCA) is a mandatory component of the EQR as part of Protocols 1, 2, 3, and 4, as well as Protocols 5 and 7 (if applicable). Box 3 shows the general content of the EQR protocols.

Box 3. Content of the EQR Protocols

- Purpose of the EQR-related activity
- How to conduct each activity within the protocol, including:
  - Data sources and data collection activities to promote data accuracy, validity, and reliability
  - Proposed method(s) for analyzing and interpreting the data
  - Instructions, guidelines, worksheets, and/or tools that may be used in implementing the protocol

[16] See section 1932(c)(2)(A)(iii) of the Social Security Act and 42 CFR 438.352.

Figure 4. Overview of the EQR Protocols



Notes: CHIP regulations at 42 CFR 457.1250(a) cross-reference to all the Medicaid managed care EQR requirements at 42 CFR 438.320.

It should be noted that several protocols are organized around site visits by the EQRO. In recognition of changing practices related to the COVID-19 pandemic, site visits may be conducted onsite or virtually to obtain the information specified in the protocols.

States must ensure that the privacy of patient information is protected in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[17] throughout all EQR-related activities and the EQR technical report process. Specifically, the 2016 final rule introduced requirements that EQR technical reports do not disclose a patient's identify or any Protected Health Information (PHI).[18] Consistent with that obligation, states should ensure that their MCPs comply with HIPAA and all other federal and state laws concerning confidentiality and disclosure. The EQRO should ensure that its EQR-related data collection and reporting activities meet these requirements.

The next section of this introductory chapter discusses practical considerations for states before beginning the EQR-related activities. The following section provides tips to guide the drafting of effective EQR technical reports that document performance in regard to quality, timeliness, and access to care; identify areas for improvement; and recommend interventions to improve the process and outcomes of care. Links to the protocols and appendices are contained at the end of this chapter. The four appendices are: Information Systems Capabilities Assessment (Appendix A), Sampling Approaches for EQR Data Collection Activities (Appendix B), Acronyms Used in the Protocols (Appendix C), and External Quality Review Glossary of Terms (Appendix D).

Considerations Before Conducting EQR-Related Activities

Preparing to conduct EQR-related activities involves several steps (see Box 4). EQR-related activities may be performed by the state, an agent of the state that is not an MCP, or by an EQRO.[19] These protocols are applicable to EQR-related activities conducted by any of these entities. While most states hire an EQRO to conduct the EQR-related activities, states may elect to conduct the EQR-related activities themselves or to contract with an organization that is not an EQRO or an agent that is not an MCP to perform these activities. Regardless of which entity performs EQR-related activities, the data from all activities must be independently reviewed and evaluated by the EQRO as part of the annual EQR and EQR technical report.

[17] See 42 CFR 431 Subpart F and 457.1110.

[18] See 42 CFR 438.364(d).

[19] See 42 CFR 438.358(a).

Box 4. Steps to Prepare for EQR-Related Activities

1. **Select an entity to conduct the EQR-related activity(s)**
   - Ensure that staff conducting EQR-related activities have the training and experience needed for the particular activity(s) they will be conducting
2. Provide clear, written understanding of the parameters of the review
   - List of MCPs for review
   - Select optional EQR-related activities (if applicable) in addition to the applicable mandatory EQR-related activities
   - Designate a timeframe for review
3. Review all applicable federal regulations, state regulations or standards, and MCP state contracts
4. Confirm approach with entity and all EQR participants
   - Each organization's responsibilities in collecting, reporting, and/or analyzing data
   - Which regulations, contracts, and/or initiatives should be evaluated
   - Which reviews will occur and tools used
   - A timeline identifying the start and completion of each protocol

Nonduplication for Mandatory EQR-Related Activities

Nonduplication is intended to reduce administrative burden on MCPs and states while still ensuring relevant information is available to EQROs for the annual EQR. The expansion of nonduplication to three of the mandatory EQR-related activities (Protocols 1–3, Validation of Performance Improvement Projects, Validation of Performance Measures, and Review of Compliance with Medicaid Managed Care Regulations)[20] for all Medicaid managed care MCOs, PIHPs, and PAHPs—not just those serving only dually eligible beneficiaries—provides additional flexibility to states to reduce administrative burden. Nonduplication is an option for a state only when the Medicare or accreditation review standards are comparable to the EQR protocols (not vice versa). If a state elects to use nonduplication, it must document in its managed care quality strategy and its annual EQR technical report the EQR-related activities for which it utilizes nonduplication along with the state's rationale for its determination that the Medicare or private accreditation review standards are comparable to those in these protocols.[21] The federal requirements related to nonduplication of mandatory activities are described in 42 CFR 438.360. Like Medicaid, CHIP MCPs may submit information from a private accreditation review; however, with regard to CHIP, information documenting compliance with Medicare Advantage standards is not applicable as described in 42 CFR 457.1250(a).

Nonduplication allows a state to use information from a Medicare or private accreditation review of an MCP in place of generating that information through one or more of three mandatory EQR-

[20] Nonduplication is not an option for the fourth mandatory EQR-related activity of network adequacy validation (42 CFR 438.358(b)(1)(iv)).

[21] See 42 CFR 438.360(c) and 438.340(b)(10).

related activities (Protocols 1–3, Validation of Performance Improvement Projects, Validation of Performance Measures, and Review of Compliance with Medicaid Managed Care Regulations).[22] To do so, the following conditions must be met:

- The MCP is in compliance with the applicable Medicare Advantage or private accreditation standards[23]
- The Medicare or private accreditation review standards are comparable to those established through the EQR protocols for the three mandatory EQR-related activities
- The MCP provides the state with all applicable reports, findings, and other results of the Medicare or private accreditation review applicable to the specified EQR-related activities

The state is responsible for providing the EQRO with all information from the Medicare or private accreditation review which is being used for nonduplication. The EQRO then assesses the completeness of information from the accreditation review to determine the extent of nonduplication, including confirming the comparable information fully meets the requirements for completing the analysis and developing EQR findings and recommendations. If a state chooses nonduplication, it must ensure the completion of any EQR-related activities (or components of those activities) that are not addressed by the information from the Medicare or private accreditation review. For example, if an accreditation review did not validate long term services or supports (LTSS) or other non-Healthcare Effectiveness Data and Information Set (HEDIS®) measures required by the state as a part of an MCP's QAPI program, that validation activity would need to be completed for those measures.

It is important to note that even when information from a Medicare or private accreditation review does not completely meet the requirements of an activity, that information can still be used toward meeting the nonduplication requirements. For example, nonduplication might be able to satisfy a subset of the regulatory requirements that are subjects of the compliance review. In this example, the EQRO could use information from the nonduplication source for that subset of requirements, and then the EQR-related activity would only need to be conducted on the remaining requirements to fully assess compliance. Similarly, if a state requires its MCPs to include 10 measures in QAPI and 5 are validated as a part of an accreditation review, only the other 5 would need to be validated through the EQR-related activity. Validation information on all 10 measures would then be provided to the EQRO for the EQR.

[22] Prior to issuance of the Medicaid and CHIP 2016 final rule, such information could only be used to provide information which would otherwise be gathered from performing the mandatory EQR-related compliance review.

[23] See 42 CFR 422 subpart D.

Box 5. What is the Difference Between Nonduplication and Exemption?

Nonduplication is a way to provide information for the annual EQR without conducting part of, or all of, one or more EQR-related activities by using information yielded by a comparable review process. Under nonduplication, an MCO, PIHP, or PAHP is still subject to EQR and will be included in the annual EQR technical report. Nonduplication may be used at the state's discretion and consistent with documentation in the state's managed care quality strategy.

Exemption is an option which allows a state to exempt an MCO (but not a PIHP or PAHP) from the annual EQR process under certain circumstances. If a state exempts an MCO from EQR, the MCO will not be included in the annual EQR technical report. Exemption may be used at the state's discretion when the following three conditions are met:

- The MCO has both a current Medicare Advantage contract and a current Medicaid contract;
- The two contracts cover all or part of the same geographic area in the state; and
- The Medicaid contract has been in effect for at least two consecutive years before the exemption date, and during those same two years, the MCO has been subject to EQR and met quality, timeliness, and access to health care services standards for Medicaid beneficiaries

If a state wants to exempt an MCO from EQR, it must obtain either of the following:

- For MCOs reviewed by Medicare, the state must obtain annually the most recent Medicare review findings from the MCO, including all data, correspondence, information, and findings relevant to the MCO's compliance with Medicare standards for (1) access, quality assessment and performance improvement, health services, or delegation of these activities, (2) all measures of the MCO's performance, and (3) results and findings of all performance improvement projects for Medicare enrollees
- For MCOs reviewed by a private, national accrediting organization that CMS approves and recognizes for Medicare Advantage Organization deeming, the state must require that the MCO provide a copy of all findings from its most recent accreditation review if that review was used to meet certain requirements for Medicare external review, or to determine compliance with Medicare requirements. At a minimum, findings must include accreditation review results of evaluation of compliance with individual accreditation standards, any deficiencies, corrective action plans, and summaries of unmet accreditation requirements

Each year, the state must identify MCOs exempt from EQR on its website in the same location where EQR technical reports are posted. The state must include the name(s) of the exempt MCO(s), including the beginning date of the current exemption period, or that no MCOs are exempt from EQR.

Complete requirements for exemption of MCOs are available at 42 CFR 438.362.

When information from a Medicare or private accreditation review of an MCP is used to support one or more mandatory EQR-related activities, the EQRO's analysis of the data is eligible for FFP. The accreditation activities that produce the information are not eligible for the FFP. Note that use of discretion of the state, not its MCPs. See Box 5 for more information on the difference between nonduplication and exemption.

Tips for Drafting Compliant EQR Technical Reports

A qualified EQRO[24] is the only entity that may conduct the annual EQR, that is, the analysis and evaluation of information generated by the EQR-related activities (or via nonduplication, if

[24] See 42 CFR 438.354 for information about the competence and independence requirements for an EQRO.

applicable) regarding the quality, timeliness, and access to the health care services that an MCP, or its contractors, furnish to beneficiaries. The end product of the EQR is an EQR technical report, which must be drafted by said EQRO for the state.[25] This section provides guidance on report content and structure.

Guidance on Report Content

EQROs should produce reports that meet all federal requirements. To promote compliance with federal requirements, this section summarizes the requirements and includes considerations for drafting EQR technical reports. Table 2 provides an overview of the required elements in EQR technical reports and Table 3 identifies requirements for the PIP validation (Protocol 1), performance measure validation (Protocol 2), and review of compliance activities (Protocol 3).

[25] CHIP regulations at 457.1250 cross reference to 42 CFR 438.364.

Table 2. Required Elements in EQR Technical Reports and Tips for Drafting EQR Technical Reports

Regulatory Reference	Requirement	Tips for Drafting EQR Technical Reports
42 CFR 438.364(a)	All eligible Medicaid and CHIP plans are included in the report.	Identify the MCPs subject to EQR by plan name, MCP type, managed care authority, and population(s) served in an introduction, executive summary, or appendix.
42 CFR 438.364(a)(1)	The technical report must summarize findings on quality, access, and timeliness of care for each MCO, PIHP, PAHP, and PCCM entity that provides benefits to Medicaid and CHIP enrollees.	Include a description for all three activities noted under the regulation (1) how data were aggregated, (2) how they were was analyzed, and (3) how conclusions were drawn about the MCP's ability to furnish services. These findings should reflect a comparison to the domains of quality, timeliness, and access to healthcare services..
42 CFR 438.364(a)(3)	The technical report must include an assessment of the strengths and weaknesses of each MCO, PIHP, PAHP and PCCM entity with respect to (a) quality, (b) timeliness, and (c) access to the health care services furnished by MCO's, PIHP's, PAHP's, or PCCM entity.	Include a chart outlining each MCP's strengths and weaknesses for each EQR activity and designate a quality, timeliness, and access domain Highlight substantive findings concerning the extent to which each MCP is furnishing high quality, timely, and appropriate access to health care services. Findings should focus on the specific strengths and weaknesses the EQRO identified, rather than on numerical ratings or validation scores obtained under the EQRO's review methodology.
42 CFR 438.364(a)(4)	The technical report must include recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity.	Include recommendations for each MCP. Recommendations should share the EQRO's understanding of why the weakness exists and suggest steps for how the MCP—potentially in concert with the state—can best address the issue. If the cause for the weakness is unclear or unknown, the EQRO should suggest how the MCP and/or state can identify the cause. When determining recommendations, EQROs should consider whether the suggested actions are within the authority of the MCP (or state).

Regulatory Reference	Requirement	Tips for Drafting EQR Technical Reports
42 CFR 438.364(a)(4)	The technical report must include recommendations for how the state can target goals and objectives in the quality strategy, under §438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid or CHIP beneficiaries.	Consider connecting EQR findings to the quality strategy goals and objectives, particularly in sections of the report that assess the state's overall performance of the quality, timeliness, and access to health care services; when discussing strengths and weaknesses of a MCP or activity; or when discussing the basis of performance measures or PIPs. Note when goals in the quality strategy are considered in EQR activities and which goals they are. Describe the relationship between goals in the state's quality strategy and the four mandatory EQR activities.
42 CFR 438.364(a)(5)	The technical report must include methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities.	Aggregate findings across MCPs for each EQR activity, and show comparisons. Provide context for the individual MCP to make it easier for stakeholders to understand the results of the review and more readily determine whether issues are localized or systemic.
42 CFR 438.364(a)(6)	The technical report must include an assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.	State the prior year finding and describe the assessment of each MCP's approach to addressing the recommendation or findings issued by the state or EQRO in the previous year's EQR technical report. This is not a restatement of a response or rebuttal to the recommendation by the MCP or state. Document assessments with the same specificity used when reporting on initial findings.
42 CFR 438.364(d)	The information included in the technical report must not disclose the identity or other protected health information of any patient.	Ensure the technical report is consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 C.F.R. §431 Subpart F and § 457.1110). Ensure that MCPs comply with HIPAA and all other federal and state laws concerning confidentiality and disclosure. Ensure that EQR-related data collection and reporting activities are consistent with HIPAA requirements.

Table 3. Requirements for the PIP Validation, Performance Measure Validation, and Review of Compliance Activities and Considerations for Drafting EQR Technical Reports

Regulatory Reference	Requirement	Considerations for Drafting EQR Technical Reports
42 CFR 438.364(a)(2)(i-iv)	The technical report must include the following for **each** of the mandatory activities • Objectives • Technical methods of data collection and analysis • Description of data obtained including validated performance measurement data for each PIP • Conclusions drawn from the data.	**Objectives:** Provide the state or EQRO's objective for conducting the mandatory activity itself, including the general approach or methods of validation used by the EQRO. The state may also include the objective or aim statement for each PIP to satisfy this criteria for the PIP validation activity. **Technical methods of data collection and analysis**: Provide a description of ***how*** data was obtained by the EQRO to conduct the validation activity. If a collection tool is used, providing an example of the format of the tool, or questions asked, in an appendix is a best practice. Further, describe how data is analyzed to connect the data requested to the analytical methods that eventually support the conclusions drawn with those data and analyses. **Description of data obtained**: Based upon the collection efforts above, describe the types of data obtained – information system extracts, documents, answers to questions in data collection tools, and others – to explain the nature of the data collected and analyzed. **Note: This requirement does not apply to the compliance review activity (Protocol 3).** **Conclusions drawn from the data**: Having employed the process of data collection and validation using the types and nature of the data received, provide conclusions relevant to the mandatory activity.
438.358(b)(1)(i)	The technical report must include information on the validation of PIPs that were underway during the preceding 12 months.	Provide a validation of all PIPs underway during the 12 month period preceding the EQR review, regardless of the phase of the PIP's implementation. States often link the time-frame under review to a corresponding measurement or performance period such as state or federal fiscal year, or calendar year.
42 CFR 438.330(d)	The technical report must include a description of PIP interventions associated with each state-required PIP topic for the current EQR review cycle.	For states with many MCPs and PIPs, provide an appendix or link to each plan-level report, an appendix in an aggregate report, or a separate PIP-report that compiles the PIPs applicable to all or a group of plans. Present this information in a cohesive way that allows for brevity in the sections that describe data analysis and conclusions.

Regulatory Reference	Requirement	Considerations for Drafting EQR Technical Reports
		Note that a table listing all PIP interventions will not alone be considered as methodologically appropriate comparative information, as the table simply organizes information, but does not compare or draw conclusions from the information presented.
42 CFR 438.358(b)(1)(ii)	The technical report must include information on the validation of each MCO's, PIHP's, PAHP's, or PCCM entity's performance measures for each MCO, PIHP, PAHP, and PCCM entity performance measure calculated by the state during the preceding 12 months.	Provide a validation of all performance measures in use during the 12 month period preceding the EQR review, regardless of the phase of the performance measure's implementation. States often link the time-frame under review to a corresponding measurement or performance period such as state or federal fiscal year, or calendar year.
42 CFR 438.358(b)(1)(iii)	The technical report must include information on a review, conducted within the previous three-year period, to determine each MCO's, PIHP's, PAHP's or PCCM's compliance with the standards set forth in Subpart D and the QAPI requirements described in 42 CFR 438.330. The technical report must provide MCP results for the following 11 Subpart D and QAPI standards: 42 CFR 438.206, 457.1230(a), Availability of services 42 CFR 438.207, 457.1230(b), Assurances of adequate capacity and services 42 CFR 438.208, 457.1230(c) Coordination and continuity of care 42 CFR 438.210, 457.1230(d), Coverage and authorization of services 42 CFR 438.214, 457.1233(a), Provider selection 42 CFR 438.224, 457.1230(c), Confidentiality 42 CFR 438.228, 457.1260, Grievance and appeals system 42 CFR 230, 457.1233(b), Subcontractual relationships and delegation 42 CFR 438.236, 457.1233(c), Practice guidelines 42 CFR 438.242, 457.1233(d), Health information system 42 CFR 438.330, 457.1240(b), QAPI	For each of the 10 Subpart D standards and individual QAPI standard, ensure that the method of compliance review clearly links the EQRO's activities to the standard under review. Further, ensure that a clear compliance determination is made and recorded for each standard for each plan. A best practice is to list a compliance score of a numerical or semi-quantitative nature. EQROs that assess domains, standards, and requirements that do not neatly overlap with the regulatory standards should provide a clear crosswalk of their activities to the standards under review. As a best practice, the technical report may include a table outlining the timeline for reviewing all standards for MCPs across the three-year review period.

Guidance on Report Structure

To be of greatest use to states and other stakeholders, EQROs should draft reports that are actionable, clear, and concise; that highlight substantive findings; and that contain actionable recommendations. CMS understands that states vary in the number of Medicaid and CHIP programs and MCPs. The EQRO should prepare an aggregate report that summarizes results across all MCPs and provides state-level recommendations for performance improvement. The EQR technical reports must also meet the plan-level reporting requirements for items such as identification of strengths and weaknesses, assessment of MCP actions to address previous year's recommendations, performance measures, and others. The EQRO can address these plan-level reporting requirements via tables or appendices to the aggregate report or prepare separate aggregate reports by type of MCP if appropriate. For example, the EQRO may develop one aggregate report on all of a state's medical MCOs and a separate aggregate report on all of the state's behavioral health PIHPs. See Box 6 for guidance on using aggregate and plan-level reports.

Box 6. Using Aggregate and Plan-level Reports

States with large and varied managed care programs may group MCPs by type, geography, or populations served and provide both plan-level and aggregate reports. Plan-level reports may be effective for communicating plan-specific information while aggregate reports can communicate required comparative information and analyses.

Creating multiple reports may help CMS and the public find and review information quickly, but states and EQROs should describe the structure of reports in a statewide executive summary or in the introduction to the aggregate report.

Tips for Drafting an Effective EQR Technical Report

In addition to focusing on compliance with federal requirements, EQROs should consider these tips for drafting a report that is actionable, clear, and concise.

- **Aim for clarity and concise presentation.** While every EQR review necessarily gathers and processes a substantial amount of material, non-essential narrative makes it difficult for readers to identify the most relevant information
    - Because not all readers have deep experience in the areas covered by EQR, avoid technical language and jargon when possible
    - To maximize interpretability of results, provide context for all statistics included in the report
- **Include a clickable or hyperlinked table of contents**. For easy navigation throughout the report(s), include a clickable or hyperlinked table of contents
- **Produce a searchable PDF**. To enable stakeholders to review topics of interest and facilitate use of the reports for topic-specific analyses, produce a searchable PDF

- **Use the names of MCPs when referring to plan performance.** Findings and comparisons should refer to MCPs by name in order to facilitate transparency and stakeholder understanding of specific plan performance
- **Consider displaying previous recommendations, plan responses and actions, and new recommendations in one chart.** This enables a comprehensive view of the history of each MCP's performance based on the EQR process
    - The comparative information should include tables presenting, for all plans, performance measure scores, and PIP ratings and scores
    - Charts can be used to display compliance and non-compliance with each of the reviewed state and federal standards

Tips for State Review of EQR Technical Reports

The state is ultimately responsible for the submission of a complete report per 42 CFR 438.364. Upon receipt of EQR technical reports from the EQRO, the state should review the report for completeness and adherence to these protocols. For example, the state should confirm that the technical report includes all of the required elements set forth in 42 CFR 438 Subpart E and includes a review of all standards and regulations in Subpart E of Part 438 and other regulations incorporated by reference.

The EQR technical report must be independently developed and produced by the EQRO. The state may not substantively revise the EQR technical report submitted by the EQRO without evidence that errors or key omissions occurred.

Tips for Posting and Submitting EQR Technical Reports

As required under 42 CFR 438.10(c)(3), the state must post its finalized annual technical report(s) on its website by April 30th of each year. CMS additionally requests states submit their EQR technical report(s) to ManagedCareQualityTA@cms.hhs.gov by April 30th of each year. Box 7 provides reminders to states before posting and submitting their EQR technical reports.

Box 7. Reminders to States

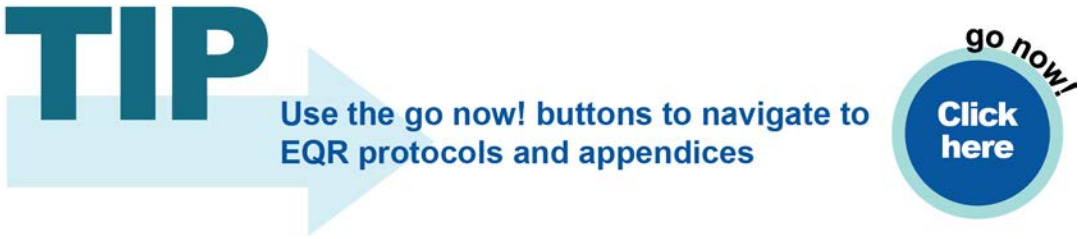
- For the purposes of the EQR protocols, we refer to EQROs as the entity conducting the EQR-related activities. While most states hire an EQRO to conduct the EQR-related activities, the state may elect to conduct the EQR-related activities themselves or to contract with an EQRO or an agent that is not an MCP to perform these activities (or a combination of these approaches). An EQRO is the only entity that may conduct the annual EQR. The end product of the EQR is an EQR technical report, which must be drafted by said EQRO.
- An accrediting body may not serve as an EQRO for a health plan it accredited within the previous 3 years.
- States cannot substantively revise the EQR technical report without evidence that errors occurred or that key information was omitted.

Getting Started on the EQR Protocols

So far, this chapter has provided background on the mandatory and optional EQR-related activities and the associated protocols, discussed considerations before conducting EQR-related activities, provided an overview of nonduplication, and shared tips on drafting the EQR technical report. Now it's time to review the protocols for each of the activities and begin planning the approach to conducting the EQR. Use the "Go Now!" buttons to navigate to the individual protocols and the appendices.

The protocols in this document are designed to support the completion of the EQR-related activities, which in turn help the state meet the requirement to conduct an EQR of its MCPs and help contracted EQROs meet the requirements of producing an annual EQR technical report. If a state prefers to use methods consistent with but not identical to these protocols to conduct EQR-related activities, the state is encouraged to discuss the alternative methods with CMS before implementation to assure the methods meet regulatory standards.

If you have any questions related to the EQR protocols or alternative methods, please contact CMS via the TA mailbox, **ManagedCareQualityTA@cms.hhs.gov**.



Mandatory EQR-Related Activities

Protocol 1 – Validation of Performance Improvement Projects **Page 26**

MCOs, PIHPs, and PAHPs are required to implement performance improvement projects (PIPs) that focus on both clinical and non-clinical aspects of care. Protocol 1 specifies procedures for EQROs to use in assessing the validity and reliability of a PIP (42 CFR 438.358(b)(i)).

Protocol 2 – Validation of Performance Measures **Page 62**

MCPs must report standard performance measures as specified by the state. The state must provide to the EQRO and the MCP the performance measures to be calculated, the specifications for the measures, and the state reporting requirements. Protocol 2 tells the EQRO how to:

- Evaluate the accuracy of the Medicaid and CHIP MCP reported performance measures based on the measure specifications and state reporting requirements
- Evaluate if the MCP followed the rules outlined by the state agency for calculating the measures (42 CFR 438.358(b)(ii))

This protocol also applies when a state requires its MCPs to submit data to the state so that the state can calculate the standard performance measures

Protocol 3 – Review of Compliance with Medicaid and CHIP Managed Care Regulations **Page 125**

The EQR is required to include a compliance review of each MCP once in a 3-year period. Protocol 3 specifies procedures to determine the extent to which MCPs comply with standards set forth at 42 CFR 438.358(b)(iii), state standards, and MCP contract requirements.

Note that states may meet the 3-year requirement in different ways: for example, some review all MCPs at the same time once every 3 years; others conduct a complete compliance review on a subset of plans each year on a 3-year cycle. While a full compliance review is required for each MCP once every 3 years, the state must address any EQR findings in the next reporting year.

Protocol 4 – Validation of Network Adequacy **Page 210**

States must ensure that Medicaid and CHIP MCPs maintain provider networks that are sufficient to provide timely and accessible care to Medicaid and CHIP beneficiaries across the continuum of services. As set forth in 42 CFR 438.68, states are required to set quantitative network adequacy standards for MCPs that account for regional factors and the needs of the state's Medicaid and CHIP populations.

The purpose of this protocol is to guide the EQRO in conducting the validation of network adequacy during the preceding 12 months to comply with requirements set forth in 42 CFR 438.68 and, if the state enrolls American Indians and Alaska Natives in the MCO, PIHP, or PAHP, 42 CFR 438.14(b)(1). This includes validating data to determine whether the network standards, as defined by the state, were met.

Optional EQR-Related Activities

Protocol 5 – Validation of Encounter Data Reported by the MCP **Page 242**

The states use managed care encounter data, which are data about a distinct service provided to an enrollee, to better understand the health services delivered by the MCP, assess and review quality, monitor program integrity, and determine capitation payment rates. Protocol 5 specifies procedures for assessing the completeness and accuracy of encounter data submitted by MCPs to the state. It also assists in the improvement of processes associated with the collection and submission of encounter data from MCPs to the state.

Protocol 6 – Administration or Validation of Quality of Care Surveys **Page 271**

Surveys are a common method of measuring health care quality, especially consumer experience with care. Protocol 6 specifies procedures for conducting various types of surveys and validating those surveys.

Protocol 7 – Calculation of Additional Performance Measures **Page 306**

The state uses performance measures to monitor the performance of MCPs over time, to understand the MCPs' impact on the Medicaid population, to compare the performance of different MCPs, and to inform the selection and evaluation of quality improvement activities. Protocol 7 specifies procedures for calculating MCP performance measures in accordance with the state specifications. It also supplies information to the state on the extent to which the MCP's information system provides accurate and complete information necessary for the calculation of performance measures.

Protocol 8 – Implementation of Additional Performance Improvement Projects **Page 323**

The state may conduct—or request an EQRO conduct—a PIP in addition to those MCOs, PIHPs, and PAHPs are required to conduct as a part of their QAPI programs. Protocol 8 specifies procedures for implementing additional PIPs.

Protocol 9 – Conducting Focus Studies of Health Care Quality **Page 332**

The state may choose to conduct a study on a particular aspect of clinical and/or non-clinical services provided by its MCPs. Protocol 9 specifies procedures to plan and carry out a focus study.

Protocol 10 – Assist with the Quality Rating of Medicaid and CHIP MCOs, PIHPs, and PAHPs **Page 342**

[Reserved]

Appendices

The EQR protocol package includes four appendices to supplement information contained in the protocols. Use the "Go Now!" buttons to navigate to the appendices.

Appendix A. Information Systems Capabilities Assessment **Page A.1**

Protocols 1, 2, 3, 4, 5, and 7 require each state to assess their MCPs' information system (IS) capabilities. The regulations at 42 CFR 438.242 and 457.1233(d) also require the state to ensure that each MCP 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 reasons other than the loss of Medicaid eligibility. Portions of the Information Systems Capabilities Assessment (ISCA) are voluntary; however, there are components that relate directly to the mandatory EQR-related activity protocols. It defines the recommended capabilities of an MCP's information system to meet the above noted regulatory requirements, as well as how to assess the strength of the MCP's information system capabilities. It includes an overview of the processes for collecting, processing, and reporting data, and guidance for:

- Completing the ISCA assessment (by MCPs)
- Reviewing ISCA and accompanying documents
- Interviewing MCP staff
- Analyzing ISCA findings

Appendix B. Sampling Approaches for EQR Data Collection Activities **Page B.1**

This appendix provides an overview of sampling approaches that can be used in Protocols 1, 2, 5, 6, 7, 8, and 9.

Appendix C. Acronyms Used in the Protocols **Page C.1**

This appendix defines acronyms used in the protocols.

Appendix D. External Quality Review Glossary of Terms **Page D.1**

This appendix defines terms used in the Protocols.

For Further Information

Technical assistance resources related to EQR, including the EQR protocols, are available on Medicaid.gov at https://www.medicaid.gov/medicaid/quality-of-care/medicaid-managed-care/external-quality-review/index.html.

Please submit any questions or requests for technical assistance related to EQR to **ManagedCareQualityTA@cms.hhs.gov**.

Protocol 1. Validation of Performance Improvement Projects

A Mandatory EQR-Related Activity

PROTOCOL ONE

ACTIVITY 1: ASSESS THE PIP METHODOLOGY

ACTIVITY 2: PERFORM OVERALL VALIDATION AND REPORTING OF PIP RESULTS

ACTIVITY 3: VERIFY PIP FINDINGS (OPTIONAL)

Background

States must require their Medicaid and CHIP managed care plans (MCPs) to conduct performance improvement projects (PIPs) that focus on both clinical and nonclinical areas each year as a part of the plan's quality assessment and performance improvement (QAPI) program, per 42 CFR 438.330 and 457.1240(b).[26] See Box 1.1 for the definition of a PIP.

Box 1.1. What is a PIP?

A PIP is a project conducted by the MCP that is designed to achieve significant improvement, sustained over time, in health outcomes and enrollee experience. A PIP may be designed to change behavior at a member, provider, and/or MCP/system level. The topic should target improvement in relevant areas of clinical and non-clinical services.

This external quality review (EQR)-related activity validates the PIPs that the MCP was required to conduct as part of its QAPI program. The external quality review organization (EQRO) reviews the PIP design and implementation using documents provided by the MCP, which may be supplemented with interviews of MCP staff. The EQRO then reports to the state on its findings from reviewing and validating the PIP(s) in the EQR technical report. As noted in the Introduction, states have the option to use information from a Medicare or

[26] At a minimum, a single PIP that focuses on both clinical and non-clinical aspects of care may satisfy this requirement. Otherwise, a state must require at least two PIPs, one clinical and one non-clinical.

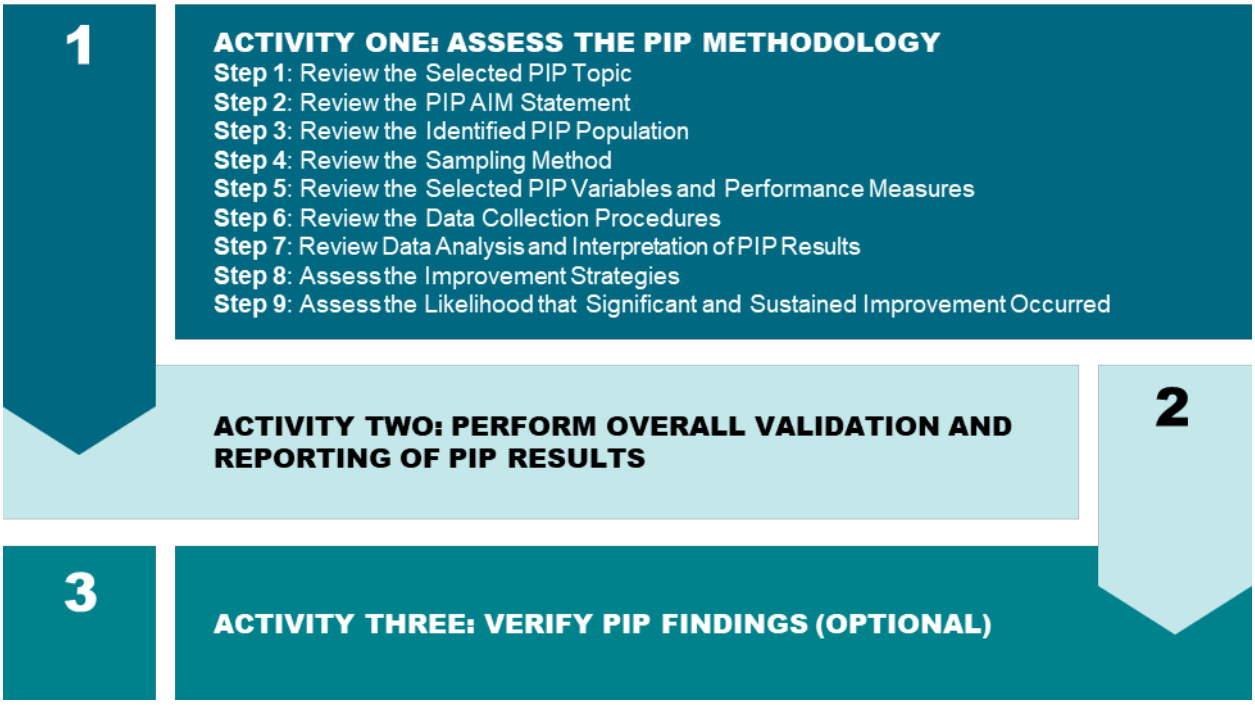
private accreditation review of an MCP to provide information for the annual EQR instead of conducting this mandatory EQR-related activity.[27, 28]

A related protocol, Protocol 8. Implementation of Additional Performance Improvement Projects, specifies procedures for implementing additional PIPs in accordance with state specifications.

Getting Started on Protocol 1

To complete this protocol, the EQRO undertakes two required activities and one optional activity for validating the PIPs for each MCP (Figure 1.1).

Figure 1.1. Protocol 1 Activities



[27] If the state elects to use nonduplication for this mandatory EQR-related activity (42 CFR 438.360, Nonduplication of mandatory activities with Medicare or accreditation review), then the state must ensure that all information from the Medicare or private accreditation review is provided to the EQRO for analysis and inclusion in the annual EQR technical report. (See 42 CFR 438.360(a)(1)–(3) for additional details regarding the circumstance under which nonduplication is an option). Use of nonduplication must be identified in the state's quality strategy (see 42 CFR 438.360(c) and 438.340(b)(10)). CHIP regulations at 457.1250 cross-references to 42 CFR 438.360, but does not allow for the use of Medicare review activities for the purposes of nonduplication.

[28] A state may not utilize nonduplication if Medicare has accepted an only attestation of a plan's quality incentive program (QIP). In the context of this EQR-related activity, the QIP would have to undergo validation as part of a Medicare review in order for nonduplication to be an option. See 42 CFR 438.360(a)(2).

Two supplemental resources are available to help EQROs validate PIPs, including:

- Worksheets for Protocol 1. PIP Validation Tools and Reporting Framework, a set of worksheets that can be used to guide and record answers for the validation of PIPs and reporting of summary PIP information, based on activities 1 through 3 and associated steps in this protocol
- Appendix B. Sampling Approaches for EQR Data Collection Activities, which provides an overview of sampling methods that could be used in this protocol

The remainder of this protocol outlines the steps associated with Activities 1 through 3.

Activity 1: Assess the PIP Methodology

The EQRO should complete the nine steps in Activity 1, listed below, and answer the questions posed in each step.

Step 1: Review the Selected PIP Topic

PIP topics should target improvement in relevant areas of clinical and non-clinical services. In this step, the EQRO determines the appropriateness of the PIP topic(s), including how the PIP topic was selected and input from enrollees or providers. CMS suggests that PIP topics align with CMS-identified priorities[29] and consider the aims of the National Quality Strategy:[30]

- Better care for patients and families
- Improved health for communities and populations
- Affordable health care

WORKSHEET 1.1

Resource for Activity 1, Step 1

Worksheet 1.1. Review the Selected PIP Topic

- Provides a template for assessing the appropriateness of the PIP topic, including how the PIP topic was selected, the consideration of the CMS Child and Adult Core Set measures, and input from enrollees or providers

[29] More information about CMS priorities and initiatives is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy

[30] More information about the National Quality Strategy is available at https://www.ahrq.gov/workingforquality/about/index.html.

In addition, the state should review its performance on the CMS Child and Adult Core Set measures[31] to identify opportunities to improve performance through a managed care PIP.

Step 2: Review the PIP Aim Statement

In this step, the EQRO assesses the appropriateness and adequacy of the aim statement. The PIP aim statement identifies the focus of the PIP and establishes the framework for data collection and analysis. The PIP aim statement should define the improvement strategy, population, and time period. It should be clear, concise, measurable, and answerable. Box 1.2 identifies considerations for developing a PIP aim statement and Table 1.1 provides a critique of illustrative PIP aim statements.

WORKSHEET 1.2

Resource for Activity 1, Step 2

Worksheet 1.2. Review the PIP Aim Statement

- Provides a template for reviewing the PIP Aim Statement

Box 1.2. Considerations for Developing a PIP Aim Statement that is Clear, Concise, Measurable, and Answerable

A PIP aim statement is clear, concise, measurable, and answerable if the statement specifies measurable variables and analytics for a defined improvement strategy, population, and time period. Potential sources of information to help form the PIP aim statement include:

- State data relevant to the topic being studied
- MCP data relevant to the topic being studied
- CMS Child and Adult Core Set measures
- Enrollee focus groups or surveys
- Relevant clinical literature on recommended care and external benchmarks

Table 1.1. Critique of Example PIP Aim Statements

	Example PIP Aim Statements	Critique
Poor PIP Aim Statement	Does the MCP adequately address psychological problems in patients recovering from myocardial infarction?	• The PIP intervention is not specified • It is unclear how impact will be measured • The population and time period are not clearly defined

[31] More information about the Child and Adult Core Sets available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/index.html.

	Example PIP Aim Statements	Critique
Good PIP Aim Statement	Will the use of cognitive behavioral therapy in patients with depression and obesity improve depressive symptoms over a six-month period during 2022?	• Specifies the PIP intervention (cognitive behavioral therapy) • Defines the population (patients with depression and obesity) and the time period (six-month period during 2022) • Specifies the measurable impact (improve depressive symptoms)

Step 3. Review the Identified PIP Population

WORKSHEET 1.3

Resource for Activity 1, Step 3

Worksheet 1.3. Review the Identified PIP Population

- Provides a template for assessing whether the PIP population was appropriately identified

In this step, the EQRO assesses whether the MCP clearly identified the population for the PIP in relation to the PIP aim statement (such as age, length of enrollment, diagnoses, procedures, and other characteristics). Depending on the nature of the PIP aim statement, PIP population, and available data, the PIP may include the entire population or a sample of the population. PIPs that rely on existing administrative data, such as claims and encounter data, registry data, or vital records, are typically based on the universe of the PIP population. PIPs that rely on either medical record review or the hybrid method (which uses a combination of administrative data and medical record review) typically include a representative sample of the identified population. If a sample was used for the PIP, go to Step 4. If the entire population was studied, skip Step 4 and go to Step 5. If HEDIS® measures and sampling methodology are used, go to Step 5.

Step 4: Review the Sampling Method

WORKSHEET 1.4

Resource for Activity 1, Step 4

Worksheet 1.4. Review the Sampling Method

- Provides a template for reviewing the suitability of the sampling method based on the PIP aim statement and population

In this step, the EQRO assesses the appropriateness of the PIP's sampling methods. Appropriate sampling methods are necessary to ensure that the collection of information produces valid and reliable results. Please refer to Appendix B, Sampling Approaches for EQR Data Collection Activities, for an overview of sampling methodologies applicable to PIPs. When HEDIS® measures are used and sampling is required (for example, for measures calculated using the hybrid method), HEDIS® sampling methodology should be used.

Step 5: Review the Selected PIP Variables and Performance Measures

In this step, the EQRO assesses the variables selected for a PIP (see Box 1.3). Variables in PIPs can take a variety of forms as long as the selected variables identify the MCP's performance on the PIP questions objectively and reliably and use clearly defined indicators of performance. The PIP should include the number and types of variables that are adequate to answer the PIP question and for which appropriate and reliable data are available to measure performance and track improvement over time. Variables used in PIPs may be continuous, categorical, or discrete (Table 1.2), and may use a variety of measurement scales to assess performance (Table 1.3).

WORKSHEET 1.5

Resource for Activity 1, Step 5

Worksheet 1.5. Review the Selected PIP Variables and Performance Measures

- Provides a template for assessing the appropriateness of selected PIP variables and performance measures

Box 1.3. Considerations for Selecting Variables for a PIP

- A variable is a measurable characteristic, quality, trait, or attribute of a particular individual, object, or situation being studied (see Table 1.2 for types of variables).
- When choosing variables, consider different types of variables and choose the variables and measurement scales that are best suited to the available data, resources, and PIP aim statement (see Table 1.3 for types of measure scales).
- CMS encourages MCPs to choose variables that reflect health outcomes or that can be linked to health outcomes and that can be examined on at least a semi-annual basis.

Table 1.2. Types of Variables for PIPs

Variable Type	Definition	Examples
Continuous	Have a range of numerical values Note: Data collected for a continuous variable can be recoded as a discrete variable (e.g., an enrollee's blood pressure is above or below a specified level)	• Age, blood pressure, temperature, height/weight, body mass index, birthweight
Categorical	Have a range of non-ordered, qualitative values (or categories)	• An enrollee survey question that asks enrollees to identify the most important among a list of incentives offered to improve well-care visit rates
Discrete	Have a limited number of possible categories Note: binary variables have two categories	• An enrollee has/has not received a flu shot in the past 12 months

Table 1.3. Types of Measurement Scales for PIP Variables

Measurement Scales	Definition	Example
Interval	The distances between numbers denote significant and interpretable differences (e.g., dollars, degrees, inches, pounds) and the differences are interpretable as higher or lower.	• The interval between an annual income of $40,000 and $30,000 = $10,000
Ordinal	Can be treated as quantitative in some circumstances, and qualitative in others	• An enrollee survey question that asks enrollees to rank their experience of care on a scale from 1 (poor experience) to 5 (excellent experience)
Nominal	The set of categories for a qualitative variable	• Mode of transportation to work (car, bus, subway, bicycle, walk)

Data availability should be considered when selecting variables for PIPs, as more frequent access to data, such as on a monthly, quarterly, or semi-annual basis, supports continuous quality improvement (QI) and Plan Do Study Act (PDSA) efforts and can allow an MCP or state to correct or revise course more quickly, if needed. If plans collect monthly, quarterly, or semi-annual data, the plan should use a methodology to ensure comparability, such as a rolling 12-month methodology. CMS encourages states to select PIP variables and performance measures that can be examined on at least a semi-annual basis.

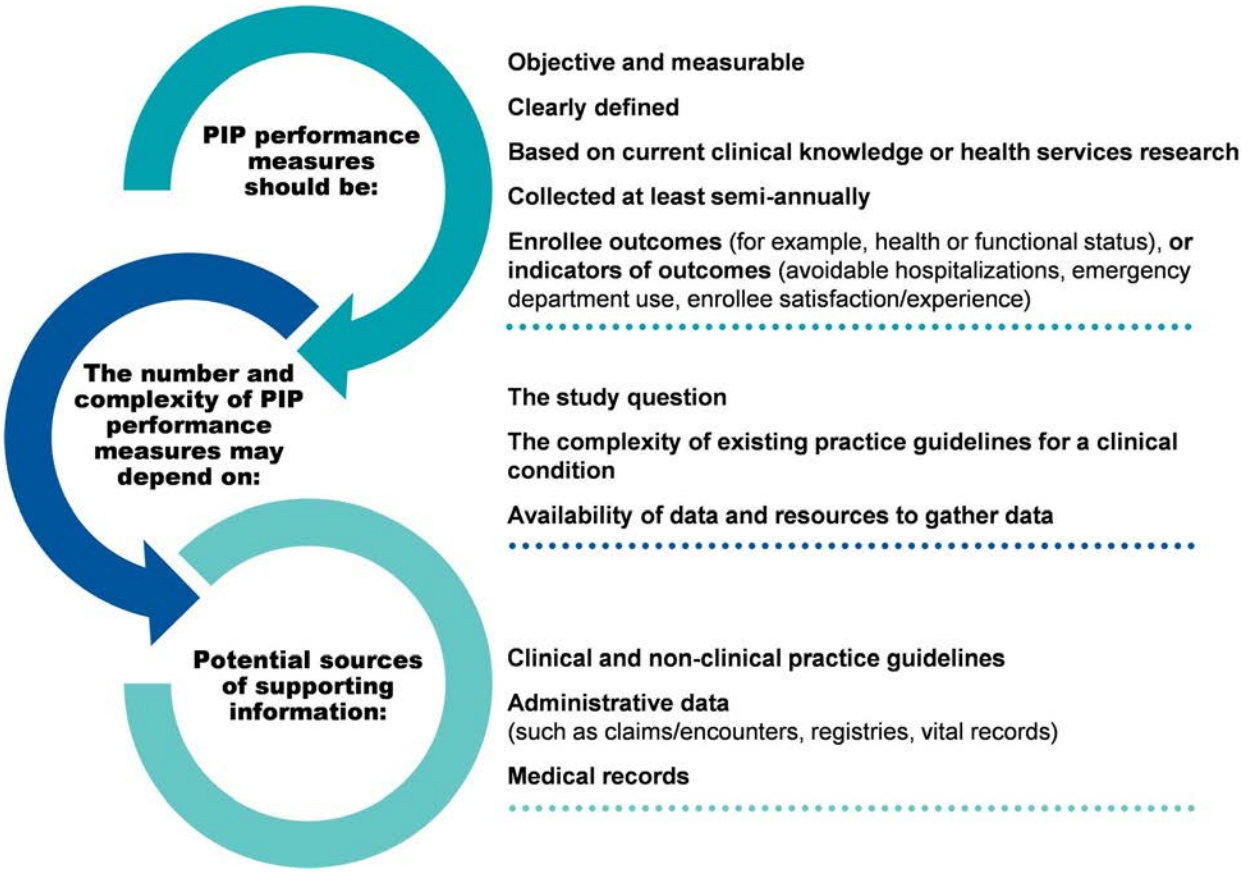
To the extent possible, CMS encourages MCPs to choose variables for PIPs that reflect health outcomes. Performance measures are then used to measure these outcomes. For this protocol, performance measures are used to monitor the performance of individual MCPs at a point in time, to track MCP performance over time, to compare performance among MCPs, and to inform the selection and evaluation of quality improvement activities. In addition, for the purpose of this protocol, "outcomes" are defined as changes in patient health, functional status, satisfaction, or goal achievement that result from health care or supportive services.[32] For example, measures of avoidable hospitalizations or emergency department visits can demonstrate the adequacy of access to preventive and primary care and effectiveness of care for acute and chronic conditions. CMS recognizes that standardized performance measures addressing outcomes may be limited because of the lag in observing changes in population health relative to the timeframe for the PIP measurement period. Moreover, health outcomes may be influenced by factors outside of the organization's control, such as poverty, genetics, and environmental factors. For these reasons, PIP outcomes do not always need to be health outcomes per se, but should be linked to health outcomes.

Figure 1.2 provides guidance for selecting PIP performance measures for tracking performance and improvement in outcomes over time. When selecting performance measures for a PIP, the

[32] See 42 CFR 438.320.

MCP should first consider existing measures because the specifications for these measures often have been refined over time, may reflect current clinical guidance, and may have benchmarks for assessing MCP performance. CMS encourages use of the CMS Child and Adult Core Set, Core Quality Measure Collaborative, and certified community behavioral health clinics (CCBHC) measures.[33] Additional examples of existing measures include NCQA's Healthcare Effectiveness Data Information Set (HEDIS®) or measures that have been developed by the Agency of Healthcare Research and Quality (AHRQ), such as the prevention quality indicators, inpatient quality indicators, patient safety indicators, and pediatric quality indicators.[34]

Figure 1.2. Guidance for Selecting PIP Performance Measures



[33] More information about the Child Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html. More information about the Adult Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html. More information about the Core Quality Measures Collaborative is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.More information about measures for behavioral health clinics is available at https://www.samhsa.gov/section-223/quality-measures.

[34] More information about HEDIS® is available at http://www.ncqa.org/hedis-quality-measurement. More information about AHRQ quality measures is available at http://www.qualityindicators.ahrq.gov/.

When there are gaps in existing measures, the MCP may develop new measures based on current clinical practice guidelines or health services research. The MCP should consider the following questions:

- Does the measure address accepted clinical guidelines relevant to the focus study question?
- Does the measure address an important aspect of care or operations that is meaningful to MCP enrollees?
- Do the available data sources allow the MCP to calculate the measure reliably and accurately? Are there any limitations on the ability to collect valid and reliable data?
- Are all criteria used in the measure defined clearly (e.g., time periods, characteristics of eligible enrollees, services to be assessed, and exclusion criteria)?

Step 6: Review the Data Collection Procedures

In this step, the EQRO assesses the validity and reliability of the procedures the MCP used to collect the data that inform the PIP measurements. Validity means that the data are measuring what is intended to be measured. Reliability means that the data are producing consistent results.

To ensure validity and reliability of the data collected as part of the PIP, the MCP should develop a data collection plan that specifies:

- The data sources for the PIP
- The data to be collected
- How and when the data are to be collected
- Frequency of data collection
- Who will collect the data
- Instruments used to collect the data

WORKSHEET 1.6

Resource for Activity 1, Step 6

Worksheet 1.6. Review the Data Collection Procedures

- Provides a template for reviewing the appropriateness of study variables and performance measures to track improvement
- Includes an assessment of data collection procedures overall and for administrative and medical record review

This step may involve three main kinds of data collection: administrative data sources, medical record review, and a hybrid method. The hybrid method uses a mix of both kinds of data collection. Procedures to collect data from administrative data systems will be different from procedures for visual inspection of medical records or other primary source documents. However, both types of data collection require assurances that data are valid and reliable. CMS encourages states to utilize data sources that they are able to collect data from on a regular basis (e.g., monthly, quarterly, and semi-annually).

- **Administrative data collection.** Evaluating an administrative data collection methodology emphasizes the system that stores the data and should focus on an estimation of the degree of

completeness of the administrative data used to measure performance and track improvement. See Section 2 of Worksheet 1.6 for a checklist of administrative data assessment questions. In addition, refer to Protocol 5, Validation of Encounter Data Reported by the Managed Care Plan for more information on assuring the validity and reliability of encounter data.

- **Medical record review.** For some variables, medical record review may be the only valid and reliable source of data. (Note that medical records may include other sources besides the individual patient medical record, such as clinical tracking logs, manual registries, case management records, and the like.) If the PIP requires medical record reviews, special attention should be given to the qualifications of the medical record reviewers, the specificity of the guidelines for data collection, and plans for ensuring inter- and intra-rater reliability. The reviewers should have a standard protocol for reviewing records, have the knowledge to interpret the records, and have been trained to identify and code the information in the records using consistent decision rules. See Section 3 of Worksheet 1.6 for a checklist of medical record review assessment questions.
- **Hybrid data collection.** The hybrid method uses both administrative and medical record data. The hybrid method, when available, should be used when administrative data or electronic health record (EHR) data are incomplete or may be of poor quality, or the data elements for the measure are not captured in administrative data.

Step 7: Review Data Analysis and Interpretation of PIP Results

In this step, the EQRO assesses the quality of the data analysis and interpretation of PIP results. The review assesses whether the appropriate techniques were used, and if the analysis and interpretation was accurate. In addition, analysis and interpretation of the PIP data should be based on a continuous quality improvement philosophy[35] and reflect an understanding of lessons learned and opportunities for improvement. Interpretation of the PIP results should involve assessing the causes of less-than-optimal performance and collecting data to support the assessment.

WORKSHEET 1.7

Resource for Activity 1, Step 7

Worksheet 1.7. Review Data Analysis and Interpretation of PIP Results

- Provides a template for assessing the quality and completeness of the analysis

Accurate data analysis is essential because the state or MCP may implement changes based on the results. The primary source for the assessment should be analytic reports of PIP results prepared by the MCP, including both baseline and repeat measurements of PIP outcomes. In

[35] Continuous Quality Improvement (CQI) refers to the ongoing study of processes to (1) improve services or outcomes, and (2) prevent or minimize the chance of adverse outcomes. To do so, the organization identifies areas for improvement and tests approaches.

addition, the EQRO may assess the reasonableness of individual MCP results in relation to existing state-level data, data from other MCPs, or industry benchmarks.

This protocol requires EQROs to assess the extent to which any change in performance is statistically significant; however, it does not specify a level of statistical significance that must be met. MCPs should indicate the level of statistical significance used in the analysis and which findings were statistically significant.

Step 8: Assess the Improvement Strategies

WORKSHEET 1.8

Resource for Activity 1, Step 8

Worksheet 1.8. Assess the Improvement Strategies

- Provides a template for assessing whether the selected improvement strategies were appropriate for achieving improvement

In this step, the EQRO assesses the appropriateness of the interventions for achieving improvement. This assessment builds on the interpretation of PIP results in Step 7. Significant, sustained improvement results from developing and implementing effective improvement strategies (including strategies that are culturally and linguistically appropriate for the target population). Selected strategies should be evidence-based, that is, there should be existing evidence (published or unpublished) suggesting that the test of change would be likely to lead to the desired improvement in processes or outcomes (as measured by the variables). Using the criteria in Worksheet 1.8, the EQRO should assess whether there is evidence that the selected interventions were appropriate to achieve the aim of the PIP.

A common approach used to guide quality improvement work is the Institute for Healthcare Improvement's (IHI) Model for Improvement (see Box 1.4). After using this model to define the parameters for the improvement effort, the MCP may test changes on a small scale using PDSA cycles. PDSA cycles provide a methodology to test changes on a small scale and to apply rapid-cycle learning principles to adjust intervention strategies over the course of the improvement. This approach involves a continuous cycle of measuring and analyzing performance and requires frequent review and adjustment. Data are evaluated on a regular basis and interventions are then adapted based on what was learned. Interventions can then be scaled to larger settings or populations if found effective. PIPs based on the Model for Improvement and PDSA process are sometimes known as rapid-cycle PIPs. The EQRO can use results from PDSA cycles to inform its assessment of the appropriateness of interventions to achieve the aim of the PIP.

Box 1.4. Using the IHI Model for Improvement to Assess Improvement Strategies

The **IHI Model for Improvement** provides a framework for conducting improvement work. The Model asks three questions:

- What is your aim, and by when do you want to accomplish the aim?
- How will you know that a change is an improvement?
- What changes can you put in place to achieve your aim?

A **PDSA** cycle is used to structure the testing of improvement strategies**.** The steps in the PDSA cycle are to:

- **Plan.** Plan the test or observation, including a plan for collecting data, and interpreting results
- **Do.** Try out the test on a small scale
- **Study.** Set aside time to analyze the data and assess the results
- **Act.** Refine the change, based on what was learned from the test. Determine how to sustain the intervention, if successful

This information about the Model for Improvement and PDSA approach was adapted from the Institute for Healthcare Improvement, available at http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx.

An additional source of information is the Agency for Healthcare Research and Quality's Health Care Innovations Exchange, available at https://innovations.ahrq.gov/qualitytools/plan-do-study-act-pdsa-cycle.

Step 9: Assess the Likelihood that Significant and Sustained Improvement Occurred

In this step, the EQRO assesses the likelihood that significant and sustained improvement occurred as a result of the PIP. This assessment builds on findings from the two previous steps. Box 1.5 suggests potential sources of information for this assessment.

WORKSHEET 1.9

Resource for Activity 1, Step 9

Worksheet 1.9. Assess the Likelihood that Significant and Sustained Improvement Occurred

- Provides a template for assessing improvement as a result of the PIP

The EQRO should review the PIP methods and findings to assess whether there is evidence of statistically significant improvement that may be associated with the intervention implemented as part of the PIP. In addition, the EQRO may supplement the quantitative assessment with information gathered through interviews with MCP staff and/or providers about the implementation and results of the PIP intervention. Qualitative information may inform the assessment of whether observed changes were likely to be attributable to the PIP intervention, as opposed to a short-term event unrelated to the intervention or random chance.

Box 1.5. Potential Sources of Supporting Information

- Statistical significance testing calculated on baseline and repeat indicator measurements (clarify that the appropriate test was used, such as a t-test for small samples)
- Benchmarks for quality specified by the state Medicaid agency or found in industry standards
- Interviews with MCP staff and providers about the implementation and results of the PIP intervention

An important goal of a PIP is to demonstrate sustained improvement. The EQRO should assess whether repeated measurements were conducted, and if so, whether significant change in performance relative to baseline measurement was observed. The repeat measurement should use the same methodology as the baseline measurement. Any deviations in methodology (such as sampling, data source, or variable definition) must be thoroughly documented. If the PIP is in the early stages of implementation, and repeated measurements are not yet available, the analysis plan should describe the methodology for subsequent measurement. The EQRO should state in its final report which findings were found to be significant from a clinical and/or programmatic perspective.

Activity 2: Perform Overall Validation and Reporting of PIP Results

The EQRO should complete the two steps in Activity 2, listed below, and answer the questions posed in each step.

In this activity, the EQRO assesses the overall validity and reliability of the PIP methods and findings to determine whether or not it has confidence in the results. The EQRO will assign two validation ratings based on the EQRO's assessment of whether the PIP (1) adhered to acceptable methodology for all phases of design and data collection, conducted accurate data analysis and interpretation of PIP results, and (2) produced evidence of improvement. The ratings will be scored on a scale of high, moderate, low, or no confidence.

WORKSHEET 1.10

WORKSHEET 1.11

Resources for Activity 2

Worksheet 1.10. Perform Overall Validation of PIP Results

- Provides a template to provide a validation rating (high confidence, moderate confidence, low confidence, or no confidence)

Worksheet 1.11. Framework for Summarizing Information about PIPs

- Provides a structure for reporting general information about the PIP, performance measures and results, validation results, and recommendations

To assign the validation ratings, the EQRO will review the assessments conducted as part of the nine steps in Activity 1, and recorded in the Worksheets for Protocol 1: PIP Validation Tools and Reporting Framework, or a similar tool. As studies always have weaknesses, the EQRO will need to assess the relative strengths and weaknesses and the extent to which they affect the confidence in the generalizability and usefulness of the PIP's findings. CMS suggests using the following validation rating to facilitate comparisons across PIPs and across states: high confidence, moderate confidence, low confidence, and no confidence.

The EQRO will report its findings to the state and the state will submit the final technical report to CMS.[36] The validation report should include a description of the PIPs that were validated and the findings of the EQRO's validation review. The EQRO and the state must include the actual validation results of the PIPs in the final EQRO technical report for submission to CMS. The EQRO is required to report the performance measurement data for the PIP validation in the EQR technical report.[37] Please see "Tips for Drafting EQR Reports" in the Introduction for further guidance to EQROs about how to produce a clear and concise report. In addition, please see Worksheet 1.11. Framework for Reporting Summary PIP Information, for a suggested format for summarizing PIP validation results in the EQR technical report.

Activity 3: Verify PIP Findings (Optional)

A state may request that the EQRO verify the data produced by the MCP to determine if the baseline and repeated measurements are accurate. While the validation of the PIP methodology and findings is a mandatory activity, the verification of data or performance measures used in the PIP is optional for EQROs. Verification activities can provide added confidence in reported PIP results as they provide greater evidence that the findings are accurate.

However, verification is a resource-intensive activity that may not be necessary. For example, if the PIP uses HEDIS® measures that have been certified by a third party, verification may not be needed. Additionally, the Information System Capabilities Assessment (ISCA) may provide assurances that the processes used to develop measures for the PIP are valid and reliable (See Appendix A. Information System Capabilities Assessment). Similarly, if the PIP relies on encounter data and the EQRO has conducted encounter data validation, the optional EQR-related activity described in Protocol 5, further assurances may be provided about the accuracy and completeness of the data used in the PIP.

If a state opts to have the EQRO verify the accuracy of the baseline and repeated measurements, the EQRO should focus on the processes through which data for the PIP were obtained, processed, and analyzed. The verification process should begin with a thorough review of existing resources:

- Documentation produced by the MCP about the data, algorithms, and testing (e.g., code reviews) related to the PIP data analysis
- The assessment of the MCP's information system produced as part of the ISCA
- Any external validations of the accuracy and completeness of MCP encounter data (such as the optional EQR-related activity)

[36] For the purposes of the EQR protocols and ease of explanation, we refer to EQROs as the entity conducting the EQR-related activities.

[37] CHIP regulations at 42 CFR 457.1250 cross-reference to 42 CFR 438.364(a)(2)(iii).

- Results of other EQR-related activities, such as performance measure validation or compliance reviews
- Results of private accreditation reviews or state Medicaid agency audits

In the event that no current assessment of an MCP's information system or encounter data exists, the state may choose to contract this function to assist in verifying the accuracy of the PIPs.

Next, the EQRO should review specific algorithms and results related to the PIP measures. Questions include:

- Was the algorithm used to produce the PIP measures sound (that is, does the algorithm measure what it is intended to measure, are the results consistent, and is the code well documented)?
- For measures calculated using administrative data: Did the MCP's information system capture enrollee information completely and accurately? To answer this question, the EQRO may need to validate a sample of records to ensure the encounter data are complete
- For measures produced through medical record review: Did the MCP conduct a re-abstraction of a small subset (validation sample) of the reviewed records to ensure the abstraction was complete and accurate? Data retrieval and analysis should be conducted on a small scale, with the validation sample following the same rules as the original PIP.

If validation of a sample of records is performed, the EQRO should perform statistical correlations between the validation sample and the original PIP data. A variety of statistical methods can be applied to assess the degree of correlation between the PIP and validation measures. Two recommended methods are the Pearson correlation coefficient for continuous data (e.g., age, income) and the Kappa statistic for categorical data (e.g., gender, race). Assessing the algorithm together with the integrity of the data will provide a strong indication of the accuracy of the PIP s findings.

END OF PROTOCOL 1

Worksheets for Protocol 1: PIP Validation Tools and Reporting Framework

Instructions. Use these or similar worksheets to assist in validating PIPs conducted by the MCP. These worksheets provide templates for validating PIPs and a framework for reporting on validated PIPs in the EQR technical report. This tool includes the following worksheets crosswalked to the applicable Activity and Step:

Worksheet Name	Protocol Activity and Step
Worksheet 1.1. Review the PIP Topic	Activity 1. Step 1. Review the Selected PIP Topic
Worksheet 1.2. Review the PIP Aim Statement	Activity 1. Step. 2. Review the PIP Aim Statement
Worksheet 1.3. Review the Identified PIP Population	Activity 1. Step 3. Review the Identified PIP Population
Worksheet 1.4. Review the Sampling Method	Activity 1. Step 4. Review the Sampling Method
Worksheet 1.5. Review the Selected PIP Variables	Activity 1. Step 5. Review the Selected PIP Variables
Worksheet 1.6. Review the Data Collection Procedures	Activity 1. Step 6. Review the Data Collection Procedures
Worksheet 1.7. Review Data Analysis and Interpretation of PIP Results	Activity 1. Step 7. Review Data Analysis and Interpretation of PIP Results
Worksheet 1.8. Assess the Improvement Strategies	Activity 1. Step 8. Assess the Improvement Strategies
Worksheet 1.9. Assess the Likelihood that Significant and Sustained Improvement Occurred	Activity 1. Step 9. Assess the Likelihood that Significant and Sustained Improvement Occurred
Worksheet 1.10. Perform Overall Validation of PIP Results	Activity 2. Perform Overall Validation and Reporting of PIP Results
Worksheet 1.11. Framework for Summarizing Information about Performance Improvement Projects (PIPs)	Activity 2. Perform Overall Validation and Reporting of PIP Results

For each PIP, please complete the following information:

MCP name	
MCP contact name and title	
Mailing address	
Phone/fax numbers	
Email address	
EQRO interview date	
Performance Improvement Project (PIP) name	
PIP period date	MM/DD/YY to MM/DD/YY
Type of delivery system (check all that apply)	□ Staff model □ Network □ IPA
Plan type	□ MCO □ PIHP □ PAHP □ PCCM entity □ LTSS □ Other: specify _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP
Enrollees	Physicians

# Medicaid and CHIP enrollees in MCP: ____ # Medicaid and CHIP enrollees in the PIP: ____ # Total number of MCP enrollees in the PIP: ____	# MCP primary care physicians: _____ # MCP specialty physicians: _____

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Worksheet 1.1. Review the Selected PIP Topic

PIP Topic _____

Assess the appropriateness of the selected PIP topic by answering the following questions about the MCP and PIP. Insert comments to explain "No" and "Not applicable (NA)" responses.

Question	Yes	No	NA	Comments
1.1 Was the PIP topic selected through a comprehensive analysis of MCP enrollee needs, care, and services (e.g., consistent with demographic characteristics and health risks, prevalence of conditions, or the need for a specific service by enrollees)? (If the PIP topic was required by the state, please check "not applicable" and note in comments.)				
1.2 Did selection of the PIP topic consider performance on the CMS Child and Adult Core Set measures?				
1.3 Did the selection of the PIP topic consider input from enrollees or providers who are users of, or concerned with, specific service areas? (If the PIP topic was required by the state, please check "not applicable" and note in comments.) • To the extent feasible, input from enrollees who are users of, or concerned with, specific services areas should be obtained.				
1.4 Did the PIP topic address care of special populations or high priority services, such as: • Children with special health care needs • Adults with physical disabilities • Children or adults with behavioral health issues • People with intellectual and developmental disabilities • People with dual eligibility who use long-term services and supports (LTSS) • Preventive care • Acute and chronic care • High-volume or high-risk services • Care received from specialized centers (e.g., burn, transplant, cardiac surgery) • Continuity or coordination of care from multiple providers and over multiple episodes • Appeals and grievances • Access to and availability of care				
1.5 Did the PIP topic align with priority areas identified by HHS and/or CMS?				
1.6 Overall assessment: In the comments section, note any recommendations for improving the PIP topic.				

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Worksheet 1.2. Review the PIP Aim Statement

PIP Aim Statement _____

Assess the appropriateness of the selected PIP topic by answering the following questions. Insert comments to explain "No" and "Not Applicable (NA)" responses.

Question	Yes	No	NA	Comments
2.1 Did the PIP aim statement clearly specify the improvement strategy, population, and time period for the PIP?				
2.2 Did the PIP aim statement clearly specify the population for the PIP?				
2.3 Did the PIP aim statement clearly specify the time period for the PIP?				
2.4 Was the PIP aim statement concise?				
2.5 Was the PIP aim statement answerable?				
2.6 Was the PIP aim statement measurable?				
2.7 Overall assessment: In the comments section, note any recommendations for improving the PIP aim statement.				

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Worksheet 1.3. Review the Identified PIP Population

PIP Population _____

Assess whether the study population was clearly identified by answering the following questions. Insert comments to explain "No" and "Not Applicable (NA)" responses.

Question	Yes	No	NA	Comments
3.1 Was the project population clearly defined in terms of the identified study question (e.g., age, length of the study population's enrollment, diagnoses, procedures, other characteristics)? • The required length of time will vary depending on the PIP topic and performance measures				
3.2 Was the entire MCP population included in the PIP?				
3.3 If the entire population was included in the PIP, did the data collection approach capture all enrollees to whom the PIP question applied? • If data can be collected and analyzed through an administrative data system, it may be possible to study the whole population. For more guidance on administrative data collection, see Worksheet 1.6.				
3.4 Was a sample used? (If yes, use Worksheet 1.4 to review sampling methods). • If the data will be collected manually (such as through medical record review), sampling may be necessary				
3.5 Overall assessment: In the comments section, note any recommendations for identifying the project population.				

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Worksheet 1.4. Review the Sampling Method

Overview of Sampling Method _____

If HEDIS® sampling is used, check here, and skip the rest of this worksheet. ☐

Assess whether the sampling method was appropriate by answering the following questions. Insert comments to explain "No" and "Not Applicable (NA)" responses. Refer to Appendix B for an overview of sampling approaches for EQR data collection activities.

Question	Yes	No	NA	Comments
4.1 Did the sampling frame contain a complete, recent, and accurate list of the target PIP population? • A sampling frame is the list from which the sample is drawn. It includes the universe of members of the target PIP population, such as individuals, caregivers, households, encounters, providers, or other population units that are eligible to be included in the PIP. The completeness, recency, and accuracy of the sampling frame are key to the representativeness of the sample				
4.2 Did the sampling method consider and specify the true or estimated frequency of the event, the confidence interval to be used, and the acceptable margin of error?				
4.3 Did the sample contain a sufficient number of enrollees taking into account non-response?				
4.4 Did the method assess the representativeness of the sample according to subgroups, such as those defined by age, geographic location, or health status?				
4.5 Were valid sampling techniques used to protect against bias? Specify the type of sampling used in the "comments" field.				
4.6 Overall assessment: In the comments section, note any recommendations for improving the sampling method.				

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Worksheet 1.5. Review the Selected PIP Variables and Performance Measures

Selected PIP Variables and Performance Measures:

_____

Assess whether the selected PIP variables were appropriate for measuring performance and tracking improvement by answering the following questions. Insert comments to explain "No" and "Not Applicable (NA)" responses.

Recall that CMS encourages MCPs to choose variables for PIPs that reflect health outcomes. Performance measures are then used to measure these health outcomes. When selecting variables, the MCP should consider existing performance measures.

Question	Yes	No	NA	Comments
PIP variables				
5.1 Were the variables adequate to answer the PIP question? • Did the PIP use objective, clearly defined, time-specific variables (e.g., an event or status that can be measured)? • Were the variables available to measure performance and track improvement over time? (CMS encourages states to select variables that can be examined on at least a semi-annual basis				
Performance measures				
5.2 Did the performance measure assess an important aspect of care that will make a difference to enrollees' health or functional status?				
5.3 Were the performance measures appropriate based on the availability of data and resources to collect the data (administrative data, medical records, or other sources)?				
5.4 Were the measures based on current clinical knowledge or health services research? • Examples may include: ○ Recommended procedures ○ Appropriate utilization (hospital admissions, emergency department visits) ○ Adverse incidents (such as death, avoidable readmission) ○ Referral patterns ○ Authorization requests ○ Appropriate medication use				

Question	Yes	No	NA	Comments
5.5 Did the performance measures: • Monitor the performance of MCPs at a point in time? • Track MCP performance over time? • Compare performance among MCPs over time? • Inform the selection and evaluation of quality improvement activities?				
5.6 Did the MCP consider existing measures, such as CMS Child and Adult Core Set, Core Quality Measure Collaborative, certified community behavioral health clinics (CCBHC) measures, HEDIS®, or AHRQ measures?				
5.7 If there were gaps in existing measures, did the MCP consider the following when developing new measures based on current clinical practice guidelines or health services research? • Did the measure address accepted clinical guidelines relevant to the PIP question? • Did the measure address an important aspect of care or operations that was meaningful to MCP enrollees? • Did available data sources allow the MCP to calculate the measure reliably and accurately? • Were all criteria used in the measure defined clearly (such as time periods, characteristics of eligible enrollees, services to be assessed, and exclusion criteria)?				
5.8 Did the measures capture changes in enrollee satisfaction or experience of care? • Although enrollee satisfaction/experience is an important outcome of care in clinical areas, improvement in satisfaction should not be the only measured outcome of a clinical project. Some improvement in health or functional status should also be addressed • For projects in nonclinical areas (such as addressing access or availability of services), measurement of health or functional status is preferred				
5.9 Did the measures include a strategy to ensure inter-rater reliability (if applicable)?				

Question	Yes	No	NA	Comments
5.9 If process measures were used, is there strong clinical evidence indicating that the process being measured is meaningfully associated with outcomes? • This determination should be based on published guidelines, including citations from randomized clinical trials, case control studies, or cohort studies • At a minimum, the PIP should be able to demonstrate a consensus among relevant practitioners with expertise in the defined area who attest to the importance of a given process				
5.10 Overall assessment: In the comments section, note any recommendations for improving the selected PIP variables and performance measures.				

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Worksheet 1.6. Review the Data Collection Procedures

Assess whether the data collection procedures were valid and reliable by answering the following questions. This worksheet includes three sections: (1) overall data collection procedures, (2) data collection procedures for administrative data sources, and (3) data collection procedures for medical record review. Insert comments to explain "No" and "Not Applicable (NA)" responses.

Section 1: Assessment of Overall Data Collection Procedures

Question	Yes	No	NA	Comments
6.1 Did the PIP design specify a systematic method for collecting valid and reliable data that represents the population in the PIP?				
6.2 Did the PIP design specify the frequency of data collection? If yes, what was the frequency (for example, semi-annually)?				

6.3 Did the PIP design clearly specify the data sources?
• Data sources may include:
  ○ Encounter and claims systems
  ○ Medical records
  ○ Case management or electronic visit verification systems
  ○ Tracking logs
  ○ Surveys
  ○ Provider and/or enrollee interviews				

6.4 Did the PIP design clearly define the data elements to be collected? • Accurate measurement depends on clear and concise definitions of data elements (including numerical definitions and units of measure)				
6.5 Did the data collection plan link to the data analysis plan to ensure that appropriate data would be available for the PIP?				
6.6 Did the data collection instruments allow for consistent and accurate data collection over the time periods studied?				
6.7 If qualitative data collection methods were used (such as interviews or focus groups), were the methods well-defined and designed to collect meaningful and useful information from respondents?				
6.8 Overall assessment: In the comments section, note any recommendations for improving the data collection procedures. **Note:** Include assessment of data collection procedures for administrative data sources and medical record review noted below.				

Section 2: Assessment of Data Collection Procedures for Administrative Data Sources

Question	Yes	No	NA	Comments
6.9 If inpatient data was used, did the data system capture all inpatient admissions/discharges?				
6.10 If primary care data was used, did primary care providers submit encounter or utilization data for all encounters?				
6.11 If specialty care data was used, did specialty care providers submit encounter or utilization data for all encounters?				
6.12 If ancillary data was used, did ancillary service providers submit encounter or utilization data for all services provided?				
6.13 If LTSS data was used, were all relevant LTSS provider services included (for example, through encounter data, case management systems, or electronic visit verification (EVV) systems)?				
6.14 If EHR data was used, were patient, clinical, service, or quality metrics validated for accuracy and completeness as well as comparability across systems?				

Section 3: Assessment of Data Collection Procedures for Medical Record Review

Question	Yes	No	NA	Comments
6.15 Was a list of data collection personnel and their relevant qualifications provided? • Data collection personnel require the conceptual and organizational skills to abstract data. These skills will vary depending on the nature of the data and the degree of professional judgment required. For example, trained medical assistants or medical records clerks may collect data if the abstraction involves verifying the presence of a diagnostic test report. However, experienced clinical staff (such as registered nurses) should be used to extract data to support a judgment about whether clinical criteria are met				
6.16 For medical record review, was inter-rater and intra-rater reliability described? • The PIP should also consider and address intra-rater reliability (i.e., reproducibility of judgments by the same abstractor at a different time)				

Question	Yes	No	NA	Comments
6.17 For medical record review, were guidelines for obtaining and recording the data developed? • A glossary of terms for each project should be developed before data collection begins to ensure consistent interpretation among and between data collection staff • Data collection staff should have clear, written instructions, including an overview of the PIP, how to complete each section of the form or instrument, and general guidance on how to handle situations not covered by the instructions. This is particularly important when multiple reviewers are collecting data				

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Worksheet 1.7. Review Data Analysis and Interpretation of PIP Results

Assess whether the data analysis and interpretation was appropriate by answering the following questions. Insert comments to explain "No" and "Not Applicable" responses.

Question	Yes	No	NA	Comments
7.1 Was the analysis conducted in accordance with the data analysis plan?				
7.2 Did the analysis include baseline and repeat measurements of project outcomes?				
7.3 Did the analysis assess the statistical significance of any differences between the initial and repeat measurements?				
7.4 Did the analysis account for factors that may influence the comparability of initial and repeat measurements?				
7.5 Did the analysis account for factors that may threaten the internal or external validity of the findings?				
7.6 Did the PIP compare the results across multiple entities, such as different patient subgroups, provider sites, or MCPs? • Comparing the performance across multiple entities involves greater statistical design and analytical considerations than those required for a project assessing performance of a single entity, such as an MCP, over time				
7.7 Were PIP results and findings presented in a concise and easily understood manner?				
7.8 To foster continuous quality improvement, did the analysis and interpretation of the PIP data include lessons learned about less-than-optimal performance? • Analysis and interpretation of the PIP data should be based on a continuous improvement philosophy and reflect on lessons learned and opportunities for improvement				
7.9 Overall assessment: In the comments section, note any recommendations for improving the analysis and interpretation of PIP results				

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Worksheet 1.8. Assess the Improvement Strategies

Assess whether the selected improvement strategies were appropriate for achieving improvement by answering the following questions. Insert comments to explain "No" and "Not Applicable (NA)" responses.

Question	Yes	No	NA	Comments
8.1 Was the selected improvement strategy evidence-based, that is, was there existing evidence (published or unpublished) suggesting that the test of change would be likely to lead to the desired improvement in processes or outcomes (as measured by the PIP variables)?				
8.2 Was the strategy designed to address root causes or barriers identified through data analysis and quality improvement processes? • Interventions that might have a short-term effect, but that are unlikely to generate long-term change (such as a one-time reminder letter to enrollees or providers) are insufficient • It is expected that interventions associated with significant improvement will be system interventions (such as educational efforts, policy changes, or targeting of additional resources) • It is expected that interventions should be measurable on an ongoing basis (e.g., quarterly, monthly) to monitor intervention progress				
8.3 Was the rapid-cycle PDSA approach used to test the selected improvement strategy? • The steps in the PDSA cycle[38] are to: ○ **Plan.** Plan the test or observation, including a plan for collecting data, and interpreting the results ○ **Do.** Try out the test on a small scale ○ **Study.** Set aside time to analyze the data and assess the results ○ **Act.** Refine the change, based on what was learned from the test. Determine how to sustain the intervention, if successful • If tests of change were not successful (i.e., did not achieve significant improvement), a process to identify possible causes and implement solutions should be identified				
8.4 Was the strategy culturally and linguistically appropriate?[39]				

[38] Institute for Healthcare Improvement: Science of Improvement, Testing Changes. Available at http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx.

[39] More information on culturally and linguistically appropriate services may be found at http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15.

Question	Yes	No	NA	Comments
8.5 Was the implementation of the strategy designed to account or adjust for any major confounding variables that could have an obvious impact on PIP outcomes (e.g., patient risk factors, Medicaid program changes, provider education, clinic policies or practices)?				
8.6 Building on the findings from the data analysis and interpretation of PIP results (Step 7), did the PIP assess the extent to which the improvement strategy was successful and identify potential follow-up activities?				
8.7 Overall assessment: In the comments section, note any recommendations for improving the implementation strategies.				

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Worksheet 1.9. Assess the Likelihood that Significant and Sustained Improvement Occurred

Assess the likelihood that significant and sustained improvement occurred by answering the following questions. Insert comments to explain "No" and "Not Applicable (NA)" responses.

Question	Yes	No	NA	Comments
9.1 Was the same methodology used for baseline and repeat measurements?				
9.2 Was there any quantitative evidence of improvement in processes or outcomes of care?				
9.3 Was the reported improvement in performance likely to be a result of the selected intervention? • It is not necessary to demonstrate conclusively (e.g., through controlled studies) that a change is an effect of the intervention; it is sufficient to show that the change might reasonably be expected to result from the intervention • It is not necessary to undertake data analysis to correct for secular trends (e.g., changes that reflect continuing growth or decline in a measure because of external forces over an extended period). The measured improvement should reasonably be determined to have resulted from the intervention				
9.4 Is there statistical evidence (e.g., significance tests) that any observed improvement is the result of the intervention?				
9.5 Was sustained improvement demonstrated through repeated measurements over time?				
9.6 Overall assessment: In the comments section, note any recommendations for improving the significance and sustainability of improvement as a result of the PIP.				

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Worksheet 1.10. Perform Overall Validation of PIP Results

Provide two overall validation ratings of the PIP results. The first rating refers to the EQRO's overall confidence that the PIP adhered to acceptable methodology for all phases of design and data collection, and conducted accurate data analysis and interpretation of PIP results. The second rating refers to the EQRO's overall confidence that the PIP produced evidence of significant improvement. Insert comments to explain the ratings. Provide comments to justify the ratings.

PIP Validation Ratings (check one box)	Comments
Rating 1: EQRO's Overall Confidence that the PIP Adhered to Acceptable Methodology for All Phases ☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence	
Rating 2: EQRO's Overall Confidence that the PIP Produced Evidence of Significant Improvement ☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence	

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Worksheet 1.11. Framework for Summarizing Information about Performance Improvement Projects (PIPs)

To assist with the analysis portion of the EQR technical report requirement, Worksheet 1.11 should be completed in its entirety for all PIPs. By doing so, it allows the EQRO to generate comparable information for all PIPs.

1. General PIP Information

Managed Care Plan (MCP) Name:
PIP Title:
PIP Aim Statement:
Was the PIP state-mandated, collaborative, statewide, or plan choice? (check all that apply) ☐ State-mandated (state required plans to conduct a PIP on this specific topic) ☐ Collaborative (plans worked together during the planning or implementation phases) ☐ Statewide (the PIP was conducted by all MCOs and/or PIHPs within the state) ☐ Plan choice (state allowed the plan to identify the PIP topic)
Target age group (check one): ☐ Children only (ages 0–17)* ☐ Adults only (age 18 and over) ☐ Both adults and children *If PIP uses different age threshold for children, specify age range here:
Target population description, such as duals, LTSS or pregnant women (please specify):
Programs: ☐ Medicaid (Title XIX) only ☐ CHIP (Title XXI) only ☐ Medicaid and CHIP

2. Improvement Strategies or Interventions (Changes tested in the PIP)

Member-focused interventions (member interventions are those aimed at changing member practices or behaviors, such as financial or non-financial incentives, education, and outreach)
Provider-focused interventions (provider interventions are those aimed at changing provider practices or behaviors, such as financial or non-financial incentives, education, and outreach)
MCP-focused interventions/system changes (MCP/system change interventions are aimed at changing MCP operations; they may include new programs, practices, or infrastructure, such as new patient registries or data tools)

3. Performance Measures and Results (Add rows as necessary)

Performance measures (be specific and indicate measure steward and NQF number if applicable):	Baseline year	Baseline sample size and rate	Most recent remeasurement year (if applicable)	Most recent remeasurement sample size and rate (if applicable)	Demonstrated performance improvement (Yes/No)	Statistically significant change in performance (Yes/No) Specify P-value
			☐ Not applicable—PIP is in planning or implementation phase, results not available		☐ Yes ☐ No	☐ Yes ☐ No Specify P-value: ☐ <.01 ☐ <.05 Other (specify):
			☐ Not applicable—PIP is in planning or implementation phase, results not available		☐ Yes ☐ No	☐ Yes ☐ No Specify P-value: ☐ <.01 ☐ <.05 Other (specify):
			☐ Not applicable—PIP is in planning or implementation phase, results not available		☐ Yes ☐ No	☐ Yes ☐ No Specify P-value: ☐ <.01 ☐ <.05 Other (specify):

4. PIP Validation Information

Was the PIP validated? ☐ Yes ☐ No

"Validated" means that the EQRO reviewed all relevant part of each PIP and made a determination as to its validity. In many cases, this will involve calculating a score for each relevant stage of the PIP and providing feedback and recommendations.

Validation phase (check all that apply):

☐ PIP submitted for approval ☐ Planning phase ☐ Implementation phase ☐ Baseline year

☐ First remeasurement ☐ Second remeasurement ☐ Other (specify):

Validation rating #1: EQRO's overall confidence that the PIP adhered to acceptable methodology for all phases of design and data collection, conducted accurate data analysis and interpretation of PIP results,

☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence

Validation rating #2: EQRO's overall confidence that the PIP produced significant evidence of improvement.

☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence

EQRO comments on validation ratings

EQRO recommendations for improvement of PIP:

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END OF WORKSHEETS FOR PROTOCOL 1

Protocol 2. Validation of Performance Measures

A MANDATORY EQR-RELATED ACTIVITY

ACTIVITY 1: CONDUCT PRE-SITE VISIT ACTIVITIES

ACTIVITY 2: CONDUCT SITE VISIT ACTIVITIES

ACTIVITY 3: CONDUCT POST-SITE VISIT ACTIVITIES

PROTOCOL TWO

Background

States use performance measures to monitor the performance of individual managed care plans (MCPs) at a point in time, to track performance over time, to compare performance among MCPs, and to inform the selection and evaluation of quality improvement activities. States specify standard performance measures which the MCPs must include in their quality assessment and performance improvement (QAPI) program.[40]

In many cases, states and MCPs use measures included in the CMS Child and Adult Core Sets to monitor and track quality of care in Medicaid and CHIP.[41] While use of these measures by states is voluntary, CMS encourages states to adopt and use the Child and Adult Core Set measures to support their managed care quality measurement and improvement initiatives. Many Core Set measures are part of Healthcare Effectiveness Data and Information Set (HEDIS®), and have national and regional benchmarks.

Federal regulations at 42 CFR 438.330(c) require states to specify standard performance measures for MCPs to include in their comprehensive quality assessment and performance improvement (QAPI) programs.[42] Each year, the MCPs must: (1) measure and report to the state the standard performance measures specified by the state; (2) submit specified data to the state which

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[40] More information about QAPI and performance measure validation is available at 42. CFR 438.330(b)(2) and (c), cross referenced by CHIP at 457.1240(b).

[41] More information about the Child Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html. More information about the Adult Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html.

[42] More information about QAPI and performance measures is available at 42. CFR 438.330(b)(2). This is cross-referenced by CHIP at 42 C.RF.R 457.1240(b).

enables the state to calculate the standard performance measures; or (3) a combination of these approaches.

This protocol is used to guide the validation of the performance measures specified by states for inclusion in MCPs' QAPI programs. It applies both when the QAPI performance measure is calculated by the MCP and when it is calculated by the state. In general, the external quality review organization (EQRO) must assess whether the performance measures calculated by the MCP[43] are accurate based on the measure specifications and state reporting requirements (42 CFR 438.330(b)(2)). The state provides the list of performance measures to be validated, the specifications for the measures, and the requirements for reporting. As noted in the Introduction, states have the option to use information from a Medicare or private accreditation review of an MCP to provide information for the annual EQR instead of conducting this mandatory EQR-related activity.[44,45] A related protocol, Protocol 7. Calculation of Additional Performance Measures, may be used by EQROs to calculate additional performance measures in accordance with state specifications.

Getting Started on Protocol 2

Protocol 2 consists of three phases of activities: pre-site visit, site visit, and post-site visit (Figure 2.1). The activities take place before, during, and after the EQRO conducts a site visit with the MCP.[46] The validation process is interactive and concurrent with MCP performance measure calculation.

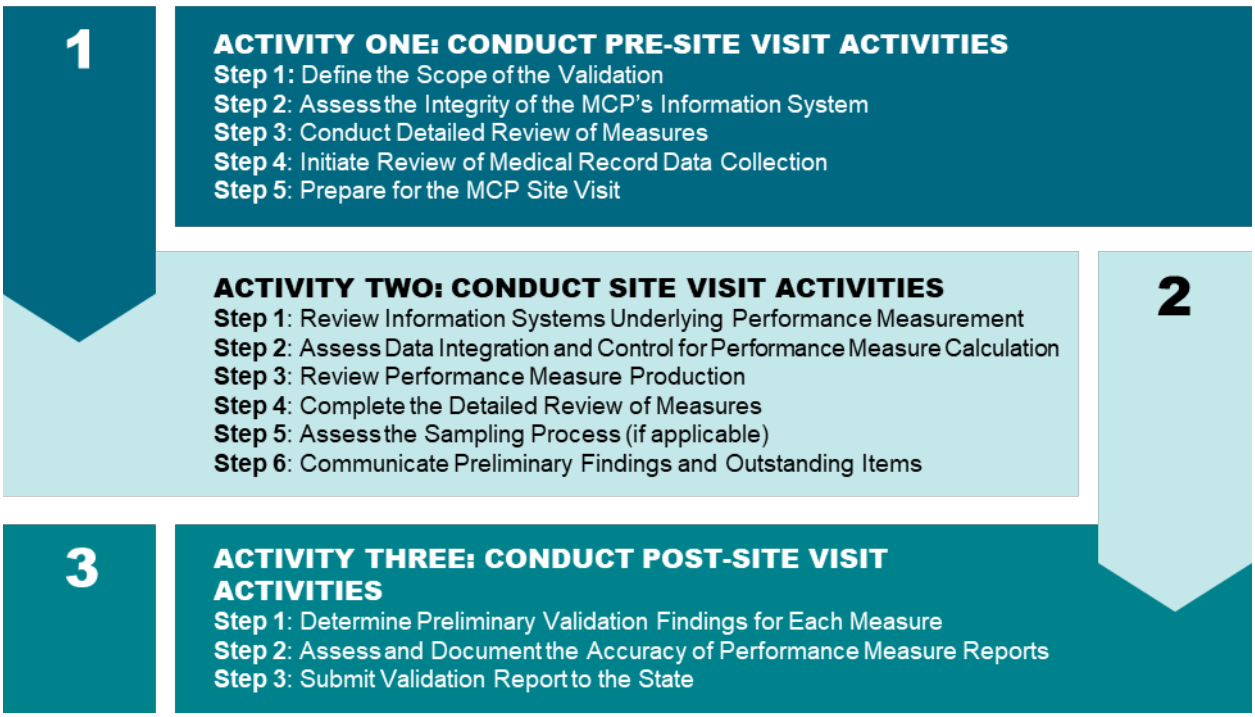
[43] While the protocol is written as if the MCP is calculating performance measures, the MCP may contract with another entity to calculate and report on its behalf. Alternatively, 42. CFR 438.330(c)(ii) allows the state to require the MCP to submit data to the state, which the state then uses to calculate the performance measure. CHIP regulations cross-reference to these regulations at 457.1240(b),. This protocol applies in either circumstance.

[44] If the state elects to use nonduplication for this mandatory EQR-related activity (42 CFR 438.360 (Nonduplication of mandatory activities with Medicare or accreditation review), then the state must ensure that all information from the Medicare or private accreditation review is provided to the EQRO for analysis and inclusion in the annual EQR technical report. (See 42 CFR 438.360(a)(1)–(3) for additional details regarding the circumstance under which nonduplication is an option). Use of nonduplication must be identified in the state's quality strategy (see 42 CFR 438.360(c) and 438.340(b)(10)). CHIP cross-references to this requirement at 42 CFR 457.1250, but does not allow for the use of Medicare review activities for the purposes of nonduplication.

[45] A state may not utilize nonduplication if Medicare has accepted an only attestation of a plan's QIP. In the context of this EQR-related activity, the QIP would have to undergo validation as part of a Medicare review in order for nonduplication to be an option. See 42 CFR 438.360(a)(2).

[46] In the event that onsite activities are not feasible due to the COVID-19 pandemic, site visits may be conducted virtually.

Figure 2.1. Protocol 2 Activities



Two supplemental resources are available to help EQROs validate performance measures:

- Worksheets for Protocol 2. Performance Measurement Validation Tools, which can be used to prepare for and conduct pre-site, site, and post-site activities
- Appendix A. Information System Capabilities Assessment, which is used to assess the MCP's data collection, processing, and reporting systems

The remainder of this protocol outlines the steps associated with Activities 1 through 3.

TIP

Navigate to the corresponding worksheet by clicking the WORKSHEET box under each section

Activity 1: Conduct Pre-Site Visit Activities

Step 1: Define the Scope of the Validation

The performance measures each state requires will depend on the specific needs of the state. The state will provide the EQRO with a list of the performance measures to be validated along with requirements for data collection and reporting (e.g., sampling guidelines and instructions for calculating numerators and denominators).

The EQRO should use Worksheet 2.1. List of Measures to be Validated to enumerate the performance measures to be validated under Protocol 2, including their data source, reporting frequency, and format. Five data sources are used to produce MCP performance measures:

1. Administrative data, such as claims/encounter data, registries, or vital records
2. Medical record review
3. Administrative data supplemented by medical record review, referred to as the "hybrid" method
4. Electronic health records
5. Surveys (survey administration and validation is addressed in Protocol 6)

WORKSHEET 2.1

WORKSHEET 2.2

Resources for Activity 1, Step 1

Worksheet 2.1. List of Performance Measures to be Validated

- Provides a template for identifying the measures the EQRO will validate for the state, including the source, how frequently to calculate each measure, and when each measure is due to the state

Worksheet 2.2. Performance Measure Validation Template

- Provides a template for documenting audit specifications for the validation components of each performance measure listed in Worksheet 2.1., and to assess the MCP's measurement and reporting process for each component

For each of the measures to be validated, the EQRO should complete Worksheet 2.2. Performance Measure Validation Template (or a similar tool). The worksheet is used to systematically gather information about the validation components and audit specifications based on existing documentation about the measure. Elements include:

- Documentation related to the data collection and calculation method
- Denominator calculation(s), including adequacy of the data sources to calculate the denominator, operationalization of the measure-specific eligibility criteria, and adherence to the measurement period
- Numerator calculation(s), including adequacy of the data sources to calculate the numerator, appropriateness of codes used to identify numerator compliance, avoidance of double counting, and adherence to the measurement period
- Sampling methodology (if used)

- Reporting of rates and other supporting information, including documentation of deviations (if any)

Worksheet 2.2 also contains an example of a completed performance measure validation worksheet similar to what an EQRO would use before, during, and after its site visit. The illustrative template is for Chlamydia Screening in Women (CHL-CH, Measure Steward: National Committee for Quality Assurance, National Quality Forum [NQF] # 0033), which is included in both the Child and Adult Core Sets and calculated using the administrative method. During Activity 1, Step 1, the EQRO should begin to populate the audit specifications based on the available measure documentation. Note that the worksheet is intended to serve as a "living document" for the measure validation process and the EQRO can adapt the template if necessary.

Step 2: Assess the Integrity of the MCP's Information System

This step helps focus the validation activities on aspects of the MCP's information system that are most likely to be an issue in the validation process. Before validating individual performance measures, the EQRO must assess (1) the integrity of the MCP's information system, (2) the completeness and accuracy of the data produced, and (3) the readiness of the MCPs' data systems for calculating performance measures. As part of this step, the EQRO conducts an Information Systems Capabilities Assessment (ISCA) for each MCP as described in the following sections.

WORKSHEET A.1

WORKSHEET A.2

Resources to Conduct an Information Systems Capabilities Assessment (ISCA)

The ISCA is used to validate MCP information systems, processes, and data. The ISCA provides a foundation for the validation of performance measures.

Appendix A

- Explains how to conduct the ISCA

Worksheet A.1. ISCA Tool

- Provides a template for MCPs to document the capabilities of the information systems, processes, and data

Worksheet A.2. ISCA Interview Guide

- Provides a guide to EQROs for conducting follow-up interviews with MCP staff to record responses and document specific issues based on findings from Worksheet A.1

Conduct an Information Systems Capabilities Assessment

Before conducting the site visit, the EQRO should provide the MCP with information on the ISCA process, including Worksheet A.1 Information System Capabilities Assessment Tool. The ISCA is used to validate MCP information systems, processes, and data. The ISCA corresponds to the objectives identified in this protocol and addresses key components of calculating performance measures including:

- General information about the MCP
- Membership/enrollment data systems
- Claims/encounter data processing
- Provider data

- Data completeness
- Integration of data for performance measure calculation

The ISCA provides information about the timing of any other recent, independent, documented assessment such as a HEDIS Compliance Audit™. If the MCP recently had a comprehensive, independent assessment of its information systems, the EQRO may review those results. If the MCP has not had an ISCA within a timeframe determined by the state,[47] the EQRO will conduct an ISCA as part of this protocol. It is recommended that EQROs request that MCPs provide any assessments of their information technology (IT) systems conducted in the previous two years. The EQRO should document the strengths and weaknesses of the MCP information system relevant to the types of data used by the MCP in calculating performance measures. The EQRO should take into account systems issues (such as missing data), when validating individual performance measures and determining whether they are reportable.

Assess MCP Data Systems and Types

The EQRO should assess every data system and type of data the MCP processes to ensure the required data are current and accurate, particularly at the time it extracts data for its performance measures. The EQRO should assess changes in the MCP's data systems that might affect the production of the performance measures. Major changes, upgrades, or consolidations within the system, or acquisitions/mergers with other MCPs may impact the accuracy or completeness of required data elements. Elements that should be assessed for each MCP data system and type include:

- Membership/enrollment data
- Provider data
- Claims and encounter data
- Medical records data
- Pharmacy, laboratory, and other ancillary data

Membership/Enrollment Data

The EQRO should assess:

- The MCP's ability to track members over time, changes in enrollment, name changes, and changes in coverage

[47] There is no statutory or regulatory requirement for the frequency with which ISCAs should be conducted. Each state must determine the maximum interval between assessments of MCP information systems, balancing the cost to the state and burden on the MCP with the need to ensure that changes to the MCP's information systems are assessed frequently enough to support accurate performance measurement.

- The MCP's processes to ensure membership/enrollment data are current and accurate
- Changes in the MCP's membership data systems that might affect the production of the performance measures
- Whether transactions between the MCP and state data systems (such as state eligibility files) affect measure calculation through updating, correcting, or overwriting source data (e.g., race or ethnicity information)

The EQRO should determine whether each MCP member is uniquely identifiable and can be linked to the state's Medicaid and CHIP eligibility file. The membership/enrollment database should capture the following information for every member:

- Unique member identifier (ID), including state-issued Medicaid and CHIP ID and CMS-issued Medicare number (if applicable)
- Eligibility category
- Date of birth
- Sex
- Race and ethnicity
- Primary language
- Disability status
- Enrollment and/or termination dates, including multiple enrollment and termination dates within and across programs (preferably exact dates rather than monthly indicators)
- Primary care provider (e.g., provider name, provider ID number, provider location)

Collecting and assessing membership and enrollment data is increasingly important due to the quality strategy requirement for identifying, evaluating, and reducing health disparities based on age, race, ethnicity, sex, primary language, and disability status (42 CFR 438.340(b)(6)). Under this requirement, states must identify this demographic information for each Medicaid enrollee and provide it to the MCP, PIHP, or PAHP at the time of enrollment.

In addition, to facilitate geographic stratification of performance (such as analyses of access and timeliness of care), complete and accurate information on the household's location of residence (e.g., ZIP code) is also desirable.

Finally, to facilitate surveys of patient experience, complete contact information is essential. At a minimum, name and address are required; phone numbers and email addresses are highly desirable. See Protocol 6. Administration or Validation of Quality of Care Surveys for more information.

Provider Data

The EQRO should review an MCP's provider data system(s) to assess the MCP's ability to track providers over time, across multiple office locations, and through changes in participation. In addition, the EQRO should assess how many contracted providers use electronic health records (EHRs) and the extent to which EHRs are used in the calculation of an MCP's performance measures.

Claims and Encounter Data

Claims and encounter data should cover all types of services offered by the MCP and not separately contracted by the state, such as hospital inpatient, hospital outpatient, primary care, skilled nursing facility, nursing facility (custodial care), specialty care, behavioral health care, family planning services, home health care, radiology, laboratory, pharmacy, dental care, and vision care. The EQRO should note the following for each type of claim/encounter data captured:

- Total number of diagnosis and procedure codes (such as Healthcare Common Procedure Coding System (HCPCS) codes and Current Procedural Terminology (CPT)® codes, the American Dental Association's Common Dental Terminology (CDT)© codes, and ICD-10 Procedure Coding System codes), captured by the system
- Whether the principal diagnosis, secondary diagnoses, and procedure codes can be accurately distinguished in the system
- Maximum number of digits/characters captured for each data field in each type of claim or encounter

The accuracy and validity of measures may be adversely affected if the information system truncates codes or is unable to collect and/or differentiate among a sufficient number of codes. The EQRO should understand the various coding systems and forms used by the MCP and its vendors to capture and process clinical information through its claims and encounter databases. The EQRO should assess how well the information system translates or maps these codes back to the criteria for MCP performance measure reporting, and how it ensures the accuracy of these translation processes.

The EQRO should also determine, through review of existing documentation or in consultation with the MCP, whether certain diagnosis or procedure codes required for performance measurement are not accurately or completely captured in the claims and encounter data systems, such as maternity or dental care, behavioral health care, and preventive care services.

Medical Record Data

The EQRO should use medical record data to review:

- Methods used to retrieve information from medical records

- Training and tools that medical record review staff receive
- Processes used to ensure accurate data retrieval, inter-rater reliability, and data entry into a database used to produce performance measures

With increasing adoption of EHRs and state use of Health Information Exchanges, MCPs and provider practices may use newer methods to extract information from the medical record. As noted earlier, the EQRO should assess how electronic records are used in performance measure calculation, and whether there are any special considerations in the validity and reliability of these records for accurate measurement.

Pharmacy, Laboratory, and Other Ancillary Data

Pharmacy data use standardized codes for prescription drugs such as those promulgated by the National Council for Prescription Drug Programs (NCPDP).[48] Laboratory services frequently use a similar, nationally recognized system of coding (known as LOINC®).[49]

Due to the diversity in the size, type, and ownership of pharmacy, laboratory, and other ancillary providers, non-standard codes should be examined. When found, the EQRO should assess the MCP's system for cross-walking these different codes to store the necessary information in its performance measure database. The EQRO should understand the MCP's mapping system of non-standard codes to standardized codes and the mechanism used to ensure the accuracy of these translation processes.

If the MCP does not collect pharmacy, laboratory, or other ancillary data through an administrative or claims database, it may retrieve these data from medical records. However, medical records often are an unreliable source due to non-standard coding and terminology, poor coordination of records, and insufficient record linkages between primary care and specialist providers. These issues should be addressed during the claims/encounter data review and the medical record review, and, if necessary, reflected on any corrective action plan.

The EQRO must assess the ability of the information system to link these different sources of data. For example, to identify enrollees with diabetes, a MCP may need to combine diagnosis code data from inpatient or ambulatory encounters (not all ongoing conditions are reported at every encounter) with pharmacy data, lab data, and/or a disease registry, an MCP's disease management system, or a medical management system used by MCP staff, if one exists. Thus, to determine whether enrollees with diabetes have received a retinal examination from an ophthalmologist or optometrist within the previous year, the MCP would have to link diagnosis and procedure code data from encounter forms, medical records, and/or claims data with

[48] More information about NCPDP codes is available at https://www.ncpdp.org/.

[49] More information about LOINC codes is available at https://loinc.org/.

information about the specialty of the providers that performed the examinations for these members.

Synthesis of Findings

The EQRO will review the findings from the ISCA across each of the data systems and types. The EQRO should note any problem areas related to the adequacy of the MCP's data systems to calculate and report the required performance measures. Where a response is incomplete, indicates an inadequate process, or requires clarification, the EQRO should flag the issue for follow-up and further review during the site visit.

Step 3: Conduct Detailed Review of Measures

The next step is to conduct a detailed review of measures, incorporating findings from the ISCA. In its detailed review, the EQRO should identify measures that are most vulnerable to inaccurate results based on its knowledge of the MCP's data systems and processes. For example, if the MCP uses global billing for maternity care, calculation of maternity measures could be affected by the lack of separate claims for prenatal and postpartum care, and thus, performance measurement results for such measures could be significantly under-reported. Similarly, the EQRO should identify certain types of claims that may require linkage from other data sources (such as laboratory, behavioral health, or dental) because the necessary codes may not be available for all members.

WORKSHEET 2.2

Resources for Detailed Review of Measures

A detailed review of each measure includes the following:

- Source code for the measure
- Data mapping, if applicable
- Measure workflow
- Data output at each stage of the measure calculation
- Record-level numerator and denominator data

Worksheet 2.2. Performance Measure Validation Template

- Provide a template for documenting audit specifications for the validation components of each performance measure listed in Worksheet 2.1., and to assess the MCP's measurement and reporting process for each component

The detailed review of each measure involves a systematic assessment of the code and output to assess adherence to the specifications as well as the impact of any systems issues on the accuracy and completeness of the data. In addition, the EQRO should pay special attention to frequently-encountered issues in developing its audit specifications based on findings from the ISCA:

- Claims-dependent denominators
- Complex continuous enrollment criteria
- Use of global billing
- Identification of live births (including linkage of mother and infant records)

- Procedure codes that are infrequently billed by providers (such as developmental screening, documentation of Body Mass Index [BMI], or BMI percentile in the medical record)
- Ability to link claims and pharmacy data
- Identification of practitioner type (especially mental health providers)
- Multiple numerator events
- Vendor-supplied data

During the detailed measure review, the EQRO should develop targeted audit specifications for each measure to account for potential systems issues. The EQRO should record its audit specifications and interim findings on Worksheet 2.2. Performance Measure Validation Template, or a similar worksheet. Box 2.1 provides additional information on validation of HEDIS® measures calculated with HEDIS®-certified software.

Box 2.1. Review of HEDIS® Measures Calculated with HEDIS®-certified Software

- If the state requires HEDIS® measures and the MCP used HEDIS®-certified software to calculate the measures, the EQRO does not need to review source code for those measures. However, the EQRO is required to verify that the measures were calculated as specified by the software and that systems issues did not compromise the accuracy and completeness of the performance measures. As an example, when an MCP pays for prenatal and postpartum care as part of a bundled maternity care payment, HEDIS® measures may be calculated according to the specifications but the rates may be significantly under-reported using administrative data due to the lack of separate claims for prenatal and postpartum care. Thus, the EQRO is required to review and validate the accuracy and completeness of HEDIS® measures based on findings from the ISCA.

Step 4: Initiate Review of Medical Record Data Collection

The purpose of this step is to verify the accuracy of the medical record review conducted by the MCP when medical record data are used to calculate and report performance measures. If a plan only used administrative data, this step is not necessary.

To validate the integrity of the medical record review processes, the EQRO conducts the validation in two phases: the first phase assesses the initial implementation of the process to allow corrections at an early stage; the second phase is a retrospective review of the accuracy of the medical record review abstraction process.

WORKSHEET 2.3

Resource for Activity 1, Step 4

Worksheet 2.3. Medical Review Validation Template

- Provides instructions for conducting the medical record review and worksheets to summarize re-abstraction findings from the review (Worksheet 2.3, Table 1) and to record the impact of findings from the review (Worksheet 2.3, Table 2)

Review of Implementation of Medical Record Review

During the early implementation of the medical record abstraction process, the EQRO will confirm the following about MCP activities:

1. Selection of staff with appropriate experience and credentials
2. Development of high-quality abstraction tools to collect the required information
3. Provision of effective staff training about the review process
4. Implementation of sound oversight procedures to assess reviewer performance (such as validation of a sample of records or tests of inter-rater reliability)

The EQRO may review a convenience sample of records across measures to identify potential problems for MCP correction. NCQA's HEDIS Compliance Audit™ recommends selecting up to 10 difficult-to-review measures and obtain copies of at least 2 complete medical record review tools and charts per measure. If the state requires fewer than 10 measures that rely on medical record data, the EQRO should conduct the sample review for all medical record-dependent measures. Completing this step early in the process allows the MCP to address identified issues and resolve them during the initial stages of data collection.

Re-abstraction and Validation of Medical Record Review

The EQRO will conduct a retrospective medical record review for at least two measures that include medical record review either alone or in combination with administrative data (known as the hybrid method). The EQRO should target statistical validation to measures that are new, complex, and dependent on the medical record data or those with previously identified issues. For each measure, the EQRO will request a sample of 30 medical records with positive numerator events and compare the completed abstraction information to the medical record to determine the rate of agreement. If the agreement rate is less than 100 percent, the EQRO will assess the degree of bias. Worksheet 2.3. Medical Record Review Validation Template provides a detailed description of the medical record review process and validation tool. The EQRO should summarize findings for the MCP from the medical record review validation, including error rates for the measures that were validated (see Table 2 in Worksheet 2.3) and recommendations for improving the medical record review process.

Step 5: Prepare for the MCP Site Visit

Before conducting the site visit, the EQRO will contact the MCP to:

- Explain the procedures and timeline for performance measure validation activities
- Communicate the EQRO's policies and procedures for safeguarding confidential information and signed confidentiality agreements
- Organize the site visit to ensure the availability of necessary documentation and staff (see Box 2.2).

WORKSHEET 2.4

Resource for Activity 1, Step 5

Worksheet 2.4. Potential Documents and Process for Review

- Provides a checklist of documents, data, and procedures the MCP should make available before or during the site visit

Box 2.2. Potential Site Visit Participants

During the site visit, the MCP should arrange for staff and vendors to meet with the EQRO to provide information about the processes to processes to calculate or report performance measures. The EQRO may want to suggest to the MCP that corporate staff—particularly Information Systems (IS) staff—be included in the site visit as corporate staff may provide additional insight into some interview questions. Participants may include:

- The Director of Health/Medical Information Systems
- Information system programmers or operators
- Director of Member/Patient Services and staff
- Director of Utilization Management and staff
- Director of Quality Improvement and staff

At this stage, the EQRO should also request confirmation of the list and description of state-required performance measures. The EQRO will provide the MCP a list of documents, data, and procedures that may be reviewed before or during the site visit (refer to Worksheet 2.4. Potential Documents and Processes for Review).

Activity 2: Conduct Site Visit Activities

Site visit activities provide an opportunity for the EQRO to follow up on findings from the pre-site information system assessment and to confirm or clarify information about the production and reporting of performance measures through document review or discussions (see Box 2.3).

Box 2.3. Purpose of the Site Visit

- Confirm, observe, and query systems used to produce performance measure results, including membership, medical, pharmacy, provider, and other ancillary or supplemental data sources
- Investigate and follow up on issues identified from the ISCA
- Assess data integration and control procedures for accurate production of the performance measures
- Assess data completeness
- Confirm processes for calculating and reporting the performance measures

During the site visit, the EQRO will complete the following steps, which are described below:

1. Review the information systems underlying performance measurement
2. Assess data integration and control for performance measure calculation
3. Review performance measurement production
4. Complete the detailed review of measures
5. Assess the sampling process
6. Communicate preliminary findings and outstanding items

Step 1: Review Information Systems Underlying Performance Measurement

The review of the ISCA which had begun during the pre-site phase continues during the site visit. During this phase, the EQRO reviews the information system components that the MCP uses to produce performance measures via (1) staff interviews, (2) primary source documents, (3) systems and processes used to calculate performance measures, (4) data entry observation, and (5) data files. These sources are described below.

WORKSHEET 2.5

Resource for Activity 2, Step 1

Worksheet 2.5. Interview Guide for MCP Data Integration and Control Personnel

- Provides a list of interview questions for key staff involved in the production of performance measures using questions tailored to the MCP's processes for producing these measures. Tailor the questions as appropriate

1. Staff Interviews

The EQRO will interview key staff (scheduled and confirmed ahead of the visit) involved in the production of performance measures using questions tailored to the MCP's processes for producing performance measures based on findings from the ISCA. These interviews also provide an opportunity to supplement the review of information system policies, procedures, and data (described below). See Worksheet 2.5. Interview Guide for MCP Data Integration and Control Personnel.

2. Primary Source Verification

The EQRO will review the primary source documents, including paper forms and other input to the MCP systems, and confirm that the information from the primary source matches the information used for performance measurement. In addition, the EQRO will review the processes used to input, confirm entry, and identify errors, as well as processes used to transmit and track the data through systems. Typical forms the EQRO will review include:

- Member-initiated enrollment data
- Hospital claims/encounters
- Ambulatory claims/encounters
- Prescription data
- Practitioner demographic forms
- Practitioner credentialing forms
- Claims logs
- Lab results

3. System and Process Review

The EQRO will review the MCP's documentation describing the systems and processes used to calculate performance measures to confirm they adhere to state policies and procedures. These include systems and processes for collecting, storing, and reporting data. All documentation received and examined must be recorded.

4. Observation

The EQRO will observe key MCP processes required for performance measure calculation to assess data entry and other data manipulations. Examples include:

- Data entry of membership updates, claims/encounter data, and practitioner data (e.g., confirm that mandatory fields are required and invalid data elements are identified, such as invalid birth dates or invalid service dates)
- Claims operations including overrides or exceptions
- Computer operations and security plans to confirm procedures are followed

The EQRO will directly observe the Extract, Transform, and Load (ETL) process[50] and its replication by two separate operators through the process using an observation guide to confirm the activities, as well as the process where data are incomplete (e.g., a claim without a provider identification number).

5. Data File Review

The EQRO will directly examine data files to confirm the data are stored and processed according to the documentation provided. Examples of files to review include:

- Transaction files for clinical services, membership, and practitioner changes
- Intermediate files created by extracts, queries, and analysis applications
- Data repository files

[50] ETL is when these three database functions (extract, transform, and load) are combined into one tool to pull data out of one database and place it into another database.

Step 2: Assess Data Integration and Control for Performance Measure Calculation

In this step, the EQRO will assess the MCP's ability to link data from multiple sources and the extent to which the MCP has created systems and processes to ensure the accuracy of the calculated performance measures. Worksheet 2.6. Data Integration and Control Findings helps the EQRO review:

WORKSHEET 2.6

Resource for Activity 2, Step 2

Worksheet 2.6 Data Integration and Control Findings Tool

- Guides the EQRO's review of data integration and control elements during the site visit

- Accuracy of data transfers to the assigned performance measure repository
- Accuracy of file consolidations, extracts, and derivations
- Adequacy of the performance measure data repository to calculate and report performance measures
- Management of report production and reporting software

Step 3: Review Performance Measure Production

The EQRO will review the MCP's documentation of all steps undertaken in the production of the performance measures, including:

WORKSHEET 2.7

WORKSHEET 2.8

Resource for Activity 2, Step 3

Worksheet 2.7. Data and Processes Used to Produce Performance Measures: Documentation and Review Checklist

- Helps the EQRO check the documentation of steps taken in the production of the performance measures

Worksheet 2.8. Data and Processes Used to Produce Performance Measures: Findings

- Provides a template for recording findings based on measurement plans, policies, and programming specifications

- Data collection from various sources (e.g., membership, enrollment, provider, claims, or encounter files; medical records; laboratory, pharmacy, or other ancillary records)
- Steps taken to integrate the required data into a performance measure data set or repository
- Procedures or programs to query the data set/repository to identify denominators, generate appropriate samples, determine numerators, and apply proper algorithms to the data in order to produce valid and reliable performance measures

Step 4: Complete the Detailed Review of Measures

In Step 4, the EQRO determines the extent to which the MCP correctly used the technical specifications to produce accurate performance measure results. All validation components should be addressed during this step using Worksheet 2.2. Performance Measure Validation Template (or similar tool).

To ensure the integrity and comparability of the performance measures, the EQRO should pay special attention to factors affecting the accuracy and completeness of the denominators and numerators. For example, the EQRO should assess whether the MCP used the appropriate data and methods to identify the entire eligible population for the denominator (including linkage of data from separate sources, application of inclusions and exclusions, and creation of complex episodes, where applicable). In addition, the EQRO should determine whether the MCP correctly identified and assessed qualifying medical events for the numerator to include all appropriate events, while excluding events that do not qualify. The EQRO should determine whether the numerators and denominators were calculated appropriately based on all applicable codes (such as diagnoses, procedures, and prescription drugs) and all available data sources (such as membership/enrollment data, claim/encounter data, provider data, utilization or medical management information systems data, or data extracted from medical records).

WORKSHEET 2.2

WORKSHEET 2.9

WORKSHEET 2.10

WORKSHEET 2.11

Resource for Activity 2, Step 4

Worksheet 2.2. Performance Measure Validation Template

- Provide a template for documenting audit specifications for the validation components of each performance measure listed in Worksheet 2.1., and to assess the MCP's measurement and reporting process for each component

Worksheet 2.9. Policies, Data, and Information Used to Produce Measures: Review Checklist

- Provides a checklist that tracks documents and data used to assess the accuracy of the MCP's performance measure calculations

Worksheet 2.10. Measure Validation Findings

- Provides a template for documenting adherence to guidance for the denominator; programming logic, source code, and calculations; identifying medical events; exclusion criteria; population estimates; identifying the at-risk population; inclusion of qualifying events in the numerators; and medical record data in the numerator

Worksheet 2.11. Interview Guide for Assessing Processes and Procedures Used to Produce Numerators and Denominators

- Provides a list of interview questions that can be tailored to supplement findings recorded in Worksheet 2.10

For performance measures requiring medical record review, please use Worksheet 2.3. Medical Record Review Validation Tool. The EQRO should validate the results of the medical record review for 30 enrollees who met the numerator requirements for at least two measures. For more information, refer to Activity 1, Step 4.

Step 5: Assess the Sampling Process (if applicable)

The EQRO will determine whether the sample represents the entire eligible population in all relevant dimensions. The MCP's sampling method should not exclude any population subgroups to which the performance measure applies. For example, when assessing well-child care, the sample should not exclude children with special health care needs whose primary care provider is a specialist other than a pediatrician or family practitioner.

Step 6: Communicate Preliminary Findings and Outstanding Items

At the conclusion of the site visit, the EQRO will communicate preliminary findings to the MCP, including any outstanding items for follow-up. The information communicated during the closing conference will appear in the EQRO's subsequent preliminary report to the MCP. In addition, the EQRO should provide a list of outstanding items before completing the preliminary report to allow the MCP the maximum time to resolve identified issues.

WORKSHEET 2.12

WORKSHEET 2.13

Resource for Activity 2, Step 5

Worksheet 2.12. Policies, Procedures, and Data Used to Implement Sampling: Review Checklist

- Guides this review by providing a list of documents, data, and procedures to assess the sampling process

Worksheet 2.13. Sampling Validation Findings

- For each measure involving a sample, this worksheet helps assess the extent to which:
  - The MCP followed the specified sampling method to produce an unbiased sample representative of the entire included population
  - The MCP maintains its performance measurement population sample frame to allow for a sample to be re-drawn or used as a source for replacement
  - Sample sizes collected conform to the methodology in the performance measure specifications
  - The sample is representative of the entire population
  - Proper substitution methodology is followed for performance measures that include medical record reviews

Activity 3: Conduct Post-Site Visit Activities

Post-site visit activities focus on assessing MCP corrective actions and reporting findings to the state using the format and timeframes established by the state. The EQRO will:

1. Analyze all data and submit a preliminary report to the MCP detailing areas of concern, suggested methods for correction, and a timeline for the MCP to make corrections
2. Re-validate selected performance measures and the measurement processes the MCP used to make corrections
3. Re-evaluate the corrected information and submit a report of validation findings to the state
4. Determine preliminary validation findings for each measure
5. Assess accuracy of MCP's performance measure reports to the state, and
6. Submit the validation report to state

Note that throughout this EQR-related activity or during any part of an EQR, the state may decide that immediate corrective action is required.

WORKSHEET 2.3

WORKSHEET 2.6

WORKSHEET 2.10

WORKSHEET 2.13

Resource for Activity 3

Information gathered in Activities 1 and 2 using the following worksheets and tools may be helpful when preparing the final validation report:

Worksheet 2.3. Medical Record Review Validation Template

- Describes procedures and sample tools for validating medical review findings

Worksheet 2.6. Data Integration and Control Findings Tool

- Provides a template for recording findings from interviews with data integration and control MCP personnel

Worksheet 2.10. Measure Validation Findings

- Provides a template for recording findings from the measures record validation review

Worksheet 2.13. Sampling Validation Findings

- Provides a template to record findings from the sampling assessment process

Worksheet 2.14. Framework for Summarizing Information About Performance Measures

- Provides a template for summarizing information about performance measure results

Step 1: Determine Preliminary Validation Findings for Each Measure

In the preliminary validation findings report, the EQRO will document findings, identify areas of concern, and make suggestions for corrective action or long-term improvement for each of the performance measures the EQRO validated. The report should indicate which MCP performance measures and elements of the measures were invalid and therefore, should not be reported (if any). The report should also provide the MCP with correctional guidance for improving the overall measure production process. In addition to communicating written findings, the EQRO may participate in meetings with key MCP personnel responsible for the calculation

and reporting of performance measures to assist the MCP with implementing recommended corrective action.

Once the EQRO has submitted its preliminary findings to the MCP, the MCP may offer comments and documentation to correct errors and omissions in the EQRO's preliminary report. At the discretion of the state, the MCP may recalculate performance measures based on the findings. The EQRO must then revalidate the revised performance measure(s) and incorporate the MCP's comments or revised performance measure validation findings. If the state chooses not to allow measure re-validation, the recommendations will be reviewed in the following year as part of the MCP assessment of progress toward recommended improvements.

Step 2: Assess and Document the Accuracy of Performance Measure Reports

The EQRO will assess and document the extent to which the MCP reported the calculated performance measures correctly in its final report to the state, and verify the reporting of each performance measure by reviewing:

- Procedures for submitting reports that meet state requirements (such as specified format, supporting documentation, and timing)
- Documentation that the MCP appropriately implemented procedures to properly submit required reports to state

Step 3: Submit Validation Report to the State

The EQRO will always use the state's decision rules for determining the degree to which each of the MCP's reported performance measures are accurate and complete. The decision rules for compliance should be consistent across MCPs within the state. The final report should follow the state's required format, and include the following elements:

- A list of the measures validated by the EQRO
- A description of the EQRO's validation activities including:
  - The EQRO team members involved in the validation
  - A summary of the validation strategy
  - The data collection methods and analysis
  - List of site visit participants (EQRO, MCP, and vendor)
  - Other considerations relevant to the site visit process
- Worksheets, tools, and other supporting documentation

WORKSHEET 2.14

Resource for Activity 3, Step 3

Worksheet 2.14. Framework for Summarizing Information About Performance Measures

- Provides a template for summarizing information about performance measure results

- Analyses and conclusions based on the validation process for each performance measure including:
    - The validation status of each performance measure (including the results of the medical record review)
    - Actual results of the performance measures (not just the results of the validation)
    - Findings on the MCP's information systems capabilities and data integration, including documentation of the timing of the state's most recent ISCA and a description of what documentation was reviewed by the EQRO
- Recommendations for improving the process for calculating and reporting performance measures, including implications for the MCP's data systems, methods, and staffing (e.g., programming and analytic capacity)

When possible, the validation report should also identify recommendations from the previous year's report submitted to the state, and discuss progress made on these recommendations over the past year based on information gathered during the validation process.

END OF PROTOCOL 2

Worksheets for Protocol 2: Performance Measure Validation Tools

Instructions. Use these or similar worksheets to assist in validating performance measures reported by the MCP. These worksheets provide templates for validating performance measures and a framework for summarizing information about performance measures in the EQR technical report. This tool includes the following worksheets crosswalked to the applicable Activity and Step:

Worksheet Name	Protocol Activity and Step
Worksheet 2.1. List of Performance Measures to be Validated	Activity 1. Step 1. Define the Scope of the Validation
Worksheet 2.2. Performance Measure Validation Template	Activity 1. Step. 1. Define the Scope of the Validation Activity 1. Step 3. Conduct Detailed Review of Measures Activity 2. Step 4. Complete the Detailed Review of Measures
Worksheet 2.3. Medical Review Validation Template	Activity 1. Step 4. Initiate Review of Medical Record Data Collection Activity 3. Conduct Post-Site Visit Activities
Worksheet 2.4. Potential Documents and Process for Review	Activity 1. Step 5. Prepare for the MCP Site Visit
Worksheet 2.5. Interview Guide for MCP Data Integration and Control Personnel	Activity 2. Step 1. Review Information Systems Underlying Performance Measurement
Worksheet 2.6. Data Integration and Control Findings Tool	Activity 2. Step 2. Assess Data Integration and Control for Performance Measure Calculation Activity 3. Conduct Post-Site Visit Activities
Worksheet 2.7. Data Processes Used to Produce Performance Measures: Documentation and Review Checklist	Activity 2. Step 3. Review Performance Measure Production
Worksheet 2.8. Data and Processes Used to Produce Performance Measures: Findings	Activity 2. Step 3. Review Performance Measure Production
Worksheet 2.9. Polices, Data, and Information Used to Produce Measures: Checklist	Activity 2. Step 4. Complete the Detailed Review of Measures
Worksheet 2.10. Measure Validation Findings	Activity 2. Step 4. Complete the Detailed Review of Measures Activity 3. Conduct Post-Site Visit Activities
Worksheet 2.11. Interview Guide for Assessing Processes Used to Produce Numerators and Denominators	Activity 2. Step 4. Complete the Detailed Review of Measures
Worksheet 2.12. Policies, Procedures, and Data Used to Implement Sampling: Review Checklist	Activity 2. Step 5. Assess the Sampling Process (if applicable)
Worksheet 2.13. Sampling Validation Findings	Activity 2. Step 5. Assess the Sampling Process (if applicable) Activity 3. Conduct Post-Site Visit Activities
Worksheet 2.14. Framework for Summarizing Information about Performance Measures	Activity 3. Step 3. Conduct Post-Site Visit Activities

For each MCP, please complete the following information:

MCP name	
MCP contact name and title	
Mailing address	
Phone/fax numbers	
Email address	
EQRO interview date	
Type of delivery system (check all that apply)	□ Staff model □ Network □ IPA
Plan type	□ MCO □ PIHP □ PAHP □ PCCM entity □ LTSS □ Other: specify _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP

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Worksheet 2.1. List of Performance Measures to be Validated

Instructions. This worksheet is used to identify the measures to be validated, the data source, reporting frequency, and format as described in Activity 1. Step 1. Complete the worksheet for each measure to be validated, and adapt as needed. The list below is illustrative of the performance measures that could be included in the worksheet.

Performance Measures (Illustrative)	NQF #	Admin. Data	Medical Record Review (MRR)	Hybrid (Admin. Data and MRR)	Electronic Health Record	Survey	Reporting Frequency and Format	Comments
Childhood Immunization Status (CIS-CH) (NCQA): Combo 3	0038							
Immunizations for Adolescents (IMA-CH) (NCQA): Combo 1	1407							
Well-Child Visits in the First 30 Months of Life (W30-CH) (NCQA)	1392							

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Worksheet 2.2. Performance Measure Validation Template

Instructions. For each performance measure, use this template to gather audit specifications for the validation components (as described in Activity 1. Steps 1 and 3, and Activity 2. Step 4) and to assess the MCP's measurement and reporting process for each component.

For each validation component, indicate whether the measure meets validation requirements by checking "Yes," "No," or "Not applicable." Insert comments to explain "Not met" and "Not applicable" responses. Use the following guidance to assess each component.

- **Yes:** The MCP's measurement and reporting process was fully compliant with state specifications
- **No:** The MCP's measurement and reporting process was not fully compliant with state specifications. This designation should be used for any validation component that deviates from the state specifications, regardless of the impact of the deviation on the final rate. All components with this designation must include an explanation of the deviation in the comments section
- **Not applicable:** The validation component was not applicable. Include an explanation in the comments section (e.g., sampling not required, medical record review not included)

Managed Care Plan _____

Performance Measure _____

Method for Calculating Measure: [ ] Admin [ ] Medical Record Review [ ] Hybrid [ ] EHR [ ] Survey

Validation component	Audit specifications	Yes	No	Not applicable	Comments
Documentation:					
Did appropriate and complete measurement plans and programming specifications exist, including data sources, programming logic, and computer source code?					
Were internally developed codes used?					
Denominator:					
Were all the data sources used to calculate the denominator complete and accurate (e.g., eligibility files, claims files/encounter data, medical records, provider files, pharmacy records, including those for members who received services outside the MCP's network)?					

Validation component	Audit specifications	Yes	No	Not applicable	Comments
Did the calculation of the performance measure adhere to the specifications for all components of the denominator (e.g., member ID, age, sex, continuous enrollment, clinical codes such as ICD-10, CPT®[51], DRGs, member months/member years, and adherence to the measurement period)?					
Numerator:					
Were the data sources used to calculate the numerator complete and accurate (e.g., claims files, medical records, provider files, pharmacy records, including those for members who received services outside the MCP's network)?					
Did the calculation of the performance measure adhere to the specifications for all components of the numerator (e.g., member ID, clinical codes such as ICD-10, CPT®, LOINC, DRGs, pharmacy data, relevant time parameters such as admission/discharge dates or treatment start and stop dates, adherence to the measurement period, number or type of provider)?					
If medical record abstraction was used, were the abstraction tools adequate?					
If the hybrid method was used, was the integration of administrative and medical record data adequate?					
If the hybrid method or medical record review was used, did the results of the medical record review validation substantiate the reported numerator?					
Sampling:					
Was the sample unbiased?					
Did the sample treat all measures independently?					
Did the sample size and replacement methodologies meet specifications?					

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Validation component	Audit specifications	Yes	No	Not applicable	Comments
Reporting:					
Were the state specifications for reporting performance measures followed?					
Overall assessment: In the comments section, note any recommendations for the MCP's measurement and reporting process					

Additional Audit Questions	Yes (Please explain)	No
Were any members excluded for contraindications found in the administrative data?		
Were any members excluded for contraindications found during the medical record review?		
Were internally developed codes used?		

What is the estimated impact of data incompleteness on the rate(s) calculated for this measure?	Check one	Comments
• 0–5 percentage points		
• >5–10 percentage points		
• >10–20 percentage points		
• >20–40 percentage points		
• >40 percentage points		
• Unable to determine		
What is the direction of the bias? (Check one)		
• Over-reporting		
• Under-reporting		
• Not applicable (no bias detected)		
What documentation was used to estimate the above percentage (e.g., internal reports, studies, comparison to medical records)?		

Overall Validation Finding

Provide an overall validation finding for each performance measure. The validation finding is determined by the magnitude of the errors detected for the audit elements, not by the number of audit elements determined as "NO." Consequently, it is possible that an error for a single audit element may result in a designation of "Do Not Report" (DNR) because the impact of the error materially biased the reported performance measure. Conversely, it is also possible that several audit element errors may have little impact on the reported rate and, thus the measure is "Reportable" (R).

Performance Measure Validation Finding (check one)	**Comments**
[ ] R = Reportable; measure was compliant with state specifications [ ] DNR = Do not report; MCP rate was materially biased and should not be reported [ ] NA = Not applicable; the MCP was not required to report the measure [ ] NR = Measure was not reported because the MCP did not offer the required benefit	
Overall assessment: In the comments section, note justification and recommendations for the validation finding.	

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Example of Worksheet 2.2. Performance Measure Validation Template

Below is an example of a completed, customized performance measure validation worksheet similar to what an EQRO would prepare before its site visit. This worksheet is based on the Child and Adult Core Set specifications for the performance measure.

Performance Measure: Chlamydia Screening in Women Ages 16 to 20 (CHL-CH) and Ages 21 to 24 (CHL-AD) (NCQA)

Method for Calculating Measure: [X] Admin [ ] Medical Record Review [ ] Hybrid [ ] EHR [ ] Survey

Validation component	Audit specifications	Yes	No	Not applicable	Comments
Documentation:					
Did appropriate and complete measurement plans and programming specifications exist, including data sources, programming logic, and computer source code?	• Obtain and review all file layouts, code, documentation • Code and documentation mapped to measure specification	X			
Denominator:					
Were all the data sources used to calculate the denominator complete and accurate (e.g., eligibility files, claims files, provider files, pharmacy records)?		X			

Validation component	Audit specifications	Yes	No	Not applicable	Comments
Did the calculation of the performance measure adhere to the specifications for all components of the denominator (e.g., member ID, age, sex, continuous enrollment, clinical codes such as ICD-10, CPT®, DRGs, member months/member years, and adherence to the measurement period)?	• Medicaid population appropriately segregated from commercial and Medicare • Population defined as active Medicaid enrollment as of 12/31 of measurement year • Members ages 21-24 as of 12/31 of the measurement year • Only females selected • Members enrolled in MCP on 12/31 of the measurement year • Continuously enrolled from 1/1 to 12/31 of the measurement year with no more than one break of up to 45 days allowed • Shifts between Medicaid and CHIP enrollment were not counted as breaks; shifts between Medicaid and CHIP and commercial enrollment were counted as breaks.	X			
Numerator:					
Were the data sources used to calculate the numerator complete and accurate (e.g., claims files, medical records, provider files, pharmacy records, including those for members who received services outside the MCP's network)?	• Sexually active based on pharmacy and claims/encounter data • Properly identified enrollees. Based on the ISCA findings, the data sources used for the numerator were accurate	X			

Validation component	Audit specifications	Yes	No	Not applicable	Comments
Did the calculation of the performance measure adhere to the specifications for all components of the numerator (e.g., member ID, clinical codes such as ICD-10, CPT®, LOINC, DRGs, pharmacy data, relevant time parameters such as admission/discharge dates or treatment start and stop dates, adherence to the measurement period, number or type of provider)?	• Exclusions were performed according to state specifications • Only the codes listed in specifications as defined by state were counted as exclusions • Standard codes listed in state specifications (and/or properly mapped internally developed codes) were used • Members were counted only once; double counting was prevented • Service performed between 1/1 and 12/31 of the measurement year	X			
If medical record abstraction was used, were the abstraction tools adequate?				X	Not applicable; no medical record abstraction
If the hybrid method was used, was the integration of administrative and medical record data adequate?				X	Not applicable; hybrid method not specified for this measure
If the hybrid method or medical record review was used, did the results of the medical record review validation substantiate the reported numerator?				X	Not applicable; hybrid method not specified for this measure
Sampling:					
Did the sample treat all measures independently?				X	Not applicable; no sampling
Did the sample size and replacement methodologies meet specifications?				X	Not applicable; no sampling

Validation component	Audit specifications	Yes	No	Not applicable	Comments
Reporting:					
Were the state specifications for reporting performance measures followed?	• Measure-eligible population is accurate and documented (inclusions, exclusions) • Method is accurate and documented (measurement period, data source) • Information on numerator, denominator, rate is accurate and documented • Deviations (if any) are accurate and documented	X			
Overall assessment: In the comments section, note any recommendations for the MCP's measurement and reporting process					Measure meets all audit specifications and is reportable by the state

Additional Audit Questions	Yes (Please explain)	No
Were any members excluded for contraindications found in the administrative data?		X
Were any members excluded for contraindications found during the medical record review?		X (Not applicable)
Were internally developed codes used?		X

What is the estimated impact of data incompleteness on the rate(s) calculated for this measure? (Check one)	
• 0–5 percentage points	X
• >5–10 percentage points	
• >10–20 percentage points	
• >20–40 percentage points	
• >40 percentage points	
• Unable to determine	
What is the direction of the bias? (Check one)	
• Over-reporting	
• Under-reporting	

• Not applicable (no bias detected)	X
What documentation was used to estimate the above percentage (e.g., internal reports, studies, comparison to medical records)?	Internal reports

Overall Validation Finding

Provide an overall validation finding for each performance measure. The validation finding is determined by the magnitude of the errors detected for the audit elements, not by the number of audit elements determined as "NO." Consequently, it is possible that an error for a single audit element may result in a designation of "Do Not Report" (DNR) because the impact of the error materially biased the reported performance measure. Conversely, it is also possible that several audit element errors may have little impact on the reported rate and, thus the measure is "Reportable" (R).

Performance Measure Validation Finding (check one)	**Comments**
[X] R = Reportable; measure was compliant with state specifications [ ] DNR = Do not report; MCP rate was materially biased and should not be reported [ ] NA = Not applicable; the MCP was not required to report the measure [ ] NR = Measure was not reported because the MCP did not offer the required benefit	
Overall assessment: In the comments section, note justification and recommendations for the validation finding.	
Performance Measure Validation Finding	Adhered to all specifications and no data concerns detected.

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Worksheet 2.3. Medical Record Review Validation Template

Instructions. This template provides instructions for conducting the medical record review (as described in Activity 1. Step 4 and Activity 3) and two tables to summarize re-abstraction findings from the review (Table 1) and record the impact of findings from the review (Table 2).

The purpose of medical record review (MRR) validation is to verify the accuracy of the MRR conducted by each MCP. For each of at least two measures that included medical record review, the EQRO will validate the medical records of 30 enrollees found to meet numerator requirements. In states with separate Medicaid and CHIP programs, the EQRO will review 30 enrollees in each CHIP MCP and 30 enrollees in each Medicaid MCP for each of at least two measures that included medical record review. Only those members included in a hybrid sample will be selected—the EQRO will not conduct medical record audits to validate administrative data.

For each measure in which medical record review was used, the EQRO will request a list of all of the members in the MCP's MRR sample. From that list:

- The EQRO will identify a sample of 30 members who meet numerator requirements
- MCPs will then be asked to provide access to or copies of medical records so that the EQRO can verify that each member was appropriately included in the denominator and received the required numerator service(s)
- In cases where there are fewer than 30 numerator positives, the EQRO will review all records for that measure

To provide sufficient time for each MCP to gather the required medical record documentation, the EQRO may direct the MCPs to submit their lists of members in their hybrid sample twice— the first list as a preliminary submission and the second list as a final submission:

- Submitting a first list before completion of the MRR process would allow an MCP additional time to retrieve medical record documentation
- Soon after receipt of the first list, the EQRO will provide the MCP with the list of medical records for which documentation must be submitted
- Only a portion of the 30 medical records for the validation sample will be included in the EQRO's first sample request list
- The remainder of the 30 records will be selected from the final list. While the first submission of MRR findings is optional, it is recommended

The EQRO should accept the first list submission approximately one month before the scheduled audit or another time specified by the EQRO. If an MCP chooses to submit a first list of medical records, it must still submit a final listing sufficiently in advance of the scheduled audit as directed by the EQRO. For each submission:

- MCPs will need to identify all members for whom MRR has been conducted and indicate which members have been found to be numerator positives through MRR
- The final list must reflect the MCP's final medical record review findings, with members for whom a medical record was never found identified as not having met the numerator requirements

No predetermined "passing" grade is set for the medical record audit. Rather, auditors will use the MRR results to determine if the hybrid rate (or solely MRR rate if applicable) is biased, and to what extent that bias affects the final reported rate for that measure. The EQRO will identify to the state what effects bias, as well as incomplete data, will have on the MCP's calculation of the performance measure. For each of the evaluated measures, auditors will determine the impact of the findings from the MRR validation process on the MCP's Final Audit Designation.

Step 1: Calculate the Medical Record Review Error Rate

The EQRO will review up to 30 records identified by the MCP as meeting numerator requirements (as determined through MRR) for the measures audited. Records are randomly selected from the entire population of MRR numerator positives identified by the plan, as indicated on the MRR numerator listings submitted to the EQRO:

- If fewer than 30 medical records are found to meet numerator requirements, all records are reviewed
- Administrative numerator positives are not included as part of this validation process

The EQRO will calculate a MRR error rate for each performance measure calculated by the hybrid method or solely from MRR as illustrated in Table 1.

Table 1: Summary of Medical Record Review (MRR) Re-abstraction Findings

Column A	Column B	Column C	Column D	Column E	Column F
Performance measure	**Number of MMR positives selected for audit**	**Number of medical records received**	**Number of medical records found compliant**	**Accuracy rate (%) (col. D/col. B)**	**Error rate (%) (100% - col. E)**

Column A: Name of performance measure

Column B: Total number of MRR numerator positive records re-abstracted by EQRO as part of the medical record review validation process (i.e., 30, or the total population if less than 30 MRR numerator positives were reported)

Column C: Total number of medical records submitted to EQRO as part of the medical record review validation process (i.e., should be equal to Column B or less than Column B if one or more records were not submitted on time)

Column D: Total number of medical records reviewed by EQRO and identified as meeting numerator requirements

Column E: Accuracy rate = percent of records selected for audit that were identified as meeting numerator requirements (Column D/Column B)

Column F: Error rate = percent of records selected for audit that were identified as not meeting numerator requirements (100% - Column E)

Step 2: Determining the Potential Impact of Medical Record Review Re-abstraction Findings on Final Audit Designations

The next step in MRR validation is to determine whether any medical record review errors significantly biased the final reported rate for a given performance measure. To make this determination, the EQRO, as directed by the state, should develop and follow decision rules such as the following:

Sample Decision Rules:

- **Error Rate of 10 Percent or Less.** If the error rate (Table 1, column F) is 10 percent or less, then the measure automatically passes the MRR validation. The Final Audit Designation is then determined based on the auditors' findings from the ISCA conducted as Pre-Site Visit Activity 3 and Site Visit Activity 1. As long as no errors leading

to significant bias are discovered during the other components of the audit process, the final rate is considered as having met the validation standards

- **Error Rate of Greater than 10 Percent.** If the error rate (Table 1, column F) is greater than 10 percent, then the auditors determine the impact of the MRR validation findings on the final reported rate for the measure. For each of the measures under review, auditors evaluate the impact of the MCP's MRR processes on its final reported rate by extrapolating findings from the audited medical record sample to the universe of all MRR positives. Details on this process are in Table 2
- **The maximum amount of bias allowed for the final rate to be considered reportable is "X" percentage points (to be determined by each state).** If the amount of error in the MCP's MRR process (Table 2, line 8) does not cause the final reported rate to be biased by more than X percentage points, then the measure passes the MRR validation. The compliance designation is then determined based solely on the auditors' findings from the ISCA. As long as no errors leading to significant bias are discovered during the other components of the performance measure audit process, the final rate is considered valid
- **If the amount of error in the MCP's medical review process (Table 2, line 8) ultimately causes the final reported rate to be biased by more than X percentage points,** the rate is automatically considered invalid. The performance measure is then designated as invalid

Table 2: Impact of MRR Findings

Line #	Description	Measure A	Measure B	Measure C
1	Final data collection method used (e.g., MRR, hybrid)			
2	Error rate (percentage of records selected for audit that were identified as not meeting numerator requirements, as shown in Table 1, column F)			
3	Is error rate <10%? (Yes or No) • If yes, MCP passes MRR validation; no further MRR calculations necessary • If no, the full table must be completed to determine the impact on the final rate			
4	Denominator (the total number of members identified for the denominator of this measure, as identified by the MCP)			
5	Weight of each medical record (impact of each medical record on the final overall rate; determined by dividing 100% by the denominator in line 4)			
6	Total number of MRR numerator positives identified by the MCP using MRR			
7	Expected number of false positives (Estimated number of medical records inappropriately counted as numerator positives; determined by multiplying the error rate in line 2 by line 6, the total number of MRR numerator positives reported)			

Line #	Description	Measure A	Measure B	Measure C
8	Estimated bias in final rate (The amount of bias caused by medical record review, measured in percentage points; determined by multiplying the expected number of false positives in line 7 by line 5, the weight of each medical record)			

- If line 8 is <=X%, then the final rate is not considered to be significantly biased by MRR alone. If the other components of the audit process did not identify any other issues that would introduce bias into the rate, the rate will be considered valid
- If line 8 is >X%, then the final rate is considered to be significantly biased. The measure will be considered invalid

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Worksheet 2.4. Potential Documents and Processes for Review

Instructions. To assist the EQRO in assessing the MCP's information system and validity of reported performance measures, this worksheet provides a checklist of documents, data, and procedures the MCP should make available before or during the site visit (as described in Activity 1, Step 5). Record any questions or concerns raised by the review of documents and/or processes, and any specific checks or tests the EQRO would like to conduct or have demonstrated during the site visit. The EQRO can use its discretion in selecting which ones to review.

For example:

- Compare samples of data in the repository to transaction files. Are any members, providers, or services lost in the process?
- Is the required level of coding detail maintained (e.g., all significant digits, primary and secondary diagnoses remain)?
- If the MCP uses a performance measure repository, review the repository structure. Does it contain all the key information necessary for performance measure reporting?
- How does the MCP test the process used to create the performance measure reports?
- Does the MCP use any algorithms to check the reasonableness of data integrated to report the MCP-level performance measures?
- Examine report production logs and run controls. Is there adequate documentation of the performance measure report generation process? How are report generation programs documented? Is there version control in place?

Checklist of documents and processes for review	Reviewed? Y/N	Comments for site visit
1. Data integration and control		
Procedures and standards for all aspects of the data repositories used in producing performance measures, including building, maintaining, managing, and testing performance measures		
Manuals that include application system development methodology, database development, and design and decision support system utilization		
System documentation including flow charts and codes for backups, recovery, archiving, and other control functions		
Procedures to consolidate information from disparate transaction files		
Record and file formats and descriptions, for entry, intermediate, and repository files		
Electronic formats and protocols		
Electronic transmission procedures documentation		
Processes to extract information from the repositories		
Source code data entry, data transfer, and data manipulation programs and processes		
Descriptive documentation for data entry, transfer, and manipulation programs and processes		

Checklist of documents and processes for review	Reviewed? Y/N	Comments for site visit
If applicable, procedures for coordinating vendor activities to safeguard the integrity of the performance measurement data		
Samples of data from repository and transaction files to assess accuracy and completeness of the transfer process		
Comparison of actual results from file consolidation and data abstracts to those which should have resulted according to documented algorithms		
Documentation of data flow among vendors to assess the extent to which there was proper implementation of procedures to safeguard the integrity of the performance measure data		
Documentation of data cut-off dates		
Documentation of proper run controls and of staff review of report runs		
Copies of files and databases used for performance measure calculation and reporting		
Procedures governing production process for MCP performance measures, including standards and schedules		
2. Collection, calculation, and documentation of performance measures		
Policies for the documentation of data requirements, data issues, validation efforts, and results		
A project or measurement plan for each performance measure		
Documentation of programming specifications, including work flow, data sources, and uses which include diagram or narrative descriptions		
Documentation of the original universe of data that includes record-level patient identifiers, which can be used to validate programming logic for creating denominators, numerators, and samples		
Documentation of computer queries, programming logic, or source code used to create final denominators, numerators, and interim data files		
Documentation that includes dated job log or computer run for denominators and numerators, with record counts for each programming step and iteration		
Documentation of medical record review including: • Qualifications of medical record review supervisor and staff • Reviewer training materials • The use of audit tools, including completed copies of each record-level reviewer determination • All case-level critical performance measure data elements used to determine a positive or negative event or exclude a case, and • Interrater reliability testing procedures and results		

Checklist of documents and processes for review	Reviewed? Y/N	Comments for site visit
Documentation of statistical test results and any corrections or adjustments to data along with justification for such changes		
Documentation of sources of any supporting external data or prior years' data used in reporting		
Policies to assign unique membership ID that allows all services to be properly related to the specific appropriate enrollee, despite changes in status, periods of enrollment or disenrollment, or changes across product lines (e.g., CHIP and Medicaid).		
Procedures to identify, track, and link member enrollment by product line, product, geographic area, age, sex, member months, and member years		
Procedures to track individual members through enrollment, disenrollment, and possible re-enrollment		
Procedures to track members through changes in family status, changes in benefits or managed care type (if they switch between Medicaid coverage and another product within the same MCP)		
Methods to define start and cessation of coverage		
Procedures to link member months to member age		
Description of software or programming languages used to query each database		
Description of software used to execute sampling of population files when sampling is used		
Member database		
Provider data (including facilities, labs, pharmacies, physicians, etc.)		
Database record layout and data dictionary		
Survey data used for performance measures (See Protocol 6)		
Policies to maintain files from which the samples are drawn in order to keep population intact in the event that a sample must be re-drawn, or replacements made		
Computer source code or logic identifying specified sampling techniques and documentation that the logic matches the specifications set forth for each performance measure, including sample size and exclusion methodology		
Methods used for sampling for measures calling for medical record or hybrid data		
Documentation assuring that sampling methodology treats all measures independently and that there is no correlation between drawn samples		
Observation or documentation of procedures in which a biased sample was identified and corrected		

Checklist of documents and processes for review	Reviewed? Y/N	Comments for site visit
Documentation of "frozen" or archived files from which the samples were drawn, and if applicable, documentation of the MCP's process to re-draw a sample or obtain necessary replacements		
For performance measures that are easily under-reported, procedures to capture data that may reside outside the MCP's datasets		
Procedures for mapping non-standard codes to standard coding		
Policies, procedures, and materials that provide evidence of proper training, supervision, and adequate tools for medical record abstraction tasks (this may include medical record abstraction tools, training material, checks of inter-rater reliability, etc.)		
Procedures for assuring that combinations of record-review data with administratively determined data are consistent and verifiable		
Evidence that MCP's use of codes to identify medical events were correctly evaluated when classifying members for inclusion or exclusion in the numerator		
Evidence that MCP has counted each member and/or event only once		
Programming logic or demonstration that confirms that any non-standard codes used in determining the numerator have been mapped to a standard coding scheme in a manner that is consistent, complete, and reproducible		
Programming logic or source code that identifies the process for integrating administrative and medical record data for numerator		
Procedures for properly executing complex medical algorithms, such as • Claim-dependent events • Events that require matching claims and pharmacy data • Events that require matching visit codes, and • Events that require accurately identifying and computing multiple numerator events		
Procedures for displaying denominator counts, numerator counts, precision levels, sums and cross-totals		
Procedures for reporting small sample sizes (to be consistent with required methodology established by state)		
Programming logic and/or source code for arithmetic calculation of each measure		
Review of reported measures to assess consistency of common elements (e.g., membership counts, number of pregnancies and births, etc.)		

Checklist of documents and processes for review	Reviewed? Y/N	Comments for site visit
Programming logic and/or source code for measures with complex algorithms, to ensure adequate matching and linkage among different types of data		
Documentation showing confidence intervals of calculations when sampling methodology used		
Documentation showing calculation of levels of significance of changes		
Procedures for submitting reports that meet state requirements (e.g., specified electronic format, supporting documentation, and timing)		
Documentation that procedures for properly submitting required reports to state were implemented appropriately		

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Worksheet 2.5. Interview Guide for MCP Data Integration and Control Personnel

Instructions. As part of the EQRO's review of information system components the MCP uses to produce performance measures, the EQRO should interview key staff (including appropriate vendor staff) involved in the production of performance measures using questions tailored to the MCP's processes for producing those measures. These interviews are an opportunity to supplement the review of information system policies, procedures, and data (as described in Activity 2, Step 1). Please tailor the questions below as appropriate.

MCP Contact and Background Information

Please insert or verify the MCP contact information below, including the MCP name, MCP contact name and title, mailing address, telephone and fax numbers, email address, and date of interview, if applicable.

MCP name:	
MCP contact name(s):	
Title(s):	
Mailing address:	
Phone number(s):	
Email address:	
Interview Date:	
EQRO reviewers:	
Year of first Medicaid enrollment:	
Year of first CHIP enrollment:	
Year of first MCP performance report (any product line)	

1. Has the MCP previously undergone validation of its state performance measure reporting process? If so, when did the validation take place and who conducted it?

2. How is performance measure data collection accomplished? (Check all that apply)

   [ ] By querying the applicable information system on-line

   [ ] By using extract files created for analytical purposes? If so, how frequently are the files updated? How do they account for claim/ encounter for accuracy?

   [ ] By using a separate relational database or data warehouse? If so, is this the same system from which all other reporting is produced?

   [ ] Reports created from an NCQA-certified vendor software product? If so, how frequently are the files updated? How are reports checked for accuracy?

3. Review the procedure(s) for consolidating claims/encounter, member, provider, and other data necessary for performance reporting (whether it be into a relational database or file extracts on a measure-by-measure basis):

   - How many different sources of data are merged together to create reports?
   - What control processes are in place to ensure that this merger is accurate and complete?

4. How does the MCP test the process used to create the performance measure reports?

5. Does the MCP use any algorithms to check the reasonableness of data integrated to report the MCP performance measures?

6. Is performance measurement reporting programming reviewed by supervisory staff?

7. Please describe any internal backup for performance measure programmers, if one exists. Do others know the programming language and the structure of the actual programs? Please describe what documentation exists, if any.

8. How does the MCP prevent loss of claim and encounter data when systems fail?

9. Please describe the administrative data backup systems are in place.

10. What types of authorization are required to be able to access claims/encounter, provider, membership, and performance measure repository data?

11. Please describe documentation review and demonstrations provided.

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Worksheet 2.6. Data Integration and Control Findings Tool

Instructions. During the site visit (described in Activity 2, Step 2 and Activity 3), this tool helps the EQRO review the:

- Accuracy of data transfers to the assigned performance measure repository
- Accuracy of file consolidations, extracts, and derivations
- Adequacy of the performance measure data repository to calculate and report performance measures, and
- Management of report production and reporting software

For each data integration and control element, please indicate whether it was met, not met, or not applicable (N/A), and any relevant comments.

1. Accuracy of data transfers to assigned performance measure repository	Met	Not met	N/A	Comments
MCP processes accurately and completely transfer data from the transaction files (e.g., membership, provider, encounter/claims) into the repository used to keep the data until the calculations of the performance measures have been completed and validated				
Samples of data from repository are complete and accurate				

2. Accuracy of file consolidations, extracts, and derivations	Met	Not met	N/A	Comments
MCP's processes to consolidate diversified files and to extract required information from the performance measure repository are appropriate				
Actual results of file consolidations or extracts were consistent with those which should have resulted according to documented algorithms or specifications				
Procedures for coordinating the activities of vendors ensure the accurate, timely, and complete integration of data into the performance measure database				
Computer program reports or documentation reflect vendor coordination activities, and no data elements needed for performance measure reporting are lost or inappropriately modified during transfer				

3. If the MCP uses one, the structure and format of the performance measure data repository facilitates any required programming necessary to calculate and report required performance measures	Met	Not met	N/A	Comments
The repository's design, program flow charts, and source codes enable analyses and reports				
Proper linkage mechanisms have been employed to join data from all necessary sources (e.g., identifying a member with a given disease/condition)				

4. Assurance of effective management of report production and of the reporting software	Met	Not met	N/A	Comments
Documentation governing the production process, including MCP production activity logs, and MCP staff review of report runs was adequate				
Prescribed data cutoff dates were followed				
The MCP has retained copies of files or databases used for performance measure reporting, in the event that results need to be reproduced				
Reporting software program is properly documented with respect to every aspect of the performance measurement reporting repository, including building, maintaining, managing, testing, and report production				
MCP's processes and documentation comply with the MCP standards associated with reporting program specifications, code review, and testing				

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Worksheet 2.7. Data and Processes Used to Produce Performance Measures: Documentation Review Checklist

Instructions. During the site visit, this tool helps the EQRO check the documentation of steps taken in the production of the performance measures. It is intended to guide document review (as described in Activity 2, Step 3).

Documentation	Reviewed	Not Reviewed	Not applicable	Comments
Documentation of overall policies and procedures				
Policies which stipulate and enforce documentation of data requirements, issues, validation efforts and results				
Procedures for displaying denominator counts, numerator counts, precision levels, and totals				
Procedures for reporting small sample sizes (consistent with state's required methodology)				
All reported measures to assess consistency of common elements (e.g., membership counts, number of pregnancies and births, etc.)				
Documentation for each measure:				
Programming logic and/or source code for arithmetic calculation				
A project or measurement plan, including work flow				
Documentation of programming specifications and data sources				
Documentation of the original universe of data including record-level patient identifiers that can be used to validate entire programming logic for creating denominators, numerators, and samples				
Documentation of computer queries, programming logic, or source code used to create denominators, numerators, and interim data files				
Documentation of medical record review for each measure, as appropriate, including: qualifications of medical record review supervisor and staff; reviewer training materials, audit tools used (including completed copies of each record-level reviewer determination), all case-level critical performance measure data elements used to determine a positive or negative event or exclude a case from same, and inter-rater reliability testing procedures and results				

Documentation	Reviewed	Not Reviewed	Not applicable	Comments
Documentation of results of statistical tests and any corrections or adjustments to data along with justification for such changes for each measure, as appropriate				
Documentation showing calculation of levels of significance of changes for each measure				
Documentation showing confidence intervals of calculations when sampling methodology used				
Documentation of sources of any supporting external data or prior years' data used in reporting				
Overall assessment: In the comments section, note: • How are policies governing documentation of data requirements for performance measurement (e.g., data file and field definitions, mapping between standard and non-standard codes) updated and enforced? Who is responsible for this? • How are programming specifications for MCP performance measures documented? Who is responsible for this? • Are documentation processes up to date?				

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Worksheet 2.8. Data and Processes Used to Produce Performance Measures: Findings

Instructions. Record findings based on measurement plans, policies, and programming specifications, as described in Activity 2, Step 3.

1. Measurement plans and policies that stipulate and enforce documentation of data requirements, issues, validation efforts, and results. These include the following audit elements	Met	Not Met	N/A	Comments
Data file and field definitions used for each measure				
Maps to standard coding if not used in original data collection				
Statistical testing of results and any corrections or adjustments made after processing				
Overall assessment: In the comments section, note any recommendations for improving measurement plans and policies				

2. Documentation of programming specifications (which may be either a schematic diagram or in narrative form) for each measure includes at least the following audit elements:	Met	Not Met	N/A	Comments
All data sources, including external, supplemental data (whether from a vendor, public registry, or other outside source), and any prior year data, if applicable				
A project or measurement plan, including workflow				
Detailed medical record review methods and practices, including: • The qualifications of medical record review supervisor and staff • Reviewer training materials • Audit tools used (including completed copies of each record-level reviewer determination) • All case-level critical performance measure data elements used to determine a positive or negative event or exclude a case from same, and • Inter-rater reliability testing procedures and results				
Detailed computer queries, programming logic, or source code used to identify the population or sample for the denominator and/or numerator				
Documentation of the original universe of data including record-level patient identifiers that can be used to validate entire programming logic for creating denominators, numerators, and samples				

2. Documentation of programming specifications (which may be either a schematic diagram or in narrative form) for each measure includes at least the following audit elements:	**Met**	**Not Met**	**N/A**	**Comments**
If sampling is used, a description of sampling techniques and documentation assuring the reviewer that samples used for baseline and repeat measurements of the performance measures were chosen using the same sampling frame and methodology				
Documentation of calculation for changes in performance from previous periods, if applicable, including statistical tests of significance				
Data that are related from measure to measure are consistent (e.g., membership counts, provider totals, number pregnancies and births)				
Appropriate statistical functions are used to determine confidence intervals when sampling is used in the measure				
When determining improvement in performance between measurement periods, appropriate statistical methodology is applied to determine levels of significance of changes				
Overall assessment: In the comments section, note any recommendations for improving programming specifications for each performance measure				

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Worksheet 2.9. Policies, Procedures, and Data Used to Produce Performance Measures: Review Checklist

Instructions. Use this checklist to track documents and data used to assess the accuracy of the MCP's performance measure calculations (as described in Activity 2, Step 4).

Policies, Procedures, and Data to be Reviewed	Reviewed	Not Reviewed	Comments
Policies to assign unique membership ID that allows all services to be properly related to the specific appropriate enrollee, despite changes in status, periods of enrollment or disenrollment, or changes across product lines (e.g., Medicare and Medicaid)			
Procedures to identify, track, and link member enrollment by product line, product, geographic area, age, gender, member months, member years			
Procedures to track individual members through enrollment, disenrollment, and possible re-enrollment			
Procedures to track members through changes in family status, changes in employment or benefits or managed care type (if they switch between Medicaid coverage and another product within the same MCP)			
Methods to define start and cessation of coverage			
Procedures to link member months to member age			
Description of software or programming languages used to query each database			
Programming logic and/or source code for arithmetic calculation of each measure			
Programming logic and/or source code for measures with complex algorithms, to ensure adequate matching and linkage among different types of data			
Member database			
Provider data (including facilities, labs, pharmacies, physicians, etc.)			
Database record layout and data dictionary			
Survey data			
For performance measures which are easily under-reported, procedures to capture data that may reside outside the MCP's data sets			
Procedures for mapping non-standard codes to standard coding to ensure consistency, completeness, and reproducibility			
Policies, procedures, and materials that evidence proper training, supervision, and adequate tools for medical record abstraction tasks (may include medical			

Policies, Procedures, and Data to be Reviewed	Reviewed	Not Reviewed	Comments
record abstraction tools, training material, checks of inter-rater reliability, etc.)			
Procedures for assuring that combinations of record-review data with administratively determined data are consistent and verifiable			
Evidence that MCP's use of codes to identify medical events were correctly evaluated when classifying members for inclusion or exclusion in the numerator			
Evidence that MCP has counted each member and/or event only once			
Programming logic or demonstration that confirms that any non-standard codes used in determining the numerator have been mapped to a standard coding scheme in a manner that is consistent, complete, and reproducible			
Programming logic or source code that identifies process for integrating administrative and medical record data for numerator			
Programming logic and/or source code for arithmetic calculation of each measure			
Programming logic and/or source code for measures with complex algorithms, to ensure adequate matching and linkage among different types of data			
Overall assessment: In the comments section, note any recommendations to improve documentation or demonstrations provided by the MCP			

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Worksheet 2.10. Measure Validation Findings

Instructions. For each performance measure, the EQRO can use this worksheet to document adherence to guidance for (1) the denominator; (2) programming logic, source code, and calculations; (3) identifying medical events; (4) time parameters; (5) exclusion criteria; (6) population estimates; (7) identifying the at-risk population; (8), inclusion of qualifying medical events in the numerator; and (9) medical record data in the numerator. This worksheet is relevant to Activity 2, Step 4, and Activity 3.

Audit Element	Met	Not Met	N/A	Comments
Denominator. For each performance measure, all members of the relevant populations identified in the performance measure specifications (who were eligible to receive the specified services) were included in the population from which the denominator was produced. The eligible population included members who received the services as well as those who did not. The same standard applies to provider groups or other relevant populations identified in the specifications of each performance measure.				
Programming logic, source code, and calculations. For each measure, adequate programming logic or source code identifies, tracks, and links member enrollment within and across product lines (e.g., Medicaid and CHIP), by age and sex, as well as through possible periods of enrollment and disenrollment) and appropriately identifies all relevant members of the specified denominator population for each of the performance measures. This is determined by evaluating that:				
1. Calculations of continuous enrollment criteria were correctly carried out and applied to each measure (if applicable)				
2 Proper mathematical operations were used to determine patient age or age range				
3. The MCP can identify the variable(s) that define the member's sex in every file or algorithm needed to calculate the performance measure denominator, and the MCP can explain what classification is carried out if neither of the required codes is present				
4. The MCP has correctly calculated member months and member years, if applicable to the performance measure				
Identifying medical events. The MCP has properly evaluated the completeness and accuracy of any codes used to identify medical events, such as diagnoses, procedures, or prescriptions, and these codes have been appropriately identified and applied as specified in each performance measure.				

Audit Element	Met	Not Met	N/A	Comments
Time parameters. Any time parameters required by the performance measure specification were followed by the MCP (e.g., cut off dates for data collection, counting 30 calendar days after discharge from a hospital).				
Exclusion criteria. Performance measure specifications or definitions that exclude members from a denominator were followed. (For example, if a measure relates to receipt of a specific service, the denominator may need to be adjusted to reflect instances in which the patient refuses the service or the service is contraindicated.)				
Population estimates. Systems or methods used by the MCP to estimate populations when they cannot be accurately or completely counted (e.g., newborns) are valid.				
Identifying the at-risk population. The MCP has used the appropriate data, including linked data from separate data sets, to identify the entire at-risk population.				
Services provided outside the MCP. The MCP has adopted and followed procedures to capture data for those performance measures that could be easily under-reported due to the availability of services outside the MCP. (For some measures, particularly those focused on women and children, the member may have received the specified service outside of the MCP provider base, such as children receiving immunizations through public health services or schools, access to family planning services. An extra effort must be made to include these events in the numerator.)				
Inclusion of qualifying medical events. The MCP's use of codes to identify medical events (e.g., diagnoses, procedures, prescriptions) are complete, accurate, and specific in correctly describing what transpired and when. This included:				
1, The MCP correctly evaluated medical event codes when classifying members for inclusion or exclusion in the numerator				
2 The MCP avoided or eliminated all double-counted members or numerator events				
3. The MCP mapped any non-standard codes used in determining the numerator in a manner that is consistent, complete, and reproducible. The EQRO assesses this through a review of the programming logic or a demonstration of the program				

Audit Element	Met	Not Met	N/A	Comments
4. Any time parameters required by the specifications of the performance measure were adhered to (i.e., that the measured event occurred during the time period specified or defined in the performance measure)				
Medical record data. Medical record reviews and abstractions were carried out in a manner that facilitated the collection of complete, accurate, and valid data by ensuring that:				
1. Record review staff have been properly trained and supervised for the task				
2. Record abstraction tools required the appropriate notation that the measured event occurred				
3. Record abstraction tools required notation of the results or findings of the measured event, if applicable				
4. Medical record data from electronic sources was accurately extracted according to measure specifications				
5. Data included in the record extract files are consistent with data found in the medical records based on a review of a sample of medical record for applicable performance measures				
6. The process of integrating administrative data and medical record data for the purpose of determining the numerator is consistent and valid				
Overall assessment: In the comments section, note any recommendations (if applicable) to: • Improve the denominator • Improve programming logic, source code, or calculations • Improve the completeness or accuracy of the codes used to identify medical events • Improve the specified time parameters • Improve adherence to the exclusion criteria • Improve systems/methods to estimate populations when they cannot be accurately counted • Ensure all appropriate data are used to identify the entire at-risk population • Appropriately identify and include qualifying medical events for the numerator • Improve the proper collection of medical record data extracted for inclusion in the numerator				

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Worksheet 2.11. Interview Guide for Assessing Processes and Procedures Used to Produce Numerators and Denominators

Instructions. The following interview guide may be used to supplement findings reported in Worksheet 2.10 (as described in Activity 2, Step 4). Please tailor the questions as appropriate.

MCP Contact and Background Information

Please insert or verify the MCP contact information below, including the MCP name, MCP contact name and title, mailing address, telephone and fax numbers, email address, and date of interview, if applicable.

MCP name:	
MCP contact name(s):	
Title(s):	
Mailing address:	
Phone number(s):	
Email address:	
Interview Date:	
EQRO reviewers:	
Year of first Medicaid enrollment:	
Year of first CHIP enrollment:	
Year of first MCP performance report (any product line)	

1. If any part of your network/data/membership was excluded from a performance measure, how and why did you decide to exclude it?

2. Why did you select the reporting methodology (e.g., administrative, or hybrid) used to create each of the measures (where there was an option)?

3. Did you use the state technical specifications as the specifications for the programmers, or did your MCP write its own instructions/translations for the programmers?

4. Are there any manual processes used for calculating denominators and/or numerators? Are manual processes used for sampling?

5. Are any measures calculated by vendors? If yes, are they checked for accuracy? Please describe.

6. Do you have any concerns about the integrity of the information used to create any of the measures? Please describe.

7. Do you know of any deviations from performance measure specifications that were necessary because of data available or because of your MCP's information system capabilities?

8. Other issues.

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Worksheet 2.12. Policies, Procedures, and Data Used to Implement Sampling: Review Checklist

Instructions. This checklist provides a list of documents, procedures, and data to assess the sampling process, if applicable (as described in Activity 2, Step 5).

Documents	Reviewed	Not Reviewed	Comments
Description of software used to execute sampling sort of population files when sampling (e.g., systematic) is used			
Policies to maintain files from which the samples are drawn in order to keep population intact in the event that a sample must be re-drawn or replacements made			
Computer source code or logic identifying specified sampling techniques, and documentation that the logic matches the specifications set forth for each performance measure, including sample size and exclusion methodology			
Methods used for sampling for measures calling for hybrid data or medical record review			
Documentation assuring that sampling methodology treats all measures independently, and that there is no correlation between drawn samples			
Observation of or documentation of procedures in which a biased sample was identified and corrected			
Documentation of "frozen" or archived files from which the samples were drawn, and if applicable, documentation of the MCO's process to re-draw a sample or obtain necessary replacements			
Overall assessment: In the comments section, note any recommendations to improve documentation or demonstrations to assess the sampling process			

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Worksheet 2.13. Sampling Validation Findings

Instructions. This checklist provides a list of documents, procedures, and data to assess the sampling process across the following elements: (1) the MCP followed the specified sampling method to produce an unbiased sample that is representative of the entire included population, (2) the MCP maintains its performance measurement population files/data sets in a manner that allows a sample to be re-drawn or used as a source for replacement, (3) sample sizes collected conform to the methodology set forth in the performance measure specifications and the sample is representative of the entire population, and (4) for performance measures that include medical record review (e.g., hybrid data collection methodology), proper substitution methodology was followed. This worksheet is applicable to Activity 2, Step 4 and Activity 3.

1. Audit Element: Sampling method	Met	Not Met	N/A	Comments
Each relevant member or provider had an equal chance of being selected; no one was systematically excluded from the sampling.				
The MCP followed the specifications set forth in the performance measure regarding the treatment of sample exclusions and replacements, and if any activity took place involving replacements of or exclusions from the sample, the MCP kept adequate documentation of that activity				
Each provider serving a given number of enrollees had the same probability of being selected as any other provider serving the same number of enrollees				
The MCP examined its sampled files for bias, and if any bias was detected, the MCP is able to provide documentation that describes any efforts taken to correct it				
The sampling methodology employed treated all measures independently, and there is no correlation between drawn samples				
Relevant members or providers who were not included in the sample for the baseline measurement had the same chance of being selected for the follow-up measurement as providers who were included in the baseline				
Overall assessment: In the comments section, note any recommendations to produce an unbiased, representative sample				

2. Audit Element: Performance measurement files/data	Met	Not Met	N/A	Comments
The MCP has policies and procedures to maintain files from which the samples are drawn in order to keep the population intact in the event that a sample must be re-drawn, or replacements made, and documentation that the original population is intact				

2. Audit Element: Performance measurement files/data	Met	Not Met	N/A	Comments
Overall assessment: In the comments section, note any recommendations to improve file or data maintenance				

3. Audit Element: Performance measure specifications	Met	Not Met	N/A	Comments
Sample sizes meet the requirements of the performance measure specifications				
The MCP has appropriately handled the documentation and reporting of the measure if the requested sample size exceeds the population size				
The MCP properly oversampled in order to accommodate potential exclusions				
Overall assessment: In the comments section, note any recommendations to improve adherence to performance measure specifications				

4. Audit Element: Medical record reviews	Met	Not Met	N/A	Comments
Substitution applied only to those members who met the exclusion criteria specified in the performance measure definitions or requirements				
Substitutions were made for properly excluded records and the percentage of substituted records was documented				
Overall assessment: In the comments section, note any recommendations to improve use of proper substitution methodology				

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Worksheet 2.14. Framework for Summarizing Information About Performance Measures

Instructions. Use this worksheet or a similar tool to summarize the results for each performance measure validated for each managed care plan. This worksheet can be used as a framework for summarizing validation at the plan level. In addition, the information in this worksheet can be aggregated across plans and measures to generate information on state-level performance and areas for improvement.

1. Overview of Performance Measure

Managed Care Plan (MCP) name:
Performance measure name:
Measure steward: ☐ Agency for Healthcare Research and Quality (AHRQ) ☐ Centers for Disease Control and Prevention (CDC) ☐ Centers for Medicare & Medicaid Services (CMS) ☐ National Committee for Quality Assurance (NCQA) ☐ The Joint Commission (TJC) ☐ No measure steward, developed by state/EQRO ☐ Other measure steward (specify) _____
Is the performance measure part of an existing measure set? (check all that apply) ☐ HEDIS® ☐ CMS Child or Adult Core Set ☐ Other (specify) _____
What data source(s) was used to calculate the measure? (check all that apply) ☐ Administrative data (describe) _____ ☐ Medical records (describe) _____ ☐ Other (specify) _____
If the hybrid method was used, describe the sampling approach used to select the medical records: ☐ Not applicable (hybrid method not used)
Definition of denominator (describe):
Definition of numerator (describe):
Program(s) included in the measure: ☐ Medicaid (Title XIX) only ☐ CHIP (Title XXI) only ☐ Medicaid and CHIP
Measurement period (start/end date)

2. Performance Measure Results (If measure contains more than one rate, add columns to the table)

Performance measure	Rate 1	Rate 2	Rate 3	Rate 4
Numerator				
Denominator				
Rate				

3. Performance Measure Validation Status

Describe any deviations from the technical specifications and explain reasons for deviations (such as deviations in denominator, numerator, data source, measurement period, or other aspect of the measure calculation).
Describe any findings from the ISCA or other information systems audit that affected the reliability or validity of the performance measure results. ☐ Not applicable (ISCA not reviewed)
Describe any findings from medical record review that affected the reliability or validity of the performance measure results. ☐ Not applicable (medical record review not conducted)
Describe any other validation findings that affected the accuracy of the performance measure calculation.
Validation rating: ☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence "Validation rating" refers to the EQRO's overall confidence that the calculation of the performance measure adhered to acceptable methodology.
EQRO recommendations for improvement of performance measure calculation:

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Example of Worksheet 2.14. Framework for Summarizing Information about Performance Measures

Instructions. Use this worksheet or a similar tool to summarize the results for each performance measure validated for each managed care plan. This worksheet can be used as a framework for summarizing validation at the plan level. In addition, the information in this worksheet can be aggregated across plans and measures to generate information on state-level performance and areas for improvement.

1. Overview of Performance Measure

Managed Care Plan (MCP) name: Plan A
Performance measure name: Follow-Up After Hospitalization for Mental Illness: 6-20 (FUH-CH)
Measure steward: ☐ Agency for Healthcare Research and Quality (AHRQ) ☐ Centers for Disease Control and Prevention (CDC) ☐ Centers for Medicare & Medicaid Services (CMS) ☒ National Committee for Quality Assurance (NCQA) ☐ The Joint Commission (TJC) ☐ No measure steward, developed by state/EQRO ☐ Other measure steward (specify) _____
Is the performance measure part of an existing measure set? (check all that apply) ☐ HEDIS® ☒ CMS Child or Adult Core Set ☐ Other (specify) _____
What data source(s) was used to calculate the measure? (check all that apply) ☒ Administrative data (describe): The administrative data source is the state's MMIS and data submitted by the managed care plans. ☐ Medical records (describe) _____ ☐ Other (specify) _____
If the hybrid method was used, describe the sampling approach used to select the medical records: ☒ Not applicable (hybrid method not used)
Definition of denominator (describe): Medicaid rates include managed care population (4 MCOs) age 6 and older.
Definition of numerator (describe): • 7-day follow-up: A follow-up visit with a mental health practitioner within 7 days after discharge. This includes visits that occur on the date of discharge. • 30-day follow-up: A follow-up visit with a mental health practitioner within 30 days after discharge. This includes visits that occur on the date of discharge.
Program(s) included in the measure: ☒ Medicaid (Title XIX) only ☐ CHIP (Title XXI) only ☐ Medicaid and CHIP
Measurement period (start/end date): January 1, 2020 to December 31, 2020.

2. Performance Measure Results (If measure contains more than one rate, add columns to the table)

Performance measure	Rate 1	Rate 2	Rate 3	Rate 4
Numerator	6,723	8,476		
Denominator	12,007	12,007		
Rate	56.0 (7-day follow-up)	70.6 (30-day follow-up)		

3. Performance Measure Validation Status

Describe any deviations from the technical specifications and explain reasons for deviations (such as deviations in denominator, numerator, data source, measurement period, or other aspect of the measure calculation). Plan A was compliant with the HEDIS® Information System Standards and HEDIS® Determination Standards, and continues to use NCQA-certified software vendors for HEDIS® measure production.
Describe any findings from the ISCA or other information systems audit that affected the reliability or validity of the performance measure results. ☒ Not applicable (ISCA not reviewed)
Describe any findings from medical record review that affected the reliability or validity of the performance measure results. ☒ Not applicable (medical record review not conducted)
Describe any other validation findings that affected the accuracy of the performance measure calculation. No findings to report.
Validation rating: ☒ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence "Validation rating" refers to the EQRO's overall confidence that the calculation of the performance measure adhered to acceptable methodology.
EQRO recommendations for improvement of performance measure calculation: The FUH-CH measure represents one of the objectives in the state's Quality Strategy (e.g., child health, prevention, and screening services), which seeks to assure timely, high-quality health care for all [State Medicaid Program Name] members. The EQRO has no recommendations to improve the performance measure calculation.

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

END OF WORKSHEETS FOR PROTOCOL 2

Protocol 3. Review of Compliance With Medicaid and CHIP Managed Care Regulations

A MANDATORY EQR-RELATED ACTIVITY

PROTOCOL THREE

ACTIVITY 1: ESTABLISH COMPLIANCE THRESHOLDS

ACTIVITY 2: PERFORM THE PRELIMINARY REVIEW (PRE-SITE VISIT)

ACTIVITY 3: CONDUCT MCP SITE VISIT

ACTIVITY 4: COMPILE AND ANALYZE FINDINGS (POST-SITE VISIT)

ACTIVITY 5: REPORT RESULTS TO THE STATE

Background

This protocol is used to determine the extent to which Medicaid and CHIP managed care plans (MCPs) are in compliance with federal standards. The Centers for Medicare & Medicaid Services (CMS) developed standards for MCPs, which are codified at 42 CFR 438 and 42 CFR 457, as revised by the Medicaid and CHIP managed care final rule issued in 2016. As noted in the Introduction, states have the option to use information from a Medicare or private accreditation review of an MCP to provide information for the annual EQR instead of conducting this mandatory EQR-related activity.[52, 53]

[52] If the state elects to use nonduplication for this mandatory EQR-related activity (42 CFR 438.360, Nonduplication of mandatory activities with Medicare or accreditation review), then the state must ensure that all information from the Medicare or private accreditation review is provided to the EQRO for analysis and inclusion in the annual EQR technical report. (See 42 CFR 438.360(a)(1)–(3) for additional details regarding the circumstance under which nonduplication is an option). Use of nonduplication must be identified in the state's quality strategy (see 42 CFR 438.360(c) and 438.340(b)(10)). Any requirements in this protocol which are not addressed via the review used for nonduplication must still be addressed through this protocol. CHIP cross-references to this requirement at 457.1250, but does not allow for the use of Medicare review activities for the purposes of nonduplication.

[53] A state may not utilize nonduplication if Medicare has accepted only an attestation of a plan's QIP. In the context of this EQR-related activity, the QIP would have to undergo validation as part of a Medicare review in order for nonduplication to be an option. See 42 CFR 438.360(a)(2).

Regulations Subject to Compliance Review

The standards that are the subject of this protocol are contained in 42 CFR 438, part 56, 100, 114, Subparts D and QAPI.[54] The scope of those sections includes:[55]

- Disenrollment requirements and limitations 438.56
- Enrollee rights requirements 438.100
- Emergency and post-stabilization services 438.114
- Availability of services 438.206
- Assurances of adequate capacity and services 438.207
- Coordination and continuity of care 438.208
- Coverage and authorization of services 438.210
- Provider selection 438.214
- Confidentiality 438.224
- Grievance and appeal systems 438.228
- Subcontractual relationships and delegation 438.230
- Practice guidelines 438.236
- Health information systems 438.242
- Quality assessment and performance improvement program 438.330

Standards Subject to this Protocol Added from the 2020 Final Rule

- Disenrollment requirements and limitations 438.56
- Enrollee rights requirements 438.100
- Emergency and post-stabilization services 438.114

Additional Areas for Potential Compliance Review

CMS encourages states to consider expanding the scope of the review to cover compliance with federal and state requirements beyond those specified in 42 CFR 438, including other state statutory, regulatory, or contractual requirements related to the following areas, if applicable:[56]

- Accessibility, including physical accessibility of service sites and medical and diagnostic equipment; accessibility of information (compliance with web-based information, literacy levels of written materials, and alternate formats); and other accommodations. See Section 508 of the Rehabilitation Act [29 U.S.C. 794d])

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[54] CHIP cross-references to these requirements at 42 CFR 457.1230, 457.1233, and 457.1240, except as noted. For more information, see https://www.federalregister.gov/documents/2016/05/06/2016-09581/medicaid-and-childrens-health-insurance-program-chip-programs-medicaid-managed-care-chip-delivered#sectno-citation-%E2%80%89438.206.

[55] Certain requirements in Subparts A, B, C, and F are incorporated into the compliance review through interaction with Subparts D and E.

[56] For more information, see the CMS MLTSS EQR guidance document at https://www.medicaid.gov/Medicaid/downloads/cmcs-eqr-protocols.pdf.

- Availability and use of home- and community-based services (HCBS) as alternatives to institutional care, so individuals can receive the services they need in the most integrated setting appropriate
- Credentialing or other selection processes for long-term services and supports (LTSS) providers, including those required where the enrollee can choose their caregiver (such as verification of completion of criminal background checks)
- Person-centered assessment, person-centered care planning, service planning and authorization, service coordination and care management for LTSS, including authorization/utilization management for LTSS and any beneficiary rights or protections related to care planning and service planning such as conflict-free case management, self-direction of services, and appeal rights related to person-centered planning
- Integration of managed medical, behavioral, and LTSS

Frequency of Compliance Review and Manner of Reporting

Federal regulations require MCPs to have undergone a review within the three-year period preceding each annual EQR to determine MCP compliance with federal standards as implemented by the state. States may choose to direct their EQROs to review all applicable standards at once or may spread the review over a three-year cycle in any manner they choose (for example, fully reviewing a third of plans each year or conducting a third of the review on all plans each year). However, if an EQR technical report summarizes a compliance review that does not include all required components, the report should clearly describe:

1. The three-year period covered by the current compliance review cycle
2. The quality standards not included in the current report
3. A summary of findings from all previous reviews within the current review cycle
4. The state's schedule for review of the remaining standards

Getting Started on Protocol 3

This protocol describes the process EQROs may use to determine MCP compliance with federal Medicaid and CHIP managed care regulations. In general, the EQRO must:

1. Review program documents and conduct interviews with MCP personnel to collect information, and
2. Analyze information collected and make compliance determinations

To complete this protocol, the EQRO must undertake five activities for each MCP (Figure 3.1).

Figure 3.1. Protocol 3 Activities

One supplemental resource is available to help EQROs conduct the compliance review:

- Worksheets for Protocol 3. Compliance Review Tools, which can be used to (1) structure and conduct the review of MCP documentation to determine compliance with the applicable federal regulatory and/or state provisions; (2) score MCPs' compliance with federal and state

regulations; (3) develop site visit agendas,[57] and (4) guide compliance interviews of MCP staff

The remainder of this protocol outlines the steps associated with Activities 1 through 5.

TIP

Navigate to the corresponding worksheet by clicking the WORKSHEET box under each section

Activity 1: Establish Compliance Thresholds

In this activity, the EQRO works with the state to define levels of compliance for use throughout the compliance review. Activity 1 includes two steps:

1. Determine how the state has implemented federal quality standards
2. Define the benchmark for compliance against which the MCP will be measured or scored

Step 1: Collect Information from the State

Some regulatory provisions allow the state to establish more stringent standards for their MCPs than are mandated by federal regulation. Additional state requirements may be found in MCP contracts, state managed care quality strategies, state statutes and regulations, or other resources. States cannot establish standards that are less stringent than federal regulation, nor can states exempt MCPs from compliance standards. Therefore, to complete the compliance assessment, the EQRO will need to know the state's requirements for its MCPs in the context of each required federal standard. This documentation may be provided to the EQRO in hard copy, digital copy, or both formats. Worksheet 3.1 lists the types of documents that the state may provide to the EQRO about state standards and is organized according to federal regulatory provision.

WORKSHEET 3.1

Resource for Activity 1, Step 1

Worksheet 3.1. Compliance Review

- Includes a list of the types of state policy/regulation information needed to determine MCP compliance, as well as documents the MCP may provide the EQRO to demonstrate the MCP's compliance with federal regulations and state standards (see Activity 2, Step 2)
- The completed Compliance Review Worksheet is a primary data source for analyses and a comprehensive record of compliance protocol EQR-related activities

[57] In the event that onsite activities are not feasible due to the COVID-19 pandemic, site visits may be conducted virtually.

Step 2: Define Benchmarks for Compliance

EQRO determinations will be based on compliance definitions set in advance by the state for each federal and/or state regulatory provision, component of a provision, and/or requirement or standard based on its expectations of MCP performance. While states may define degrees of compliance with each benchmarked standard, a definition for full compliance must be clearly understood by the EQRO and MCP before the review.

WORKSHEET 3.2

Resource for Activity 2, Step 2

Worksheet 3.2. Compliance Definitions

- Provides compliance definitions and examples of compliance rating scales
  - Compliance rating scales may be adjusted to best suit a state's needs

Activity 2: Perform the Preliminary Review (Pre-Site Visit)

Site visits are an effective way to collect the information needed for quality oversight and compliance determination. However, they require careful planning to maximize the information obtained and to minimize the time required for collecting that information. This activity should begin from 2 to 6 months in advance of the planned visit.

EQROs, MCPs, and states that opt to conduct virtual compliance visits should plan those visits with the same disciplined approach they would for an onsite visit as described in this protocol.

Step 1: Establish Early Contact with the MCP

It is important for the EQRO to establish and maintain consistent communication with the MCP throughout the compliance review. The EQRO is responsible for developing a communication plan specifying expectations for all parties involved. The EQRO should establish a single point of contact with the MCP, and in turn, the MCP representative can organize the response from the MCP and determine which additional staff members should be involved during the review.

Step 2: Perform a Document Review

The purpose of the document review is to identify gaps in information to ensure a comprehensive EQR process and productive interactions with the MCP during the site visit. Before planning a site visit, the EQRO should gather and assess as much information about the MCP and its practices as possible. Document review includes gathering information about the MCP's background, including its structure, enrolled population, providers, services, resources, locations, delegated functions and services, and contractors. Some information may be available from the state, while some may be obtained from the MCP. The following list suggests the type of information that would be useful during a preliminary document review:

WORKSHEET 3.1

Resource for Activity 2, Step 2

Worksheet 3.1. Compliance Review

- Includes a list of the types of state policy or regulatory information needed to determine MCP compliance (see Activity 1, Step 1), as well as documents the MCP may provide the EQRO to demonstrate the MCP's compliance with federal regulations and state standards
- The completed Compliance Review Worksheet is a primary data source for analyses and a comprehensive record of compliance protocol EQR-related activities

- Organization name and mailing address
- Contact person's name, title, phone number, and e-mail address
- Site visit location
- Organizational charts or other descriptions of the MCP
- Product lines offered
- Total individuals enrolled in the current and previous year
- Total number of network practitioners in the current and previous year, with a breakdown by type (such as primary care, OB/GYN, and other specialties)
- Total number of network organizational providers (hospitals, ambulatory care, home care, laboratories, etc.)
- Service descriptions and benefit designs available to enrollees
- Delegated activities, including MCP subcontractors

The EQRO should inform the MCP of any missing information before the site visit, to allow the MCP to respond in a timely manner (either by providing the documentation to the EQRO prior to the site visit for review or ensuring its availability during the site visit document review; see Activity 3, Step 5). The EQRO should maintain consistent documentation by recording

preliminary document review findings or questions for follow-up during the site visit in Worksheet 3.1.[58]

Activity 3: Conduct MCP Site Visit

The purpose of the MCP site visit is to collect the information necessary to assess the MCP's compliance with federal and state regulations through additional document review and interviews. The EQRO should plan the site visit, whether onsite or virtual, in accordance with the compliance review plan established in Activity 1 of this protocol. As noted in Activity 2, the EQRO should review MCP policies and procedures before the site visit to expedite the process. Steps 1 through 5 provide guidance in preparing for the site visit.

Step 1: Determine Site Visit Length and Dates

The length of a comprehensive site visit will vary according to the scope of the review, the complexity of the organization being reviewed, the number of reviewers available to conduct the review, and the amount of information collected before the site visit. A typical site visit requires 3 to 5 days. To schedule the site visit, the EQRO should offer the MCP contact a range of dates to determine when essential staff are available.

Step 2: Identify the Number and Types of Reviewers Needed

Reviewers should be skilled interviewers with the ability to read and process a variety of data in order to determine whether an MCP is in compliance with the regulations. Knowledge or experience in state Medicaid and CHIP programs and managed care is highly desirable. Reviewer orientation and training should be held to ensure familiarity with the regulatory provisions, the evaluation process, and performance expectations.

The number of reviewers needed to conduct the assessment should be based on the characteristics of the MCP being evaluated. Consideration should be given to the size and complexity of the MCP, including the size of the provider network, number of enrollees, and the scope of programs in the state contract. If multiple reviewers are participating in the site visit(s), the EQRO should identify in advance each reviewer's responsibility for assessing specific standards, reviewing specific documents, and conducting interviews.

[58] In addition to the document review described here as part of the preliminary document review, the previous version of this protocol included a step in Activity 3 for document review while onsite. However, due to the widespread use of digital documentation, an additional document review during the site visit (onsite or virtual) may not be needed. If a document review is determined by the EQRO to be necessary (and negotiated with the MCP), the EQRO may conduct it during the site visit. That step would occur before Activity 3, Step 5.

Step 3: Develop a Site Visit Agenda

Clear expectations are essential for an efficient and effective site visit. An agenda sets the expectations and schedule for the review. It also assists both the MCP and EQRO in planning staff participation, gathering documentation, and finalizing logistics such as arranging locations for document review and interviews. The EQRO should consult with the MCP throughout the agenda setting process to ensure the inclusion of appropriate staff and subcontractors.

WORKSHEET 3.3

Resource for Activity 3, Step 3

Worksheet 3.3. Sample Site Visit Agenda

- This template can be used to develop the site visit agenda. It is intended to help the MCP and EQRO in planning staff interviews, gathering documents, and finalizing logistics

Step 4: Provide Preparation Instructions and Guidance to the MCP

The EQRO should send clear instructions and guidance to the MCP before the site visit. In preparation for the site visit, the EQRO should provide MCPs with the following information:

1. The scope of the assessment
2. How the review will be conducted
3. List of required documents
4. Instructions for how documents for review should be organized
5. Forms or other data gathering instruments that should be completed before arrival (such as the Information Systems Capability Assessment (ISCA); see Appendix A)
6. Reports from prior reviews and subsequent MCP corrective actions
7. Names and contact information for expected interview participants, and
8. Administrative needs of the reviewers

Step 5: Conduct MCP Interviews

The purpose of MCP interviews is to collect data to supplement and verify what is learned through document review. In preparation for the site visit, the EQRO should review the standards identified in the state documents obtained in Activity 1 and the findings from Activity 2, Step 2. During the site visit, MCP staff should be available if the EQRO has questions or difficulty locating any needed additional documents or other information. The EQRO should notify the MCP during the site visit of any missing information to allow the MCP to respond in a timely manner. The EQRO should maintain consistent documentation by adding to Worksheet 3.1 any findings based on any additional information or documents provided by the MCP.

WORKSHEET 3.1

WORKSHEET 3.4

Resource for Activity 3, Step 5

Worksheet 3.1. Compliance Review

- Includes a list of the types of documents the MCP may provide the EQRO to demonstrate the MCP's compliance with federal regulations and state standards.
- Provides space for reviewers to document follow-up to questions from the pre-site visit documentation review. The completed Compliance Review Worksheet is a primary data source for analyses and a comprehensive record of compliance protocol EQR-related activities

Worksheet 3.4. Compliance Interview Questions

- Provides questions that are intended to guide the reviewer's discussion with MCP staff to help determine compliance with state and federal requirements
- The questions are first organized by MCP staff roles and then by regulatory provision

Prepare for the Interviews

Interviews should be tailored to the MCP being evaluated and the role of the interviewee. When planning for the interview, the EQRO should:

- Prepare a list of issues to be addressed in each interview, based on federal regulatory provisions, state standards, MCP organization characteristics, and other information gathered during pre-site visit document reviews
- Review the MCP's anticipated interview participants, and identify topics that will promote an inclusive discussion
- If multiple reviewers are assigned to an MCP, assign primary roles to each reviewer (such as interviewer or note-taker), while allowing for shared roles and responsibilities as appropriate throughout the site visit

It is strongly recommended that the EQRO completes the document review (Activity 2, Step 2) before the interviews. Some interview participants may provide additional documents during their interview. This might be done when such documents are vital to the discussion or if the review of the documents will benefit from joint review by all participants.

Interview Participants

Interviews should be conducted with groups, rather than with single individuals, because rarely does one individual have sole responsibility for a particular function. Interview groups should include participants that represent different functions, services, or departments of the MCP to enable the EQRO to collect multiple perspectives about an issue. Group interviews are also an opportunity for MCP staff to learn about compliance activities in other departments. The EQRO has the discretion to meet with less than the full list of MCP-recommended employees in situations where the EQRO feels that it can obtain the required information without the attendance of all MCP employees listed in the protocol, or the MCP has identified a more appropriate person to address questions but is not on the recommended list. Worksheet 3.4. includes questions for the following groups:

- MCP leaders
- MCP information systems staff
- Quality assessment and performance improvement program staff
- Provider/contractor services staff
- Enrollee services staff, including grievance and appeal staff
- Utilization management staff
- Medical director(s)
- Case managers and care coordinators, and
- MCP providers and contractors, as appropriate and as time and resources permit

Interview Process

The EQRO should provide the MCP interview participants with an interview agenda before the interview, which includes the interview goals, issues, topics, and a list of related materials or documents. Effective facilitation of an interview with an individual or a group requires that the EQRO:

- Maintain control of the interview discussion by politely redirecting participants to the topic or question as necessary
- Adhere to the time frames outlined in the agenda
- Listen carefully to participants and summarize or restate participant responses to ensure understanding
- Take notes using the Worksheet 3.1 or similar tool, or according to the Compliance Review Questions provided in Worksheet 3.4
- Review documents provided during the interview at an appropriate time based on the content and purpose of sharing the document

- Conclude the interview with a review of the outlined goals and compliance levels to ensure an understanding of the extent to which they were met, and
- Provide information about next steps as appropriate

Interviews & Systems Capabilities

States have the opportunity to expand the roles of other state agencies in terms of their responsibilities related to data exchanges, EHRs, interoperability, care coordination, and Medicaid or CHIP waivers. At the state's discretion, it may determine:

- Whether the EQRO will review the state's health information technology (HIT) plan for HITECH and meaningful use with respect to validation of performance measures or performance improvement project activities, and
- How the MCP's systems will support state efforts in a valid way

The EQRO is required to conduct an Information Systems Capability Assessment (ISCA) to support the compliance review under Protocol 3. Box 3.1 lists resources to conduct an ISCA.

Box 3.1. Resources to Conduct an ISCA

The ISCA is used to validate MCP information systems, processes, and data. The ISCA provides a foundation for the EQR-related activities.

- **Appendix A** explains how to conduct the ISCA.
- **Worksheet A.1**. ISCA Tool is completed by the MCP and documents the capabilities of the information systems, processes, and data
- **Worksheet A.2.** ISCA Interview Guide is used by EQROs to conduct follow-up interviews with staff to record responses and document specific issues based on findings from Worksheet A.1

Step 6: Conduct Exit MCP Interviews

The EQRO conducts an exit interview at the conclusion of the site visit with MCP staff. The purpose of the exit interview is to clarify the EQRO's understanding of the information collected throughout the compliance review process. The EQRO should provide the MCP with the opportunity to respond to initial compliance issues to ensure the findings are due to true non-compliance and not due to misunderstanding or misinterpretation of MCP documents and interviews.

Activity 4: Compile and Analyze Findings (Post-Site Visit)

Post site-visit activities include (1) collecting and documenting additional information as needed, and (2) analyzing data compiled pre-, during, and post-site visit to make compliance determinations for each regulatory provision.

Step 1: Collect Supplemental Information

In addition to information collected during the site visit, the EQRO should consider other sources of information that confirm the MCP's compliance with federal regulations and state standards. Additional sources should include the following:

- Results of Medicaid and CHIP beneficiary surveys (see Protocol 6 about administering surveys)
- Results of independent assessments of the MCP's information systems (see Appendix A about performing an ISCA)
- Results of independent assessments of MCP encounter data (see Protocol 5 about validating encounter data)
- Results of independent validations of MCP performance measures (see Protocol 2 and Protocol 7 for validating and calculating performance measures, respectively)
- Results of independent validation of performance improvement projects (PIPs) (see Protocol 1 and Protocol 8 about validating and implementing PIPs, respectively or Protocol 9 about conducting a Focus Study)
- Additional materials requested during or after the site visit, such as grievance and appeal reports and analyses

Step 2: Compile Data and Information

EQROs should use Worksheet 3.1 (or a similar template) to document additional information they review, including sources of the information and their findings about the MCP's compliance. EQROs should refer to Worksheet 3.2 for standardized compliance definitions and examples of rating scales.

WORKSHEET 3.1

WORKSHEET 3.2

Resource for Activity 4, Step 2

Worksheet 3.1. Compliance Review

- Includes a list of the types of documents the MCP may provide the EQRO to demonstrate the MCP's compliance with federal regulations and state standards
- Can be used by the EQRO to document compliance scores and justification

Worksheet 3.2. Compliance Definitions

- Provides compliance definitions and examples of compliance rating scales
- Compliance rating scales may be adjusted to best suit a state's needs

Step 3: Analyze Findings

One commonly used approach to analyzing EQR findings is to assign a numerical value to indicate the degree of compliance with a given regulatory provision. Using the resources in Worksheet 3.1, the EQRO should document both a compliance score for each regulatory provision, as well as details and justification for the compliance determination.

Regardless of the number of points on a scale, each level of compliance must be defined clearly for the state, the EQRO, and the MCP before beginning the review. While one scale may serve as the primary method of assigning levels of compliance, it does not preclude the combined use of another scale. For example, a five-point compliance scale may be appropriate for most of the provisions, but some provisions may be dichotomous (e.g., met or not met). When determinations are made for levels of compliance other than 'met' or 'not met,' such as 'partially met,' the EQRO should clearly identify specific deficiencies, as well as the rationale for and evidence of the deficiency.

Tips for analyzing EQR compliance findings

The EQRO is encouraged to use a numeric score to indicate the degree of compliance with each regulatory provision and to summarize the overall percentage of elements scored as compliant. The EQRO should clearly document the scoring methods and evidence used to determine compliance.

Activity 5: Report Results to the State

Step 1: Submit a Report Outline to the State

The EQRO should develop a report outline and submit it to the state for approval. The outline will then be used by the EQRO to draft a report to the state with the results of the MCP's compliance with federal and state requirements.

Step 2: Submit a Final Determination Report to the State

Because the state may use the report to meet its reporting requirements for federal or state agencies, the state legislature, local advocacy groups, and other interested parties, the state may need certain types of information presented in a specific format. While non-summarized findings might be of interest to some individuals, the report should include an overall summary of findings for compliance with regulatory provisions.

By design, Worksheet 3.1 separates the regulatory provisions into three major sections:

1. Standards, including enrollee rights and protections
2. Quality assessment and performance improvement (QAPI) program
3. Grievance system

Step 3: Submit Other Reports Requested by the State

The state may request a specific format for reporting results back to the MCP. Some options for reporting evaluation results to the MCP include:

1. **Compliance Issues Only.** Reviewers provide verbal feedback about general compliance issues they have identified during the course of conducting the compliance review EQR-related activity. Neither compliance determinations for individual regulatory provisions nor findings for a level of MCP performance are discussed. This type of feedback typically is

provided to the MCP leadership during a closing session or exit interview at the site visit. This provides the MCP the opportunity to offer additional information if evidence of compliance is available

2. **Compliance Issues Specific to Regulatory Provisions.** Reviewers provide verbal feedback for regulatory provisions or components of provisions that are determined less than fully compliant, in accordance with the compliance thresholds established by the state before the review. Findings for a level of MCP performance are not discussed. This type of feedback is typically presented to the MCP leadership during a closing session or exit interview at the site visit. This provides the MCP the opportunity to offer additional information if evidence of compliance is available
3. **Compliance Determinations and Deficiency Report.** Reviewers provide verbal and/or written feedback about identified compliance issues, compliance ratings for regulatory provisions, and an overall finding for MCP performance, highlighting areas of deficiency that will be presented to the state

END OF PROTOCOL 3

Worksheets for Protocol 3: Compliance Review Tools

Instructions. Use these or similar worksheets to assess the MCP's compliance with federal regulations and state standards. These worksheets include a tool for document review, compliance definitions, a sample site visit agenda, and compliance review interview questions. Each worksheet can be adapted as needed. This tool includes the following worksheets crosswalked to the applicable Activity and Step:

Worksheet Name	Protocol Activity and Step
Worksheet 3.1. Compliance Review	Activity 1. Step 1. Collect Information from the State Activity 2. Step 2. Perform a Document Review Activity 3. Step 5. Conduct MCP Interviews Activity 4. Step 2. Compile Data and Information Activity 4. Step 3. Analyze Findings Activity 5. Step 2. Submit a Final Determination Report
Worksheet 3.2 Compliance Definitions	Activity 1. Step 2. Define Levels of Compliance Activity 4. Step 3. Analyze Findings
Worksheet 3.3. Sample Site Visit Agenda	Activity 3. Step 3. Develop a Site Visit Agenda
Worksheet 3.4. Compliance Review Interview Questions	Activity 3. Step 5. Conduct MCP Interviews

Worksheet 3.1. Compliance Review

Instructions. Worksheet 3.1 includes a list of the types of documents the MCP may provide to the EQRO to demonstrate the MCP's compliance with federal regulations and state standards. It separates the regulatory provisions into three major sections:

1. Standards, including enrollee rights and protections
2. Quality assessment and performance improvement (QAPI) program
3. Grievance system

This template may be used to track which MCP documents can provide the rationale for the compliance determination for each regulatory provision (or component). This completed worksheet is intended to record compliance activities to support the analyses.

Note: In the template, MCP documents are identified using generic names, except in instances where the regulatory provisions refer to and require a specific document be present and reviewed for content.

The subject matter of each example MCP document is indicated in parenthesis as follows:

AM = Administrative/ Managerial

PS = Provider/Contractor Services

UM = Utilization Management

ES = Enrollee Services

IS = Information Systems

SP = Staff Planning, Education, Development and Evaluation

The subject matter designation does not imply that the document cannot be used as a data source for addressing other provision issues, or that it should be the sole source of data in evaluating compliance with the provisions noted.

Refer to Worksheet 3.2, Compliance Definitions for more information on approaches to compliance scoring.

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
Availability of services **Medicaid:** 42 CFR 438.206 (availability of services) and 42 CFR 10(h) provider directory) **CHIP:** 42 CFR 457.1230(a)	• The state's provider-specific network adequacy requirements and standards (and exceptions, if any) • The state's requirements for the MCP provider directory • Information on the documentation that the state uses to support its certification that the MCP complied with the state's requirements for availability and accessibility of services, including the adequacy of the provider network	• Service planning documents and provider network planning documents (e.g., geographic assessments, provider network assessments, enrollee demographic studies, population needs assessments)(AM) • Service availability and accessibility expectations and standards (AM) • Other performance standards and quality indicators established by the MCP (AM) • Any measurement or analysis reports on service availability and accessibility (AM) • List of all care and service providers in the MCP's network (may be the same as the provider directory) (AM) • Organization strategic plans (AM) • Administrative policies and procedures (AM) • Medicaid and CHIP and other enrollee survey results (AM) • Utilization management policies and procedures (UM) • Service authorization policies and procedures (UM) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS) • Provider/Contractor oversight and evaluation policies and procedures, audit tools (PS) • Medicaid and CHIP enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Medicaid and CHIP enrollee handbooks (ES) • Medicaid and CHIP provider directory • Medicaid and CHIP enrollee orientation curriculum (ES) • Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Furnishing of services and timely access	• Obtain a copy of the state Medicaid and CHIP agency's standards for timely enrollee access to care and services required of Medicaid and CHIP and MCPs.	• Service planning documents and provider network planning documents (e.g., geographic assessments, provider network assessments,	**Medicaid:** Fully Met Substantially Met

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
Medicaid: 42 CFR 438.206(c)(1): Furnishing of services and timely access **CHIP:** 42 CFR 457.1230(a): Availability of services		enrollee demographic studies, population needs assessments)(AM) • Service availability and accessibility expectations and standards (AM) • Other performance standards and quality indicators established by the MCP (AM) • Any measurement or analysis reports on service availability and accessibility (AM) • List of all care and service providers in the MCP's network (may be the same as the provider directory) (AM) • Organization strategic plans (AM) • Administrative policies and procedures (AM) • Medicaid and CHIP and other enrollee survey results (AM) • Utilization management policies and procedures (UM) • Service authorization policies and procedures (UM) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS) • Provider/Contractor oversight and evaluation policies and procedures, audit tools (PS) • Medicaid and CHIP enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Medicaid and CHIP Enrollee Handbooks (ES) • Medicaid and CHIP provider directory • Medicaid and CHIP Enrollee Orientation Curriculum (ES) • Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES)	Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Access and cultural considerations **Medicaid:** 42 CFR 438.206(c)(2): Furnishing of services and cultural considerations.	• Descriptive information on the state's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. • The requirements the state has communicated to the MCP with respect to how the MCP is expected to	• Service planning documents and provider network planning documents (e.g., geographic assessments, provider network assessments, enrollee demographic studies, population needs assessments)(AM) • Service availability and accessibility expectations and standards (AM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
CHIP: 42 CFR 457.1230(a): Access standards	participate in the state's efforts to promote the delivery of services in a culturally competent manner.	• Other performance standards and quality indicators established by the MCP (AM) • Any measurement or analysis reports on service availability and accessibility (AM) • List of all care and service providers in the MCP's network (may be the same as the provider directory) (AM) • Organization strategic plans (AM) • Administrative policies and procedures (AM) • Medicaid and CHIP and other enrollee survey results (AM) • Utilization management policies and procedures (UM) • Service authorization policies and procedures (UM) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS) • Provider/Contractor oversight and evaluation policies and procedures, audit tools (PS) • Medicaid and CHIP enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Medicaid and CHIP Enrollee Handbooks (ES) • Medicaid and CHIP provider directory (ES) • Medicaid and CHIP Enrollee Orientation Curriculum (ES) • Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES)	**CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Assurances of adequate capacity and services **Medicaid:** 42 CFR 438.207: Assurances of adequate capacity and services **CHIP:** 42 CFR 457.1230(b): Assurances of adequate capacity and services	• Medicaid and CHIP agency documentation and submission timing standards to assure that the MCP has an appropriate range of preventive, primary care, specialty, and LTSS services that are adequate for the anticipated number of enrollees in the MCP's service area. • Medicaid and CHIP agency documentation and submission timing standards to assure that the MCP maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the	• MCP 42 CFR 438.207(b) compliance documentation • MCP 42 CFR 438.207(c) compliance documentation • MCP 42 CFR 457.1230(b) compliance documentation	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
	needs of the anticipated number of enrollees in the service area.		Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Coordination and continuity of care for all enrollees **Medicaid**: 42 CFR 438.208: Coordination and continuity of care **CHIP**: 42 CFR 457.1230(c): Coordination and continuity of care	The state's requirements regarding the obligation to and methods by which an MCP must: • a) Ensure enrollees have an ongoing source of care appropriate to their needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee. The enrollee must be provided information on how to contact their designated person or entity • b) Coordinate the services the MCP furnishes to enrollees (between settings, between MCPs, between MCP and FFS, and with services provided by community and social supports) • c) Make a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees • d) Share with the state or other MCPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities • e) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards • f) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with applicable privacy requirements	• Practice guidelines adopted by the MCP (AM) • Provider/Contractor Services policies and procedures manuals (PS) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS) • Medicaid and CHIP enrollee services policies and procedures (ES) • Medicaid and CHIP enrollment and disenrollment policies and procedures (ES) • Medicaid and CHIP Enrollee Handbooks (ES) • Care coordination policies and procedures, and enrollee records (ES) • Sample of Medicaid and CHIP enrollee records (ES) • Medicaid and CHIP enrollment and disenrollment policies and procedures (ES) • A copy of the state-MCP contract provisions, which specify the methods by which the MCP assures the state Medicaid and CHIP agency that it does not request disenrollment for reasons other than those permitted under the contract.	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Additional coordination and continuity of care requirements: LTSS **Medicaid:** 42 CFR 438.208: Coordination and continuity of care	• Methods used by the Medicaid and CHIP agency to identify to the MCP enrollees who need LTSS. • Whether the MCP is required to meet identification, assessment, and treatment planning requirements for dually-enrolled beneficiaries.	• Practice guidelines adopted by the MCP (AM) • Provider/Contractor Services policies and procedures manuals (PS) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
CHIP: 42 CFR 457.1230(c): Coordination and continuity of care	• Any Medicaid and CHIP agency LTSS assessment mechanisms requirements, including the requirement to use appropriate providers or individuals meeting the Medicaid and CHIP agency's LTSS service coordination requirements. • The state's quality assurance and utilization review standards.	• Enrollee services policies and procedures (ES) • Enrollee Handbooks (ES) • Care coordination policies and procedures, and enrollee records (ES) • Sample of enrollee records (ES)	Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Additional coordination and continuity of care requirements: SHCN **Medicaid**: 42 CFR 438.208: Coordination and continuity of care **CHIP**: 42 CFR 457.1230(c): Coordination and continuity of care	• Methods used by the Medicaid and CHIP agency to identify to the MCP individuals with special health care needs (SHCNs). • Whether the MCP is required to implement mechanisms for identifying, assessing, and producing a treatment plan for persons with SHCNs using the state's definition of SHCNs. • Whether the MCP is required to meet identification, assessment, and treatment planning requirements for dually-enrolled beneficiaries. • Any Medicaid and CHIP agency SHCN assessment mechanisms requirements, including the requirement to use appropriate providers or individuals meeting the Medicaid and CHIP agency's LTSS service coordination requirements. • Whether the Medicaid and CHIP agency requires the MCP to produce a treatment or service plan for enrollees with SHCN that are determined through assessment to need a course of treatment or regular care monitoring. • The state's quality assurance and utilization review standards.	• Practice guidelines adopted by the MCP (AM) • Provider/Contractor Services policies and procedures manuals (PS) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS) • Enrollee services policies and procedures (ES) • Enrollee Handbooks (ES) • Care coordination policies and procedures, and enrollee records (ES) • Sample of enrollee records (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Disenrollment **Medicaid:** 42 CFR 438.56: Disenrollment: Requirements and limitations **CHIP:** 42 CFR 457.1212: Disenrollment	• Obtain from the Medicaid and CHIP agency Information on: • Reasons for which the MCP may request the disenrollment of an enrollee. • Methods by which the MCP assures the Medicaid and CHIP agency that it does not request disenrollment for reasons other than those permitted under the contract.	• Medicaid and CHIP enrollment and disenrollment policies and procedures (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
	• Whether the state chooses to limit disenrollment. • Medicaid and CHIP agency enrollee disenrollment request policies. • Whether the Medicaid and CHIP agency allows the MCP to process enrollee requests for disenrollment. • Whether the Medicaid and CHIP agency requires enrollees to seek redress through the MCP's grievance system before the Medicaid and CHIP agency makes a disenrollment determination on the enrollee's request.		**CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Coverage and authorization of services **Medicaid:** 42 CFR 438.210(a–e)*: Coverage and authorization of services, including 42 CFR 440.230 Sufficiency of amount, duration, and scope; 42 CFR Part 441, Subpart B: Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21;* and 42 CFR 438.114, Emergency and post-stabilization services **CHIP:** 42 CFR 457.1230(d): Coverage and authorization of services 42 CFR 457.1228: Emergency and post-stabilization services *Note: 42 CFR 438.210(a)(5), 438.210(b)(2)(iii), 440.230 and 441 Subpart B do not apply to CHIP	• Obtain from the state any amount, duration, and/or scope of service requirements that are greater than those set forth in 42 CFR 440.230 or, for enrollees under the age of 21, as set forth in 42 CFR Part 441, Subpart B. • Obtain from the state any statutory, regulatory and policy definitions of "medical necessity", as well as any quantitative and non-quantitative treatment limitation limits set forth in those sources. • Obtain from the state Medicaid and CHIP agency the state-established standards for MCP processing of standard authorization decisions. • Any Medicaid and CHIP agency drug authorization requirements, including whether the Medicaid and CHIP agency requires approval of outpatient drugs before its dispensing under Section 1927(d)(5)(A) of the Act.	• Provider contracts (PS) • Contracts or written agreements with organizational subcontractors (AM) • Completed evaluations of entities conducted before delegation is granted (AM) • Medicaid and CHIP and other enrollee grievance and appeals data (AM) • Utilization management policies and procedures (UM) • Coverage rules and payment policies (UM) • Data on claims denials (UM) • Service authorization policies and procedures (standard, expedited and extensions) (UM) • Policies and procedures for notifying providers and enrollees of denials of service (UM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
Information requirements for all enrollees **Medicaid:** 42 CFR 438.100(b)(2)(i) Enrollee right to receive information in accordance with 42 CFR 438.10: Information requirements **CHIP**: 42 C.F.R 457.1220: Enrollee rights 42 C.F.R 457.1207: Information requirements	• Whether the Medicaid and CHIP agency, enrollment broker, or MCP must provide all required information to enrollees. • Medicaid and CHIP agency developed definitions for managed care terminology, including appeal, co-payment, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services and devices, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, medically necessary, network, non-participating provider, physician services, plan, preauthorization, participating provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, rehabilitation services and devices, skilled nursing care, specialist, and urgent care. • Medicaid and CHIP agency developed model enrollee handbooks and enrollee notices. • The language(s) that the Medicaid and CHIP agency determines are prevalent in the MCP's geographic service area, and all non-English languages that the Medicaid and CHIP identifies. • Policies relevant to written material language and format, for example, policies relevant to inclusion of taglines. • Any interpretation services that the Medicaid and CHIP agency makes available to enrollees. • How the Medicaid and CHIP agency defines 'reasonable time' for purposes of providing the enrollee handbook to enrollees. • Medicaid and CHIP agency developed or approved language	• Medicaid and CHIP and other enrollee survey results (AM) • Provider contracts (PS) • Enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Enrollee marketing materials • Medicaid and CHIP marketing plans, policies and procedures (ES) • Medicaid and CHIP enrollment and disenrollment policies and procedures (ES) • Enrollee Handbooks (ES) • Enrollee grievance and appeals policies and procedures (ES) • Staff Handbooks (SP) • Staff Orientation and Training Curriculum (SP) • MCP provider directory (ES) • MCP Formulary (ES) • MCP website (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
	describing grievance, appeal, and fair hearing procedures and timeframes, for inclusion in the enrollee handbook. • Medicaid and CHIP agency policy on whether enrollee are required to pay costs for services while an appeal or state fair hear is pending – and the final decision is adverse to the enrollee – for purposes of the enrollee handbook. • Any content required by the state for the enrollee handbook that is not covered in 42 CFR 438.10(g). • Information on how the state has defined a "significant change" in the information MCPs are required to give enrollees pursuant to 42 CFR 438.10(g). • Any applicable Medicaid and CHIP laws on enrollee rights.		
Enrollee right to receive information on available treatment options **Medicaid**: 42 CFR 438.100(b)(2)(iii) Enrollee right to receive information on available treatment options and alternatives . . . including requirements of 42 CFR 38.102: Provider-enrollee communications **CHIP**: 42 CFR 457.1222: Provider-enrollee communication	• Information on whether or not the MCP has documented to the state any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular Medicaid and CHIP service or services.	• Medicaid and CHIP and other enrollee survey results (AM) • Provider contracts (PS) • Medicaid and CHIP enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Medicaid and CHIP enrollee marketing materials (ES) • Medicaid and CHIP marketing plans, policies and procedures (ES) • Medicaid and CHIP enrollment and disenrollment policies and procedures (ES) • Medicaid and CHIP Enrollee Handbooks (ES) • Medicaid and CHIP Enrollee Orientation Curriculum (ES) • Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Staff Handbooks (SP) • Staff Orientation and Training Curriculum (SP)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Enrollee right to participate in decisions regarding his or her care and	• A written description of any state law(s) concerning advance directives. The written description may include information from state statutes on	• Medicaid and CHIP and other enrollee survey results (AM) • Provider contracts (PS)	**Medicaid:** Fully Met Substantially Met

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
be free from any form of restraint **Medicaid:** 42 CFR 438.100(b)(2)(iv) and (v): Enrollee right to: - participate in decisions regarding his or her care, including the right to refuse treatment; - Be free from any form of restraint . . . as specified in other Federal regulations And related: 42 CFR 438.3(j): Advance directives **CHIP:** 42 CFR 457.1220: Enrollee rights	advance directives, regulations that implement the statutory provisions, opinions rendered by state courts and other states administrative directives. [Note to reviewers: Each state Medicaid and CHIP agency is required under Federal regulations at 42 CFR 431.20 to develop such a description of state laws and to distribute it to all MCPs. Revisions to this description as a result of changes in State law are to be sent to MCPs no later than 60 days from the effective date of the change in state law.] • Information on whether or not the MCP has documented to the state any moral or religious objection to fulfilling the regulatory provisions pertaining to advance directives	• Medicaid and CHIP enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Medicaid and CHIP enrollee marketing materials (ES)	Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Compliance with other Federal and state laws **Medicaid:** 42 CFR 438.100(d): Compliance with other federal and state laws **CHIP**: 42 CFR 457.1220: Enrollee rights	• Obtain from the state Medicaid and CHIP agency the identification of all State laws that pertain to enrollee rights and with which the state Medicaid and CHIP Agency requires its MCPs to comply.	• Medicaid and CHIP and other enrollee survey results (AM) • Provider contracts (PS) • Medicaid and CHIP enrollee services policies and procedures (ES) • Statement of enrollee rights (ES) • Medicaid and CHIP enrollee marketing materials (ES) • Medicaid and CHIP marketing plans, policies and procedures (ES) • Medicaid and CHIP enrollment and disenrollment policies and procedures (ES) • Medicaid and CHIP Enrollee Handbooks (ES) • Medicaid and CHIP Enrollee Orientation Curriculum (ES) • Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Staff Handbooks (SP) • Staff Orientation and Training Curriculum (SP)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Provider Selection **Medicaid**: 42 CFR 438.214: Provider selection	• Obtain from the state information on any credentialing, re-credentialing, or other provider selection and retention requirements established by the state that address acute, primary,	• Service planning documents and provider network planning documents (e.g., geographic assessments, provider network assessments,	**Medicaid:** Fully Met Substantially Met

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
CHIP: 42 CFR 457.1233(a): Provider selection	behavioral, substance use disorder, and LTSS providers, as appropriate.	enrollee demographic studies, population needs assessments) (AM) • Contracts or written agreements with organizational subcontractors (AM) • Procedures and methodology for oversight, monitoring, and review of delegated activities (AM) • Contracts or written agreements with organizational subcontractors (AM) • Completed evaluations of entities conducted before delegation is granted (AM) • Provider/Contractor files, 15-20 individual health care professional files, and 15-20 institutional provider files (PS) • Credentialing committee or other provider review mechanism meeting minutes (PS) • Sample of files of practitioners who have not been appointed or reappointed (PS)	Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Sub-contractual relationships and delegation **Medicaid:** 42 CFR 438.230: Subcontractual relationships and delegation **CHIP:** 42 CFR 457.1233(b): Subcontractual relationships and delegation	• Obtain from the state the "periodic schedule" established by the State according to which the MCP is to monitor and formally review on an ongoing basis all subcontractors' performance of any delegated activities.	• Procedures and methodology for oversight, monitoring, and review of delegated activities (AM) • Contracts or written agreements with organizational subcontractors (AM) • Completed evaluations of entities conducted before delegation is granted (AM) • Ongoing evaluations of entities performing delegated activities	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Practice Guidelines **Medicaid:** 42 CFR 438.236: Practice guidelines **CHIP**: 42 CFR 457.1233(c): Practice guidelines	• Information on any state statutory, regulatory, or policy requirements concerning MCP practice guidelines.	• Provider contracts (PS) • Contracts or written agreements with organizational subcontractors (AM) • Practice guidelines (AM) • Provider/Contractor Services policies and procedures manuals (PS)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
		• Medicaid and CHIP enrollee services policies and procedures (ES)	Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Health information systems **Medicaid:** 42 CFR 438.242 **CHIP:** 42 CFR 457.1233(d):	• Information on whether or not the state has required the MCP to undergo, or has otherwise received, a recent assessment of the MCP's health information system. If the state has required or received such an assessment, obtain a copy of the information system assessment from the state or the MCP. Also obtain contact information about the person or entity that conducted the assessment and to whom follow-up questions may be addressed. • State specifications for data on enrollee and provider characteristics that must be collected by the MCP. • Information on whether or not the state has conducted a recent review and validation of the MCP's encounter data, or required the MCP to undergo, or has otherwise received, a recent validation of the MCP's encounter data. If the state has required or received such a validation review, obtain a copy of the review from the state or the MCP. Also obtain contact information about the person or entity that conducted the validation and to whom follow-up questions may be addressed. • State specifications for how MCPs are to (1) collect data elements necessary to enable the mechanized claims processing retrieval systems to provide for electronic transmission of claims data in the format consistent with the Transformed Medicaid Statistical Information System (T-MSIS); (2) collect and transmit data on enrollee and provider characteristics specified by the state, on all services furnished to enrollees through an	• QAPI project descriptions, including data sources and data audit results (AM) • Medicaid and CHIP and other enrollee grievance and appeals data (AM) • Analytic reports of service utilization (UM) • Information systems capability assessment reports (IS) • Policies and procedures for auditing data or descriptions of other mechanisms used to check the accuracy and completeness of data (internally generated and externally generated data) information system • Completed audits of data or other evidence of data monitoring for accuracy and completeness both for MCP data and information system • Provider/Contractor Services policies and procedures manuals (PS) • Provider contracts (PS)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

MCP Standards, Including Enrollee Rights and Protections			
Federal regulation source(s)	**Medicaid and CHIP agency policy/ regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
	encounter data system; and (3) Ensure that data received from providers is accurate and complete. • Specifications for submitting encounter data to the Medicaid and CHIP agency in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format. • Make all collected data available to the state and upon request to CMS. • The state's procedures and quality assurance protocols to ensure that enrollee encounter data submitted by the MCP is a complete and accurate representation of the services provided to its enrollees.		

Quality Assessment and Performance Improvement Program			
Federal regulation source(s)	**State policy/regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
Quality Assessment and Performance Improvement: General rules **Medicaid:** 42 CFR 438.330(a): General rules **CHIP:** 42 CFR 457.1240(b): Quality assessment and performance improvement program	• In the event that CMS specifies national performance measures or PIP topics, whether or not the state has requested an exemption from the national performance measures or PIPs.	• MCP QAPI implementation documentation (AM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Quality Assessment and Performance Improvement Program			
Federal regulation source(s)	**State policy/regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
Basic elements of quality assessment and performance improvement program **Medicaid:** 42 CFR 438.330(b): Basic elements of quality assessment and performance improvement programs **CHIP:** 42 CFR 457.1240(b): Quality assessment and performance improvement program	• The state's specifications for performance improvement projects (PIPs) required per paragraph (d) of this section. • The state's specifications for how the MCP should identify, measure and report performance measures required per paragraph (c) of this section. • The state's requirements for detection by the MCP of over- and under-utilization. • The state's requirements for assessment by the MCP of the quality and appropriateness of care furnished to enrollees with special health care needs, as defined in the state's quality strategy under 438.340 (as cross-referenced for CHIP in 457.1240(e)). • The state's requirements for assessment by the MCP of the quality and appropriateness of care furnished using LTSS, if applicable, including assessment of care between care settings and a comparison of services and supports received with those set forth in the enrollee's treatment/service plan. • The state's requirements for the MCP's participation in efforts by the State to prevent, detect, report, investigate and remediate critical incidents, that occur within the delivery of LTSS as well as to track and trend results in order to make systems improvements, if applicable	• Policies and procedures related to QAPI project metrics (AM) • QAPI project quality indicators, the selection or development criteria, and processes for selection or development (AM) • Performance standards and quality indicators established by the MCP (AM) • Performance measure reports and data provided to the state (AM) • Utilization management policies and procedures (UM) • Medicaid and CHIP and other enrollee LTSS tracking reports (AM) • Policies and procedures related to data collection and data quality checks for QAPI projects (AM) • Policies and procedures for assessment of LTSS services between care settings and comparison of services and supports received with those set forth in the enrollee's treatment/service plan (AM) • Policies and procedures for assisting the state in the prevention, detection and remediation of critical incidents that occur within the delivery of LTSS.	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Quality Assessment and Performance Improvement Program			
Federal regulation source(s)	**State policy/regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
Performance measurement **Medicaid:** 42 CFR 438.330(c): Performance measurement **CHIP:** 42 CFR 457.1240(b): Quality assessment and performance improvement program	• Information on the standard performance measures identified by the state. • For an MCP providing long-term services and supports, the standard performance measures relating to quality of life, rebalancing, and community integration activities for individuals receiving long-term services and supports. • Information on whether the MCP calculates the performance measure and reports to the state or whether the MCP provides data to the state, which then calculates the PM.	• Performance measure reports and data provided to the state (AM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Performance improvement projects **Medicaid:** 42 CFR 438.330(d) and **CHIP:** 42 CFR 457.1240(b)	• Information on any PIP requirements specified by the state. • Information on how often the state requests that each MCP report the status and results of each project conducted per paragraph (d)(1) of this section. • Information on if the state permits an MCP exclusively serving dual eligibles to substitute an MA Organization quality improvement project conducted undeR 422.152(d) of this chapter for one or more of the performance improvement projects otherwise required under this section.	• Reports and status documentation of MCP internal QAPI evaluations (AM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Quality Assessment and Performance Improvement Program			
Federal regulation source(s)	**State policy/regulation information needed to determine MCP compliance**	**Applicable MCP documents**	**Reviewer determination (See Worksheet 3.2 for approaches to compliance scoring)**
QAPI evaluations review **Medicaid:** 42 CFR 438.330(e)(2): Program and review by the state **CHIP:** 42 CFR 457.1240(b): Quality assessment and performance improvement program	• Information on whether the state requires its MCPs to develop a process to evaluate the impact and effectiveness of its own quality assessment and performance improvement program. If so, information on the frequency with which that evaluation must be conducted, and on the state's requirements for how MCPs conduct that process.	• Reports and status documentation of MCP internal QAPI evaluations (AM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Grievance System			
Federal Regulation Source(s)	**State Policy/Regulation Information Needed to Determine MCP Compliance**	**Applicable MCP Documents**	**Reviewer Determination (See Worksheet 3.2 for approaches to compliance scoring)**
Grievance Systems **Medicaid:** 42 CFR 438.228: Grievance and appeal systems	• Obtain information on: • Whether or not the Medicaid and CHIP agency delegates responsibility to the MCP for providing each enrollee (who has received an adverse decision with respect to a request for a covered service) notice that he or she has the right to a state fair hearing or review to reconsider their request for the covered service.	• Enrollee grievance and appeals policies and procedures (ES) • Enrollee grievance and appeal tracking reports (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
General requirements **Medicaid**: 42 CFR 438.402: General requirements **CHIP:** 42 CFR 457.1260: Grievance system	• Information on: • Whether enrollees are required or permitted to file a grievance with either the state or the MCP, or both. • Whether providers, or authorized representatives, can act on behalf of the enrollee to request an appeal, file a grievance, or request a state fair hearing or review request. • Whether state offers external medical review.	• Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Medicaid and CHIP and other enrollee grievance and appeals data (AM) • Analytic reports of service utilization (UM) • Information systems capability assessment reports (information systems) • Policies and procedures for auditing data or descriptions of other mechanisms used to check the accuracy and completeness of both internally generated and externally generated data (Information systems) • Completed audits of data or other evidence of data monitoring for accuracy and completeness both for MCP data and contractor (delegate) data (information systems) • Provider/Contractor Services policies and procedures manuals (PS) • Provider contracts (PS)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes::

Grievance System			
Federal Regulation Source(s)	**State Policy/Regulation Information Needed to Determine MCP Compliance**	**Applicable MCP Documents**	**Reviewer Determination (See Worksheet 3.2 for approaches to compliance scoring)**
Timely and Adequate Notice of Adverse Benefit Determination **Medicaid:** 42 CFR 438.404: Timely and adequate notice of adverse benefit determination **CHIP:** 42 CFR 457.1260: Grievance system	• Information on the timeframes within which it requires MCPs to make standard (initial) coverage and authorization decisions and provide written notice to requesting enrollees. These timeframes will be the required period within which MCPs must provide Medicaid and CHIP enrollees written notice of any intent to deny or limit a service (for which previous authorization has not been given by the MCP) and the enrollee's right to file an MCP appeal.	• Data on claims denials (UM) • Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • MCP adverse benefit determinations (ES) • Timing data on adverse benefit determination mailings (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Handling of Grievances and Appeals **Medicaid**: 42 CFR 438.406: Handling of grievances and appeals **CHIP:** 42 CFR 457.1260: Grievance system	• Information on any state requirements concerning handling of grievances and appeals that differ from those required under 438.406. • *Note: See the 'Disenrollment' section in Worksheet 3.2 above for grievances during disenrollment.	• Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Medicaid and CHIP and other enrollee grievance and appeals data (AM)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Grievance System			
Federal Regulation Source(s)	**State Policy/Regulation Information Needed to Determine MCP Compliance**	**Applicable MCP Documents**	**Reviewer Determination (See Worksheet 3.2 for approaches to compliance scoring)**
Resolution and notification: Grievances and appeals **Medicaid**: 42 CFR 438.408: Resolution and notification, Grievances and appeals **CHIP:** 42 CFR 457.1260: Grievance system	• Information on: • The state-established standard time frames during which the state requires MCPs to (1) dispose of a grievance and notify the affected parties of the result, and (2) resolve appeals and notify affected parties of the decision. • The methods prescribed by the state that the MCP must follow to notify an enrollee of the disposition of a grievance. • Information on whether providers, or authorized representatives, can act on behalf of the enrollee to request an appeal, file a grievance, or request a state fair hearing request.	• Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Medicaid and CHIP enrollee grievance and appeal tracking reports (ES) • MCP appeal resolution notices (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Expedited resolution of appeals **Medicaid:** 42 CFR 438.410: Expedited resolution of appeals **CHIP:** 42 CFR 457.1260: Grievance system		• Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Medicaid and CHIP enrollee grievance and appeal tracking reports (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Grievance System			
Federal Regulation Source(s)	**State Policy/Regulation Information Needed to Determine MCP Compliance**	**Applicable MCP Documents**	**Reviewer Determination (See Worksheet 3.2 for approaches to compliance scoring)**
Information about the grievance system to providers and subcontractors **Medicaid:** 42 CFR 438.414: Information about the grievance and appeal system to providers and subcontractors **CHIP:** 42 CFR 457.1260: Grievance system	• Information on: • Whether the state develops or approves the MCP's description of its grievance system that the MCP is required to provide to all Medicaid and CHIP enrollees (per 438.10(g)(2)(xi). [Note that under regulations at 42 CFR 438.10(g)(1) the state must either develop a description for use by the MCP or approve a description developed by the MCP.] • If the states approves, rather than develops, the description of the MCP's grievance system, information on whether or not the state has already approved the MCP's description.	• Contracts or written agreements with organizational subcontractors (AM) • Completed evaluations of entities conducted before delegation is granted (AM) • Provider contracts (PS) • Provider/Contractor procedure manuals (PS)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Recordkeeping requirements **Medicaid:** 42 CFR 438.416: Recordkeeping requirements **CHIP:** 42 CFR 457.1260: Grievance system	• Information on any audits or other reviews of MCP records of grievances and appeals conducted by the state.	• Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES) • Medicaid and CHIP enrollee grievance and appeal tracking reports (ES) • Sample records of grievances and appeals (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:

Grievance System			
Federal Regulation Source(s)	**State Policy/Regulation Information Needed to Determine MCP Compliance**	**Applicable MCP Documents**	**Reviewer Determination (See Worksheet 3.2 for approaches to compliance scoring)**
Continuation of benefits while the MCP appeal and the state Fair Hearing are pending 42 CFR 438.420: Continuation of benefits while the MCO, PIHP, or PAHP appeal and the state fair hearing are pending (Note: This requirement does not apply to CHIP)	• Information on any state requirements concerning continuation of benefits pending appeal and state fair hearing that differ from those required under 42 CFR 420. • Information on any audits or other reviews of MCP records of appeals conducted by the state, to determine MCP compliance with federal continuation of benefits requirements. • Whether state permits managed care plans to recover the cost of services. See (d) reference to "state's usual policy."	• Medicaid enrollee grievance and appeals policies and procedures (ES)	**Medicaid-only:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes:
Effectuation of reversed appeal resolutions **Medicaid:** 42 CFR 438.424: Effectuation of reversed appeal resolutions. **CHIP:** 42 CFR 457.1260: Grievance system	• Information on which entity- the state or the MCP- is required to pay for services when the state fair hearing officer reversed a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending.	• Medicaid and CHIP enrollee grievance and appeals policies and procedures (ES)	**Medicaid:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes: **CHIP:** Fully Met Substantially Met Partially Met Minimally Met Not Met Not Applicable Reviewer Notes::

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Notes: MCP documents are identified using generic names, except in instances where the regulatory provisions refer to and require a specific document be present and reviewed for content.

The subject matter of each applicable MCP document is indicated in parenthesis as follows: AM = Administrative/ Managerial; PS = Provider/Contractor Services; UM = Utilization Management; ES = Enrollee Services; IS = Information Systems; SP = Staff Planning, Education, Development and Evaluation.

The subject matter designation does not imply that the document cannot be used as a data source for addressing other provision issues, or that it should be the sole source of data in evaluating compliance with the provisions noted.

Worksheet 3.2. Compliance Definitions

Instructions. This worksheet provides examples of compliance scoring and compliance definitions. Either method can be used by a state to distinguish levels of MCP compliance.

1. **Compliance Scoring.** One commonly used approach to analyzing compliance review findings is to assign a numerical value to indicate the degree of compliance with a given regulatory provision. An EQRO can provide a compliance score for each regulatory provision on Worksheet 3.1. Compliance Review, followed by details and justification for the compliance determination. Before the review, the state is directed to define what constitutes compliance and determine the rating or scoring system for what the EQRO will review. The state and EQRO can adapt a compliance rating scale to best suit their needs. Some examples include:

   ✓ Two-point rating or scoring. Either the requirement is met or not met:

   - Met = 1
   - Not Met = 2

   ✓ Three-point rating or scoring. This scale provides credit when a requirement is partially met:

   - Fully Met = 1
   - Partially Met = 2
   - Not Met = 3

   ✓ Five-point rating or scoring. This scale allows for the scoring of all five levels of compliance:

   - Fully Met = 1
   - Substantially Met = 2
   - Partially Met = 3
   - Minimally Met = 4
   - Not Met = 5

One of the above rating or scoring scales may serve as the primary system, or alternative scales may be adapted to certain regulatory provisions. In an extensive compliance review, the state may assert that the definition of compliance for most regulatory provisions are appropriate for a 5-point rating scale, with two or three particular provisions rated as “met” or “unmet.”

2. **Compliance Definitions Options.** The following definitions describe the extent of compliance with a given regulatory provision:

   ✓ Full compliance:

   - All documentation listed under a regulatory provision, or component thereof, is present, and
   - MCP staff provide responses to the EQRO that are consistent with each other and with the documentation; ***or***
   - A state-defined percentage of all data sources—either documents or MCP staff—provide evidence of compliance with regulatory provisions

- ✓ Substantial Compliance:
  - After review of the documentation and discussion with MCP staff, it is determined that the MCP has met most of the requirements as stated above
- ✓ Partial Compliance:
  - All documentation listed under a regulatory provision, or component thereof, is present, but MCP staff are unable to consistently articulate evidence of compliance; ***or***
  - MCP staff can describe and verify the existence of compliant practices during the interview(s), but required documentation is incomplete or inconsistent with practice; ***or***
  - Any combination of "Met," "Partially Met" and "Not Met" determinations for smaller components of a regulatory provision would result in a "Partially Met" designation for the provision as a whole
- ✓ Minimal Compliance:
  - After review of the documentation and discussion with MCP staff, it is determined that although some requirements have been met, the MCP has not met most of the requirements
- ✓ Non-compliance:
  - No documentation is present and MCP staff have little to no knowledge of processes or issues that comply with regulatory provisions; ***or***
  - No documentation is present and MCP staff have little to no knowledge of processes or issues that comply with key components (as identified by the state) of a multi-component regulatory provision, regardless of compliance determinations for remaining, non-key components of the regulatory provision

About Targeted Regulatory Components

If all applicable federal requirements are met, the state may focus on specific aspects or components of its regulatory provisions to make performance improvement more manageable and targeted. If less than full compliance with a full set of state regulations is defined by the state as acceptable, the state must identify to the EQRO and the MCP specific regulatory provisions of the compliance review for which the MCP is accountable. This must take place before the review begins. However, over the three-year compliance review cycle, the EQRO must review all compliance requirements.

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 3.3. Sample Site Visit Agenda

Instructions. This worksheet provides a template to develop the site visit agenda. The agenda is intended to help both the MCP and EQRO in planning staff interviews, gathering documentation, and determining logistics (such as meeting space).

The EQRO should prepare the agenda and send it in advance to the individual representing the MCP in the regulatory compliance review process. The MCP representative is responsible for identifying additional MCP participants. The agenda should also provide the locations where the meetings and any additional document review will occur. The EQRO should determine the number of days for the site visit based on the estimated duration and number of meetings required to carry out the site visit. At the end of each day, the EQRO should lead a concluding meeting to discuss outstanding information and answer questions. At the end of the final day, the EQRO should provide concluding remarks and identify next steps in the review process.

Sample EQRO Site Visit Agenda (Add more days as needed)

- Introductions between the EQRO reviewers and MCP participants
- Site Visit Purpose: To clarify MCP compliance with federal Medicaid managed care regulations
- Day 1 Activities: [Insert number of interviews and document review, if applicable]
- Day 1 Final Meeting [Insert time]: Identification/discussion of outstanding issues

Time	Regulatory compliance issue	Location	Participants	Comments/Documents
(EQRO)	(EQRO)	(MCP)	(BOTH)	(EQRO)
(EQRO)	(EQRO)	(MCP)	(BOTH)	(EQRO)
Add more rows as needed				

Note: The organization responsible for completing each part of the agenda is identified above in parenthesis.

- Day 2 Activities: [Insert number of interviews and document review, if applicable]
- Day 2 Final Meeting [Insert time]: Concluding issues and comments; description of next steps
- Day 2 Exit Interviews [Insert time]: Opportunity to respond to initial compliance issues (if applicable) and clarify reviewer understanding

Time	Regulatory compliance issue	Location	Participants	Comments/Documents
(EQRO)	(EQRO)	(MCP)	(BOTH)	(EQRO)
(EQRO)	(EQRO)	(MCP)	(BOTH)	(EQRO)
Add more rows as needed				

*The organization responsible for completing each part of the agenda is identified above in parenthesis.

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 3.4. Compliance Interview Questions

Instructions. Worksheet 3.4 includes a list of questions the reviewer may ask MCP staff to help determine compliance with state and federal requirements as summarized in Activity 3, Step 6. The purpose of the MCP interviews is to collect data to supplement and verify what is learned through the preliminary document review and onsite or virtual site visit document review. The questions are first organized by MCP staff roles, and then broken out by regulatory provision.

Reviewers are encouraged to interview MCP staff in appropriate groups whenever possible in order to accomplish a comprehensive review from more than one perspective, and to achieve efficient and productive interviews.

The MCP interviewee groups who are most often interviewed are included in this guide:

- MCP leaders
- MCP information systems staff
- Quality assessment and performance improvement program staff
- Provider/contractor services staff
- Enrollee services staff
- Utilization management staff
- Medical directors
- Case managers and care coordinators
- MCP providers and contractors (as appropriate)

The EQRO should advise the MCP of the specific issues for which the MCP will be interviewed during the site visit. The MCP representative for the compliance review process should select and report to the EQRO in writing the membership of each of the interviewee groups that are capable of responding to the EQRO site visit interview topic requests.

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

MCP Leaders Interview

The leadership interview is an opportunity to speak with the senior representatives of the MCP about their understanding of MCP requirements. MCP leaders include:

- Chief executive officer (CEO)
- Chief operating officer (COO)
- Chairman of the governing body, or a representative
- Medical director (including psychiatric medical director, if applicable)
- Chief elected or appointed officer of the MCP 's licensed independent practitioners
- Chief information officer (CIO)
- Compliance officer
- Quality improvement committee chairperson
- Quality improvement program director or coordinator, and
- Human resources leader

As determined by the MCP representative, usually in consultation with the CEO, other senior staff of the MCP may also be in attendance. However, attendance at this interview should be carefully limited in order to foster candor and exchange of information.

I. MCP Standards and Enrollee Rights and Protections

Availability of services (42 CFR 438.206 and 457.1230(a))

1. Please describe the MCP's process for assessing whether its network of appropriate providers[59] is sufficient to provide adequate access to each type of covered service and major specialty within each type of covered service.

    a. What issues were considered in the assessment process?

2. How does the MCP determine the adequacy of its network to serve its Medicaid and CHIP enrollees?

3. What assumptions and methodologies are used to project the number, type (training, experience, and specialization), and location of primary care providers and specialists necessary to serve Medicaid and CHIP enrollees?

4. What assumptions and methodologies are used to project the number, type (training, experience, and specialization), and location of LTSS providers necessary to serve Medicaid enrollees?

5. If the state has established access requirements for LTSS, how does the MCP evaluate its current network in comparison to the requirements?

[59] Per 42 CFR 438.2 and 457.10, provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the state in which it delivers the services.

a. Are there any areas where the requirements are not met? If so, how is the MCP remedying these gaps?

Out-of-network providers (42 CFR 438.206(b)(3) through (5) and 457.1230(a))

1. Approximately what proportion of Medicaid and CHIP enrollee provider encounters are made to out-of-network providers? If this is a significant percent, what are the reasons for this?

2. What are the reimbursement methods for out-of-network providers? Which types of providers are paid using each method?

   [**Probe:** Do you receive claim, encounter data from out-of- network providers similar to the claim, or encounter data that you receive from your network providers?]

3. How does your MCP ensure that any costs to the Medicaid and CHIP enrollee for out-of-network services is no greater than the costs the enrollee would incur if they used a network provider for the same service?

Furnishing of services and timely access (42 CFR 438.206(c)(1) and 457.1230(a))

1. Please describe how the MCP monitors compliance with its Medicaid and CHIP standards for timely access to care and services.

2. How does the MCP ensure the 24 hours per day, 7 day per week availability of Medicaid and CHIP services included in its contract with the state when medically necessary?

3. How does the MCP determine that the individual and institutional providers it contracts with have sufficient capacity to make services available when medically appropriate 24 hour per day, 7 days per week to Medicaid and CHIP enrollees?

4. How does the MCP ensure that its provider network's hours of operation do not discriminate against Medicaid and CHIP enrollees (i.e., are not different for Medicaid and CHIP enrollees than for commercial enrollees)?

5. How is inappropriate use of emergency department visits addressed? What proportion of emergency department visits are potentially avoidable?

6. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

Access and cultural considerations (42 CFR 438.206(c)(2) and 457.1230(a))

1. What have been the state Medicaid and CHIP agency's efforts to promote the delivery of services in a culturally appropriate manner to all enrollees, including those with diverse cultural and ethnic backgrounds?

   a. How has your MCP participated in these efforts?

   b. What documentation exists describing your efforts and the results of these efforts?

2. What efforts has the MCP made to promote services to enrollees with limited English proficiency and those with low literacy?

3. How does the MCP maintain and make available information on all languages (including both spoken and signed) used by providers, including those used by LTSS providers?

4. How are call center staff made aware of MCP beneficiaries' needs so that verbal communication is easily understood by the beneficiary? For example, volume or speed of speech.

Assurances of adequate capacity and services (42 CFR 438.207(b) – (c) and 457.1230(b))

1. Please describe how your MCP demonstrates to the Medicaid and CHIP agency that it offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees in your service area.

2. Please describe how your MCP demonstrates to the Medicaid and CHIP agency that it maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

3. Please indicate whether your MCP meets the timing standards set by the Medicaid and CHIP agency for this documentation.

Coordination and continuity of care for all enrollees (42 CFR 438.208, 457.1230(c))

1. Which provider types are authorized by the Medicaid or CHIP agency to serve as enrollee primary care providers? (i.e., general practitioner, family physician, internal medicine physician, OB/GYN, pediatrician, or other licensed practitioner as authorized by the state Medicaid program)

    a. Does your MCP permit each of the provider types authorized by the Medicaid or CHIP agency to provide primary care services to serve as primary care providers?

2. What steps does the MCP take to promote Medicaid and CHIP enrollees' ongoing relationship with a usual source of primary care?

3. What processes are used to coordinate services for enrollees?

    a. Are there different types of care coordination mechanisms for different types of enrollees? If so, what are these?

    b. Are there different types of care coordination mechanisms for acute and primary services? If so, what are these?

4. If your MCP establishes separate coordination of care for medical services, LTSS, and mental health and substance abuse services, how does it ensure exchange of necessary information between care coordinators? How does it ensure information exchange among providers?

5. How are staff trained in the processes and tools required to facilitate integrated medical, behavioral, care planning, service planning, and authorization activities?

6. How does the MCP ensure coordination of its services with services enrollees may receive from other MCPs or community programs and providers?

    a. How are coordination and communication ensured when an enrollee changes MCPs or transitions between FFS and managed care?

    b. How are coordination and communication ensured when an enrollee is a member of more than one MCP (e.g., duals and separate dental or behavioral health plans)?

7. Under what circumstances may Medicaid and CHIP enrollees have direct access to specialists?

8. How does your MCP manage access to any specialty care services currently not provided in-network?

9. Does your MCP require written treatment plans to be developed for enrollees? If yes, under what circumstances are written treatment plans required?

Additional coordination and continuity of care questions: LTSS (42 CFR 438.208 and 457.1230(c))

1. Does your state's Medicaid and CHIP agency require your MCP to meet identification, assessment, and treatment planning requirements for dually-enrolled beneficiaries who need LTSS?

2. Please describe how your MCP meets any LTSS assessment mechanism requirements established by your Medicaid and CHIP agency.

3. What processes are used to coordinate services for enrollees who need LTSS?

    a. Are there different types of care coordination mechanisms for LTSS as compared to acute and primary care services? If so, what are these?

4. If your MCP establishes separate coordination of care for LTSS, how does it ensure exchange of necessary information between care coordinators? How does it ensure information exchange among providers?

5. How are staff trained in the processes and tools required to facilitate integrated medical, behavioral and LTSS assessment, care planning, service planning, and authorization activities for enrollees who need LTSS?

6. How are coordination and communication ensured when an LTSS enrollee is a member of more than one MCP?

Additional coordination and continuity of care questions: SHCN (42 CFR 438.208 and 457.1230(c))

1. How are "individuals with special health care needs" defined by the state Medicaid and CHIP agency?

    a. Has your MCP developed any other operational definition or definitions of individuals with special health care needs?
    b. If yes, what is/are these and how were they developed? How do they differ from the state definition?

2. Does the state Medicaid or CHIP agency require your MCP to screen Medicaid and CHIP enrollees to identify those with special health care needs?

3. How are individuals with special health care needs—including both individuals with special health care needs identified by this MCP and those identified by the state Medicaid or CHIP agency or its agent—identified and tracked within your MCP?

4. Does the state Medicaid agency require your MCP to assess and provide treatment plans for Medicaid and CHIP enrollees with special health care needs? If yes, how are these activities conducted?

Disenrollment (42 CFR 438.56 and 457.1212)

1. For what reasons may your MCP request the disenrollment of an enrollee?

    a. Has your MCP requested to disenroll an enrollee for any other reason?

2. Is your MCP allowed to process enrollee disenrollment requests? If so, for what reasons have enrollees requested disenrollment?

3. Are enrollees required to seek redress through your MCP's grievance system before a disenrollment request is determined? If so, what timeframes are used by your MCP to process those grievances?

Enrollee right to information (42 CFR 438.100 and 457.1220; 42 CFR 438.10 and 457.1207)

1. How does your MCP provide written notice of any change (that the state defines as "significant") to the information contained in the enrollee handbook, at least 30 days before the intended effective date of the change?

    a. How does the state define "significant"?

    b. Have you made any such "significant" changes in the last year? If yes, what were those changes?

2. How do you ensure that your staff and affiliated providers comply with federal and state laws that apply to enrollee rights?

3. What information is routinely provided to Medicaid and CHIP enrollees?

    a. What is the process for disseminating information to new and existing enrollees?

    b. How often is information distributed to existing enrollees?

    c. In what format is this information presented?

4. Please describe or provide copies of the formats in which information is presented to enrollees.

5. In what languages or alternative formats are enrollee materials and information presented? If other languages or alternative formats are used, how was it determined that materials were needed in different languages or formats?

6. Does the MCP provide written materials in alternative formats for the visually impaired? If yes, how did the MCP determine that materials were needed for the visually impaired?

7. Please describe the procedures for handling calls to the MCP from non-English speaking enrollees.

    a. What instruction or guidance is available for providers that may need interpretation assistance to provide care and services to assigned enrollees?

8. To what extent is the MCP responsible for responding to requests for information for potential Medicaid and CHIP enrollees?

9. How does the MCP inform enrollees (and potential enrollees, if applicable) about how to obtain oral interpreter services if they have limited proficiency in English?

10. Are there any benefits that an enrollee is entitled to under the Medicaid and CHP program, including LTSS benefits, but that are not made available through the MCP contract? If yes, what are those benefits? How are enrollees made aware of the Medicaid and CHIP program benefits that are outside the scope of services available through the MCP?

11. How does the MCP ascertain the primary language spoken by the individual Medicaid and CHIP enrollees?

12. Are enrollees provided with a listing of primary care providers? If yes, does this listing include providers' non-English language capabilities?

13. Does the MCP give written notice of the termination of a contracted provider to enrollees who receive primary care from, or are seen on a regular basis by, the terminated providers? If yes, how is this accomplished? Have you had to make any such notifications in the last year?

14. How does the MCP ensure that information and instructional materials intended for enrollees and potential enrollees are easily understood by those with a variety of cognitive and intellectual capabilities?

15. How does the MCP provide its enrollees information about provider appeal rights regarding coverage of a service?

16. Does the MCP provide information to providers on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCP?

17. What protocols does the MCP follow to develop materials that are readily understandable by enrollees?

18. Does the MCP require providers to have access to oral interpreter services?

19. Does the MCP provide providers with guidance or assistance in accessing interpreter services if necessary?

Enrollee right to respect, dignity, privacy (42 CFR 438.100 457.1220)

1. How does the MCP ensure that its own facilities and those of its affiliated providers comply with enrollee rights such as treatment with respect, dignity, and consideration for privacy and confidentiality of information? Please provide an example?

    a. Are there any additional considerations made for providers of LTSS, or other specialized providers, where services may be of a more intimate nature or occur in a more isolated setting? Please provide an example?

2. What processes are in place to ensure that staff members observe the MCP's policies and procedures on privacy and confidentiality of enrollee information?

3. What does the MCP do to educate staff about policies on nondiscriminatory and culturally appropriate behavior towards enrollees?

    a. How do you monitor staff compliance with these policies?

Enrollee right to receive information on available treatment options (42 CFR 438.100, 438.102; and 42 CFR 457.1220 and 457.1222)

1. How does the MCP ensure that providers share information on available treatment options and alternatives with enrollees?

    a. Does this include alternatives and options that are both within and outside the Medicaid or CHIP contract scope of benefits?

    b. How does the MCP ensure providers share information about HCBS as alternatives to institutional care?

2. What steps does the MCP take to ensure that enrollees receive information on available treatment options and alternatives in a manner appropriate to their condition and ability to understand?

Enrollee right to participate in decisions regarding his/her health care and advance directives (42 CFR 438.100 and 42 CFR 438.6; 42 CFR 457.1220)

1. How does the MCP facilitate enrollee participation in care and treatment decisions? Please describe. Could you provide an example?

2. Does the MCP have any limitations in implementing federal and state laws that apply to advance directives? If so, what are these limitations?

Enrollee rights (42 CFR 438.10 and 457.1207) and Enrollee information (42 CFR 438.100 and 457.1220, and 42 CFR 438.206-210 and 457.1230(a–d))

1. Does the MCP provide information to providers on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCP?

2. What protocols does the MCP follow to develop materials that are readily understandable by enrollees?

3. Does the MCP require providers to have access to oral interpreter services?

4. Does the MCP provide providers with guidance or assistance is accessing interpreter services if necessary?

Compliance with other federal and state laws (42 CFR 438.100 and 457.1220, and 42 CFR 438.206-210 and 457.1230(a–d))

1. What steps do MCP leaders take to ensure compliance with federal and state laws on enrollee rights?

2. Has the MCP ever been found non-compliant with any federal and state laws on enrollee rights? If yes, in what area? What steps were taken to clear the violation?

3. If a provider/contractor/sub-contractor is found to be in violation of any federal and state laws on enrollee rights, how does the MCP respond?

4. To what extent does the MCP orient new staff to federal and state laws on enrollee rights that must be observed during day-to-day operations?

    a. How does the MCP remind staff of the importance of observing these laws during interactions with other employees and with enrollees?

5. Please describe the steps taken by the MCP when staff report, or are involved in a violation of federal or state laws on enrollee rights.

Coverage and authorization of services, including emergency and post-stabilization services (42 CFR 438.210 and 457.1230(d) and 42 CFR 438.114 and 457.1228)

1. What percent of emergency department care utilized by your Medicaid and CHIP enrollees is for non-urgent care?

2. Has your MCP investigated a potential relationship between inappropriate emergency department use and enrollee access to routine and urgent care, or reviewed the most frequent diagnoses resulting in inappropriate emergency department use?

3. What was the rate of denied claims for emergency and post-stabilization services in the most recent year?

4. What was the rate of appeals for denied claims for emergency and post-stabilization services in the most recent year?

    a. Of these appeals, what was the rate in which claim denials were overturned?

5. What is the average wait time for MCP enrollees who see emergency services?

6. How many urgent care clinics with non-traditional hours are in the MCP's network?

7. How does the MCP inform enrollees of emergency coverage?

8. Are emergency back-up plans created for all enrollees? If not, how is the need for an emergency back-up plan determined? How is the emergency back-up plan shared with all appropriate parties?

9. Are certain LTSS providers or other specialized providers/provider types contracted specifically for after-hours/urgent/emergent need? If so, what types? How were these types determined?

10. How does the MCP ensure that it provides services in a sufficient amount, duration, and scope consistent with contract requirements?

11. What are the MCP's policies on service and drug limitations? What services or drugs does it limit?

    a. How does the MCP ensure that limited services can still reasonably achieve their purpose?

    b. How does the MCP ensure that services supporting individuals with ongoing or chronic conditions, or who require LTSS, are authorized in a manner that reflects the enrollee's ongoing need for such services and supports?

    c. How does the MCP ensure that family planning services are provided in a manner that protects the enrollee's freedom to choose their preferred method?

12. How does the MCP ensure that it providers all medically necessary services specified by the contract?

13. What mechanisms does the MCP use to ensure consistent application of authorization decision review criteria?

14. What mechanisms does the MCP use to notify providers and enrollees of adverse benefit determinations?

    a. What timeframes does the MCP use to process standard and expedited authorization decisions?

15. What notice methods does the MCP use for outpatient drug authorization decisions?

Provider Selection and Non-Discrimination (42 CFR 438.214 and 457.1233(a) and 42 CFR 438.12 and 457.1208)

1. What is the basis or criteria used to determine individual provider participation in the MCP's network?

2. What is the basis or criteria used to determine institutional or other non-individual practitioner (including LTSS) participation in the MCP's network?

3. What types of providers are subject to the MCP's credentialing process?

    a. How are provider qualifications (including background check requirements) verified for provider types not subject to the credentialing process?

4. Please describe the provider credentialing process used by the MCP.

5. What steps does the MCP take to ensure that it does not employ or contract with providers who have been excluded from participation in federal health care programs?

6. What steps does the MCP take to ensure that providers who serve high-risk or costly populations are not discriminated against in the selection process, and when considering reimbursement and indemnification?

7. What criteria is the basis for denial of provider participation in the MCP's network?

Sub-Contractual Relationships and Delegation (42 CFR 438.230 and 42 CFR 457.1233(b))

1. What services and activities are delegated to and performed by sub-contractors?

2. Please describe the MCP's process for identifying and selecting contractors. How is it determined that a contractor has the ability to provide the sub-contracted services?

3. Please describe how your MCP assesses the quality of sub-contracted services and sub-contractor compliance with federal, state and contractual requirements.

Practice guidelines: adoption (42 CFR 438.236(b) and 457.1233(c))

1. What organizational component of your MCP is responsible for the adoption of practice guidelines used by your MCP?

2. How does your MCP establish priorities for adoption of practice guidelines?

    a. How does your MCP consider the enrolled Medicaid and CHIP population's health needs in the adoption of practice guidelines?

3. What guidelines has your MCP adopted?

4. By what institutional process were they adopted?

5. To what extent are your MCP's guidelines "evidence-based"? By evidence-based, we mean systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

6. How does your MCP consider the enrolled Medicaid and CHIP population's health needs in the adoption of practice guidelines?

7. How are affiliated providers consulted as guidelines are adopted and re-evaluated?

8. What mechanism(s) does your MCP have for periodically evaluating and updating the guidelines it has adopted?

Practice guidelines: dissemination and application (42 CFR 438.236(c) and 457.1233(c))

1. How are practice guidelines disseminated to providers?

2. When and how are guidelines disseminated to enrollees and potential enrollees?

3. To what extent are the practice guidelines adopted by your MCP a component of your MCP's Quality Assessment and Performance Improvement (QAPI) program?

4. Is there a process in place to ensure communication between those responsible for the QAPI program and the practice guidelines adoption process?

5. What steps are taken to ensure that decision-making in the areas of utilization management or coverage determinations and other functional areas are consistent with the adopted practice guidelines?

Health information systems (42 CFR 438.242 and 457.1233(d))

1. Describe the types of data collection systems that are in place to support the clinical and administrative operations of your MCP. Specifically, what data is routinely collected to support utilization management, grievance systems, and enrollment services?

2. What processes are in place to obtain data from all components of your network (e.g., health care facilities, physician, laboratories, and LTSS, and other specialized providers)?

    a. To what extent does your MCP require and receive data in standardized formats?

    b. Are there any components of your network from which you do not receive standardized (or any) information on services?

3. How are enrollee and provider data collected and integrated across all components of your MCP's network?

    a. How is this used to produce comprehensive information on enrollee needs and utilization and to otherwise support management?

II. Quality Assessment and Performance Improvement Program

Quality assessment and performance improvement program: general rules and basic elements (42 CFR 438.330 and 457.1240(b))

1. Does the state require the MCP to address a specific topic or topics in your performance improvement projects? If yes, what types of projects are required? For each PIP, at a minimum, include how significant improvement was measured, how improvement will be/was sustained, and how beneficiary health outcomes and satisfaction will be/was measured, and how the intervention will/has improved access and/or quality of care?

    a. For duals-only MCPs, was a Medicare Advantage PIP substituted for a state-required PIP?

    b. Has CMS specified any specific PIPs? If yes, what types of projects are required? For each PIP, at a minimum, include how significant improvement was measured, how improvement will be/was sustained, and how beneficiary health outcomes and satisfaction will be/was measured, and how the intervention will/has improved access and/or quality of care?

2. Does the state require your MCP to collect and submit performance measures or to submit data to the state for it to calculate performance measures? If yes, what performance measures are specified by the state and who calculates each measure, the MCP or the state?

    a. If CMS specifies any performance measures, what performance measures are collected and submitted, if any?

    b. If the MCP provides LTSS, what LTSS performance measures are collected and submitted, including but not limited to measures of quality of life, rebalancing institutional and community-based services and community integration activities?

3. How does the MCP detect over- and under-utilization? Please provide examples of how your quality assessment and improvement program has monitored to detect under- and over-utilization. What standards and measures are used?

4. How does the MCP define enrollees with "special health care needs"? Does this definition match the state's definition of special health care needs? How are these enrollees identified/ tracked within your MCP?

5. How does the MCP assess the quality and appropriateness of care including LTSS, furnished to enrollees with special health care needs? Please provide examples.

6. Does the state require the MCP to evaluate the impact and effectiveness of its quality assessment and performance improvement program?

    a. How does the MCP conduct its evaluation? What aspects of the program are included in the evaluation?

    b. How often does the MCP conduct its evaluation?

    c. What were the findings of the MCP's most recent self-evaluation?

    d. What action did the MCP take as a result of the findings?

    e. What is reported to the state, and how often?

7. For MCPs that provide LTSS services:

    a. How does the MCP assess quality and appropriateness of care in general, including but not limited to between care settings and comparing treatment plans to service/supports received?

    b. How does the MCP participate in the state's efforts to prevent, detect, and remediate critical incidents?

8. What interventions are used or are anticipated to be used to improve LTSS quality? How will the interventions be evaluated for effectiveness? How will improvement be sustained or increased?

Quality assessment and performance improvement program: program review by the state (42 CFR 438.330(e) and 457.1240(b))

1. How does the state review the impact and effectiveness of the MCP's QAPI program, including outcomes and trended results from the PIPs, reporting on performance measures, and the results of community integration for beneficiaries receiving LTSS?

    a. What is the MCP's role in the state's evaluation?

    b. What information, if any, does the MCP provide to the state?

    c. What feedback, if any, does the MCP receive from the state? How does the MCP implement the feedback?

III. Grievance System

Grievance system: denial of services (42 CFR 438.228)

1. How does the MCP track requests for covered services that the MCP or its providers have denied?

2. What was the volume of denied claims for services in the most recent year?

3. How do you ensure that Medicaid enrollees who were denied services were notified of their right to a state fair hearing?

Grievance system: general requirements (42 CFR 438.402 and 457.1260)

1. Who in the MCP is responsible for the development and oversight of the appeals and grievance resolution process and access to state fair hearings or review?

2. What have been the volume of appeals/grievances/requests for state fair hearings or reviews in the past year and the most common areas of concern expressed by Medicaid and CHIP enrollees?

    a. How has the MCP addressed these concerns?

3. Describe the notice and appeals process for adverse actions on enrollee requests for services or payment. Please describe the particular steps, including time frames.

Grievance systems: continuation of benefits (42 CFR 438.404(b)(6))

1. Does the Medicaid enrollee's right to have benefits continue pending resolution of the appeal, the process to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services differ between medical and LTSS? Note that continuation of benefits requirements do not apply to CHIP enrollees.

    a. If so, how?

    b. Are there any special considerations required for continuation of LTSS pending resolution of an appeal?

Handling of grievances and appeals (42 CFR 438.406 and 457.1260)

1. To what extent does your MCP provide Medicaid and CHIP enrollees with assistance in completing forms and taking other procedural steps in the grievance and appeal process? How does the MCP provide assistance?

2. How does your MCP treat oral requests by Medicaid and CHIP enrollees to appeal actions?

3. As part of an appeal, to what extent do enrollees and their representatives have an opportunity to:

    a. Present evidence, and

    b. Examine the enrollee’s case file, including medical records, and any other documents and records considered during the appeals process.

4. What are the qualifications and credentials of individuals who make decisions on grievances and appeals?

    a. How does the MCP ensure that these individuals have not been involved in any previous level of review or decision-making?

    b. How does the MCP ensure that these individuals have the appropriate clinical expertise in treating the enrollee’s condition or disease, if deciding any of the following:

i. An appeal of a denial that is based on lack of medical necessity

ii. A grievance regarding denial of expedited resolution of an appeal

iii. A grievance or appeal that involves clinical issues

5. Is there a process in place to monitor either the appeal and grievance process or the areas of concern identified by enrollee appeals and grievances?

Resolution and notification: grievances and appeals (42 CFR 438.408 and 457.1260)

1. Approximately how many grievances did the MCP receive in the most recent reporting year?

2. Approximately how many appeals did the MCP receive in the most recent reporting year?

3. Approximately what percent of notices of action on requests for service authorization or payment by Medicaid and CHIP enrollees are appealed to the MCP?

4. Approximately what percent of notices of action on requests for service authorization or payment by Medicaid and CHIP enrollees are appealed to the state fair hearing process?

    a. Approximately what percent of these are overturned by the state?

Expedited resolution of appeals (42 CFR 438.410 and 457.1260)

1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? If so, please describe this process. What are the time frames for this process?

2. Are physicians allowed to request expedited appeals on behalf of an enrollee? How does the MCP protect physicians who make such requests?

Information about the grievance system to providers and subcontractors (42 CFR 438.414 and 457.1260)

1. Who in your MCP has responsibility for the functioning of the grievance process and the authority to require corrective action?

2. Did your state Medicaid and CHIP agency develop or approve the description of your MCP's grievance system provided to Medicaid and CHIP providers? [Note: clarify if the state Medicaid and CHIP agency developed or approved] If it approved your description, how is the state's approval documented?

Recordkeeping and reporting requirements: grievances and appeals (42 CFR 438.416 and 457.1260)

1. Where in your MCP are records on Medicaid and CHIP enrollee grievances and appeals kept?

MCP Information Systems Staff Interview

Instructions. This interview will assess the MCP's information management function and how it supports the other functions of the organization, such as planning and operations, quality assessment and improvement program activities, care coordination, etc. This is also an opportunity to explore the extent to which the health information needs of the entire MCP and provider network are measured, assessed, and improved.

The interview should include MCP staff responsible for health information systems issues at the MCP. It should include those responsible for technology implementation, as well as staff that are responsible for the information quality, information transmittal, information sharing, and information policy and procedure development and implementation.

Information system capabilities. The interviewees should receive a copy of the MCP's most recent Information Systems Capability Assessment (ISCA) (see Appendix A) that has either been completed by an independent organization reviewing the MCP or has been completed by the organization conducting this compliance review.[60] The findings of the ISCA will serve as a guide to conducting this interview. During this interview, validate the information provided about the MCP on the ISCA, explore any areas of concern, and gather missing or additional information for use in evaluating standards compliance, paying particular attention to how data are defined and captured across the MCP and how data transmission and integration takes place across the MCP. Questions and areas of discussion should be based on the findings of the ISCA, and may include:

1. Are the findings of the most recent assessment of the MCP's information systems capacity reflective of your own assessment of capabilities?

2. What are your information system's strengths and weaknesses?

    a. What has the MCP done to address information system problem areas?

3. What information needs does your MCP have that are not currently met by your present information system?

    a. What has the MCP done to address these needs?

4. Is the data collected from network providers on services to enrollees subject to accuracy and timeliness checks?

5. Please describe procedures used to screen all data, both internal and external, for completeness, logic, and consistency.

6. How is enrollee-specific data and information made available when and where needed by the MCP's provider network?

Delivery network (42 CFR 438.206 and 457.1230(a))

1. How does your information system track services provided by and/or reimbursed to out-of-network providers?
2. Describe the capabilities to routinely collect data on use of out-of-network providers (excluding Point of

[60] There is no statutory or regulatory requirement for the frequency with which ISCAs should be conducted. Each state must determine the maximum interval between assessments of MCP information systems, balancing the cost to the state and burden on the MCP with the need to ensure that changes to the MCP's information systems are assessed frequently enough to support accurate performance measurement.

Service-related use).

a. Is data on use of out-of-network providers separately available for Medicaid and CHIP enrollees?

Assurances of adequate capacity and services (42 CFR 438.207(b) – (c) and 457.1230(b))

1. Please describe any information system capabilities used to demonstrate to the Medicaid and CHIP agency that the MCP offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees in your service area.

2. Please describe any information system capabilities used to demonstrate to the Medicaid and CHIP agency that the MCP maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

Coordination and continuity of care for all enrollees (42 CFR 438.208 and 457.1230(c))

1. How does the MCPs information system integrate medical, behavioral and LTSS assessments, care planning, service planning and authorization information and processes?

Health information systems (42 CFR 438.242 and 457.1233(d))

1. How is the data collected from network providers on services to enrollees checked for accuracy and timeliness?

2. Please describe procedures used to screen all data, both internal and external, for completeness, logic, and consistency.

Quality Assessment and Performance Improvement Program Staff Interview

Instructions. This interview with quality improvement program leaders and staff provides an opportunity to gain a more thorough understanding of the approaches and processes used by the MCP to assess and improve quality.

Availability of services (42 CFR 438.206 and 457.1230(a))

1. What information is generated through QAPI activities to assess the MCP's availability of services?
    a. What issues were considered in the assessment process?
    b. What services, such as family planning and women's health services, have QAPI activities focused on?
2. Please describe the assessment results.
    a. Are there any service-specific results? If so, please describe them.
3. Has the MCP implemented QAPI findings relevant to the availability of services? If so, please describe them and their results.
4. How frequently does the MCP evaluate the volume and enrollee access to LTSS services? What factors are used in evaluation of the LTSS network? Note that this is not applicable to CHIP.

Furnishing of services-timely access (42 CFR 438.206(c) and 457.1230(a))

1. Please describe any recent QAPI activities implemented to monitor the MCP's compliance with its established standards for timeliness of access to care and member services.
    a. What were the results of these QAPI activities?
2. Please describe any recent QAPI activities implemented to promote cultural competency and delivery of services in a culturally competent manner.
    a. What are the results of these QAPI activities?
3. Please describe any recent QAPI activities implemented to promote physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.
    a. What are the results of these QAPI activities?

Enrollee rights (42 CFR 438.100 and 457.1220)

1. How is the enrollee's right to be free from restraint or seclusion monitored for enrollees, including, for example, those receiving LTSS? Note that requirements applying to LTSS are not applicable to CHIP.

Provider selection (42 CFR 438.214 and 457.1233(a))

1. What type of information is generated through the quality improvement program to support re-credentialing of individual practitioner providers?
2. What types of information does the quality improvement program provide to support the re-credentialing of institutional and other non-practitioner providers?

3. What types of information does the quality improvement program provide to support the evaluation of LTSS provider qualifications?

Practice guidelines (42 CFR 438.236 and 457.1233(c))

1. Through what process does your MCP ensure necessary communication occurs between those responsible for the QAPI program and the administrative function responsible for adopting practice guidelines?

Quality assessment and performance improvement program (42 CFR 438.330 and 457.1240(b))

1. Does the state require the MCP to address a specific topic or topics and/or indicators in your performance improvement projects? If yes, what types of projects are required?

2. How does the MCP detect over- and under-utilization? Please provide examples of how your quality assessment and improvement program has monitored to detect under- and over-utilization. What standards are used?

3. How does the MCP define enrollees with "special health care needs"? How are these enrollees identified/ tracked within your MCP?

4. How does the MCP assess the quality and appropriateness of care including LTSS, furnished to enrollees with special health care needs? Please provide examples.

5. Does the MCP evaluate the effectiveness of its quality assessment and performance improvement program? How often?

    a. Please describe the evaluation process. What aspects of the program are included in the evaluation?

    b. What were the findings of the MCP's most recent self-evaluation?

    c. What action did the MCP take as a result of these findings?

6. Does the state require the MCP to evaluate the impact and effectiveness of its quality assessment and performance improvement program?

    a. How does the MCP conduct its evaluation? What aspects of the program are included in the evaluation?

    b. How often does the MCP conduct its evaluation?

    c. What were the findings of the MCP's most recent self-evaluation?

    d. What action did the MCP take as a result of these findings?

    e. What is reported to the state, and how often?

7. How does the state review the impact and effectiveness of the MCP's QAPI program, including outcomes and trended results from the PIPs, reporting on performance measures, and the results of community integration for beneficiaries receiving LTSS?

    a. What is the MCP's role in the state's evaluation?

    b. What information, if any, does the MCP provide to the state?

c. What feedback, if any, does the MCP receive from the state? How does your MCP implement the feedback?

8. What evaluation findings are reported to the state and how often?

9. What interventions are used or are anticipated to be used to improve LTSS quality? How will the interventions be evaluated for effectiveness? How will improvement be sustained or increased?

Health information systems (42 CFR 438.242 and 457.1233(d))

1. How are enrollee and provider data from all components of your MCP's network used in your MCP's quality assessment and performance improvement program?

   a. Are there any components in your network for which you do not have adequate enrollee utilization and provider data?

2. How is data obtained from the meaningful use of certified electronic health records (EHRs) utilized as part of the MCP's quality improvement program?

Handling of grievances and appeals (42 CFR 438.406 and 457.1260)

1. What is the process used to monitor the appeal and grievance process?

2. What is the process to monitor areas of concern identified by enrollee appeals and grievances?

Recordkeeping and reporting requirements on grievances and appeals (42 CFR 438.416 and 457.1260)

1. To what extent is information on Medicaid and CHIP enrollee grievances and appeals analyzed and included as part of your MCP's Quality Assessment and Performance Improvement Program?

Provider/Contractor Services Staff Interview

Instructions. This is an interview of MCP staff members who are responsible for establishing and maintaining communications with the MCP's individual practitioners and other types of health care providers (e.g., organizations). This includes staff responsible for management of the credentialing process and oversight of delegated activities. Through these interviews, the reviewer(s) will assess enrollee rights; the credentialing and appointment process; oversight of the providers; and how information is communicated to providers.

Enrollee rights (42 CFR 438.100 and 457.1220 and 42 CFR 438.206-210 and 457.1230(a-d)))

1. How does the MCP inform its providers (individual, institutional, and LTSS providers) about enrollee rights and responsibilities?

    a. How does the MCP monitor for compliance with these rights by its providers?

2. To what extent, if any, does the MCP supply providers with information on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCP?

3. Does the MCP require providers to have access to oral interpreter services?

    a. Does the MCP supply providers with guidance or assistance in accessing oral interpreter services if necessary?

4. How does the MCP ensure that its own facilities and those of its affiliated providers comply with enrollee rights to treatment with respect, dignity, and consideration for privacy?

    a. Are there any additional considerations made for providers of LTSS, where services may be of a more intimate nature or occur in a more isolated setting? Please provide examples.

5. How does the MCP ensure that enrollees are not discriminated against in its own facilities and those of its affiliated providers when seeking health care services consistent with their covered benefits?

6. Please describe the MCP's credentialing, verification and oversight process for primary care providers, other health care professionals, LTSS and institutional providers.

    a. What is encompassed by reviews and evaluations of these providers?

    b. Do these processes involve visits to the providers' care delivery sites?

7. What methods are used to encourage providers to share information on available treatment options and alternatives with enrollees?

8. What processes are in place for monitoring providers to determine that they are providing information on available treatment options and alternatives?

9. What requirements does the MCP have for providers/contractors relative to enrollee advance directives?

    a. How is it determined that providers/contractors are meeting the MCP's requirements?

10. How does the MCP inform all of its network providers, including its LTSS, individual and institutional providers, about enrollee rights to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional?

    a. How does the MCP monitor for compliance with these rights by its providers?

11. How are the MCP's network providers informed of enrollees' right to request and receive a copy of their medical records, and to request that they be amended or corrected?

12. What steps does the MCP take to ensure that providers/contractors are aware of and in compliance with applicable federal and state laws on enrollee rights?

13. If a provider/contractor is found in violation of a federal or state law concerning enrollee rights, what action is taken by the MCP?

Availability of services (42 CFR 438.206 and 457.1230(a))

1. Please describe the MCP credentialing and re-credentialing process.

    a. Is the process different for Medicaid and CHIP providers than for providers serving other networks? If yes, what are the differences?

2. How is it determined that providers are geographically accessible to Medicaid and CHIP enrollees and physically accessible to enrollees with disabilities?

3. Please describe the processes for monitoring the provider network to determine that Medicaid and CHIP requirements about timeliness, availability, and accessibility are being met.

    a. What are the most recent findings from this process?

4. How often in the last year has your MCP had to arrange for services or reimbursements to out-of-network providers?

5. How does the MCP evaluate the expected utilization of institutional care in comparison with the use of HCBS as an alternative?

6. Does the MCP maintain accessibility information on its LTSS and other specialized providers? If yes, how is this maintained and shared with enrollees?

7. How does the MCP encourage the promotion of culturally competent service delivery by LTSS and other specialty providers?

8. Are there any limits to choice of LTSS and other specialty providers?

Timely access to service (42 CFR 438.206(c)(1) and 457.1230(a))

1. **Ask only if MCP is a MCO, PIHP, or PAHP:** Are your MCP's provider services available 24 hours a day, 7 days a week, when medically or otherwise necessary to meet the enrollee's needs?

    a. Are certain LTSS or other specialized providers/provider types contracted specifically for after-hours/urgent/emergent need?

    b. If yes, what types? How were these types determined?

2. Are providers included in developing beneficiary emergency back-up plans? If they are not involved in the back-up plan development, how are they made aware of their responsibility for emergency back-up?

3. Are the hours of operation of the provider network serving Medicaid and CHIP enrollees different from the hours of operation of the provider network serving other enrollees? If yes, why are they different?

4. Does the MCP continuously monitor its provider network for compliance with established standards on timeliness of access to all care and member services? If yes, how, and what are the most recent findings?

5. What steps are taken to address provider non-compliance with established standards for timeliness of access to care and member services?

    a. How are corrective actions assessed for effectiveness? Please describe the follow up and monitoring.

Coordination and continuity of care for all enrollees (42 CFR 438.208 and 457.1230(c))

1. How are primary care providers serving enrollees with special health care needs made aware of and involved in procedures for:

    a. Assessing individuals with special health care needs?

    b. Ensuring that treatment plans address the needs identified by the assessment?

    c. Assuring appropriate use of specialists?

    d. Coordinating primary care services with care provided by other MCOs, PIHPs or PAHPs serving the enrollee?

    e. Coordinating care with other providers, including specialist and LTSS providers?

Additional coordination and continuity of care questions: SHCN (42 CFR 438.208 and 457.1230(c))

1. How are specialty providers serving enrollees with special health care needs made aware of and involved in procedures for:

    a. Assessing individuals with special health care needs?

    b. Ensuring that treatment plans address the needs identified by the assessment?

    c. Coordinating specialty care services with care provided by other MCPs serving the enrollee?

    d. Coordinating care with other providers, including primary and LTSS providers?

2. How are LTSS providers serving enrollees with special health care needs made aware of and involved in procedures for:

    a. Assessing individuals with special health care needs?

    b. Ensuring that treatment plans address the needs identified by the assessment?

    c. Coordinating care with other providers, including primary and LTSS providers?

Additional coordination and continuity of care questions: LTSS (42 CFR 438.208

1. How are LTSS providers serving enrollees with special health care needs made aware of and involved in procedures for:

    a. Assessing individuals with special health care needs?

    b. Ensuring that treatment plans address the needs identified by the assessment?

c. Coordinating care with primary care and specialty providers?

Coverage and authorization of services (42 CFR 438.210 and 457.1230(d))

1. Do contracts/agreements with individuals or organizations performing utilization review offer any performance incentives? If yes, please describe the incentives. [Note to reviewers: Look for any incentives for denying, limiting, or discontinuing authorization of services.]

2. Are network providers notified of the information ordinarily required to process an authorization request?

3. Please describe the process for notifying the requesting provider of any decision to deny, limit, or discontinue authorization of services.

    a. What are the MCP's time frames for notification?

4. Does the MCP contract with all LTSS and other specialized provider types identified in the state's benefit package? If not, what provider types are not contracted? How are enrollees' needs met in lieu of this service availability?

5. Are there any universal service limitations on LTSS? If yes, what are the service limitations, and how were these determined?

Provider selection (42 CFR 438.214 and 457.1233(a))

1. What types of individual practitioners are subject to the MCP's credentialing process?

2. Please describe the MCP's credentialing processes for individual practitioners.

    a. How often does this process take place?

    b. What items of credentials information are updated during the process?

    c. Are site visits made to providers? When and how often? How is it determined that a site visit will be made?

    d. Who is involved in the MCP's credentialing activities?

3. Please describe the MCP's re-credentialing processes for individual practitioners.

    a. What types of information are monitored and reviewed during the re-credentialing process?

    b. What other operations of the MCP contribute information to be used in the re-credentialing process?

4. **Ask only if MCP is a MCO, PIHP, or PAHP:** Please describe the MCO's /PIHP's/PAHP's processes for selecting and monitoring institutional and other non- practitioner network providers (including LTSS).

    a. What information is reviewed as a part of this process?

    b. Are site visits made? When and how often?

5. Please describe the MCP's credentialing and re-credentialing processes for institutional providers.

    a. Are site visits a part of the process to credential and re-credential institutional providers?

b. How frequently is re-credentialing performed?

c. What items of information are typically reviewed during the evaluation and reevaluation process?

6. What other MCP operations contribute to the evaluation of a network institutional provider?

7. What criteria is the basis for denial of provider participation in the MCP's network?

8. How does the MCP verify the skills and requirements of LTSS providers, including self-directed support options? (i.e., background checks, exclusions, certifications and/or licensures)

Grievance systems (42 CFR 438.228)

1. Please describe the process for notifying the requesting provider of any decision to deny, limit, or discontinue authorization of services.

    a. What are the MCP's time frames for notification?

Sub contractual relationships and delegation (42 CFR 438.230 and 457.1233(b))

1. What types of activities are performed by (and thereby delegated to) contractors?

2. Please describe your MCP's process for identifying and selecting contractors.

    a. How is it determined that a contractor has the ability to perform the activities that are being delegated by the MCP?

3. What steps does your MCP take to determine that an entity to which functions will be delegated is capable of performing the delegated functions?

    a. Please describe any evaluation process that your MCP has in place.

4. For each of the activities that have been delegated:

    a. Is there any ongoing monitoring and review of entities performing delegated activities?

        i. How this is accomplished?

        ii. Is the process the same for all delegates at all times?

        iii. Are there any instances when your MCP varies the monitoring process or the timing of evaluation?

    b. Does your MCP perform an annual evaluation of the delegate's sub-contractor's performance?

        i. Please describe the process to conduct this evaluation. What is included in the evaluation?

    c. What is done with the results of delegate evaluations?

        i. Do the results of the most recent delegate subcontractor evaluations specify any necessary corrective action for problems or deficiencies identified?

        ii. Please describe some of the recommendations made to delegates in an effort to improve performance.

d. What steps does your MCP take to assure that the delegate implements corrective actions?

e. Who in the MCP is assigned responsibility for monitoring the delegate's performance?

5. Does the MCP delegate any of its activities to LTSS providers? If yes, how is the provider's ability to carry out delegated activities determined and monitored?

Practice guidelines (42 CFR 438.236 and 457.1233(c))

1. What mechanism is in place to consult affiliated providers as practice guidelines are adopted and re-evaluated?

2. How are practice guidelines disseminated to providers?

Quality assessment and performance improvement program (42 CFR 438.330)

1. How does the MCP monitor LTSS provider quality, appropriateness of care, compliance with state and plan requirements, and enforce corrective action when necessary?

2. Please describe any QAPI activities implemented to assess or improve communications with the MCP's providers.

   a. What are the results of these activities?

3. Please describe any QAPI activities implemented to assess or improve the credentialing process and oversight of the MCP's delegated activities.

   a. What are the results of these activities?

Health information systems (42 CFR 438.242 and 457.1233(d))

1. Does the MCP have data collection requirements for LTSS providers, health care facilities, and physicians?

   a. How are the requirements communicated to these organizations and individuals?

2. If issues arise in the timeliness and accuracy of the data that is being collected and submitted, who notifies the health care facility or physician?

Information about the grievance system to providers and subcontractors (42 CFR 438.414 and 457.1260)

1. When are providers given information about the MCP's Medicaid and CHIP complaint and grievance system?

   a. What is typically included in the information given to providers relative to Medicaid and CHIP grievances?

Enrollee Services Staff Interview

Instructions. The enrollee services staff interview provides an opportunity to speak with MCP staff members who are responsible for communicating with enrollees. Relevant staff includes those individuals responsible for written communication, phone responses to inquiries and problems, the complaint and grievance system and other services designed to assist Medicaid and CHIP enrollees in their use of MCP services. Through this interview, the EQRO will assess the manner in which the MCP and its provider network address issues relating to the rights of enrollees; the MCP's efforts regarding enrollee education and communication; the mechanisms in place to insure that information needed to provide services to enrollees is available throughout the MCP; and the aspects of enrollee services are measured, how collected data is assessed, and what efforts have been made to improve enrollee services.

Enrollee right to information (42 CFR 438.100 and 457.1220; 42 CFR 438.10 and 457.1207)

1. What information is routinely provided to Medicaid and CHIP enrollees?
    a. What is the process for disseminating information to new and existing enrollees?
    b. How often is information distributed to existing enrollees?
    c. In what format is this information presented?
2. Please describe or provide copies of the formats in which information is presented to enrollees.
3. In what languages or alternative formats are enrollee materials and information presented? If yes, how was it determined that materials were needed in different languages?
4. Does the MCP provide written materials in alternative formats for the visually impaired? If yes, how did the MCP determine that materials were needed for the visually impaired?
5. Please describe the procedure for handling calls to the MCP from non-English speaking enrollees.
    a. What instruction or guidance is available for providers that may need interpretation assistance to provide care and services to assigned enrollees?
6. To what extent is the MCP responsible for responding to requests for information for potential Medicaid and CHIP enrollees?
7. How does the MCP inform enrollees (and potential enrollees, if applicable) about how to obtain oral interpreter services if they have limited proficiency in English?
8. Are there any benefits that an enrollee is entitled to under the Medicaid and CHIP program, including LTSS benefits, but that are not made available through the MCP contract? If yes, what are those benefits? How are enrollees made aware of the Medicaid and CHIP program benefits that are outside the scope of services available through the MCP?
9. How does the MCP ascertain the primary language spoken by the individual Medicaid and CHIP enrollees?
10. Are enrollees provided with a listing of primary care providers? If yes, does the listing include providers' non-English language capabilities?
11. Does your MCP give written notice of termination of a contracted provider to enrollees who receive primary care from, or are seen on a regular basis by, the terminated providers? If yes, how is this accomplished? Have you had to make any such notifications in the last year?

12. Does your MCP give enrollees any notice of significant changes in the information in the Enrollee Handbook? When and how does this occur? Have you had to make any such notifications in the last year?

13. How does the MCP ensure that information and instructional materials intended for enrollees and potential enrollees are easily understood by those with a variety of cognitive and intellectual capabilities?

14. How does the MCP provide its enrollees information about provider appeal rights regarding coverage of a service?

Enrollee right to respect, dignity, and privacy (42 CFR 438.100 and 457.1220; and 42 CFR 438.206-210 and 457.1230(a-d))

1. How does the MCP ensure that its own facilities and those of its affiliated providers comply with enrollee rights to treatment with respect, dignity, and consideration for privacy and confidentiality of information?

    a. Are there any additional considerations made for providers of LTSS or other specialized services, where services may be of a more intimate nature or occur in a more isolated setting? Please provide examples.

Enrollee right to participate in decisions regarding his or her health care (42 CFR 438.100 and 457.1220); and regarding advance directives (42 CFR 438.10(g) and 457.1207; and 42 CFR 438.206-210 and 457.1230(d))

1. To what extent does the MCP allow enrollees to participate in care and treatment decisions? Please describe some of the ways in which this is accomplished.

2. To what extent are Medicaid and CHIP enrollees informed at the time of enrollment of their right to accept or refuse treatment and to execute an advance directive, and the MCP's policies on implementation of that right?

Enrollee right to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional (42 CFR 438.100 and 457.1220; and 42 CFR 438.206-210 and 457.1230(a-d))

1. How does the MCP monitor compliance of enrollee rights to service availability, coordination and continuity of care, coverage and authorization of service, and to obtain a second opinion from an appropriately qualified health professional?

    a. What are the most recent results of this monitoring?

Enrollee right to request and receive medical records (42 CFR 438.100 and 457.1220; and 42 CFR 438.206-210 and 457.1230(a-d))

1. How do enrollees obtain access to their medical records maintained by the MCP, including records maintained by providers/contractors from whom the enrollee has received services?

2. How are enrollees informed of their right to request and receive a copy of their medical records, and to request that they be amended or corrected?

3. Has the MCP received any complaints about an enrollee's inability to access their medical records in a timely manner? If yes, what was the volume and nature of the complaints? How were they resolved?

Compliance with other federal and state laws (42 CFR 438.100 and 457.1220; and 42 CFR 438.206-210 and 457.1230(a-d))

1. Does the MCP orient staff to the federal and state laws on enrollee rights that must be observed during day-to-day operations? Does the MCP remind staff of the importance of observing these laws during interactions with other employees and with enrollees?

2. Describe the procedure for handling an enrollee complaint involving a perceived violation of their rights.

Availability of services (42 CFR 438.206 and 457.1230(a))

1. What processes does the MCP take to monitor availability and accessibility of services to Medicaid and CHIP enrollees?

    a. What are the most recent findings from this process?

2. Is there any information that is routinely collected and monitored to determine that care and services are being rendered to Medicaid and CHIP enrollees in a timely manner?

    a. What are the most recent findings of this monitoring?

Availability of services-delivery network (42 CFR 438.206(b) and 457.1230(a))

1. Are Medicaid and CHIP enrollee requests for out-of-network providers tracked?

    a. How often do Medicaid and CHIP enrollees request services from out-of-network providers?

    b. What are their reasons for requesting out-of-network providers?

2. How often do Medicaid and CHIP enrollees receive services from out-of-network providers?

Availability of services-Furnishing of services (42 CFR 438.206(c) and 457.1230(a))

1. **Ask only if MCP is a MCO/ PIHP or PAHP:** Are MCO/ PIHP/PAHP and provider services available 24 hours a day, 7 days a week, when medically appropriate?

2. How frequently does enrollee services staff receive complaints about provider hours of operation not being available to enrollees when medically necessary?

3. Does the MCP conduct surveys, focus groups or other activities to receive the feedback of Medicaid and CHIP enrollees? If yes, what are the most recent findings about Medicaid and CHIP enrollee perceptions about availability of MCP and provider services?

Coordination and continuity of care (42 CFR 438.208 and 457.1230(c))

1. How are Medicaid and CHIP enrollees with special health care needs—including both individuals with special health care needs identified by your MCP and individuals identified by the state Medicaid and CHIP agency or its agent

2. How does this MCP identify and assess Medicaid and CHIP enrollees with special health care needs?

3. What proportion of Medicaid and CHIP enrollees has an ongoing source of primary care?

Coverage and authorization of services (42 CFR 438.210 and 457.1230(d))

1. How frequently does enrollee services staff receive complaints about difficulty obtaining emergency or post-stabilization services?

2. Please describe the procedure for handling member calls regarding need for emergency services.

Enrollment and disenrollment (42 CFR 438.56 and 457.1212)

1. Please describe the procedures that are followed when a request for disenrollment is received from an enrollee.

2. How is disenrollment information tracked through or by other MCP operations (e.g., grievance process, quality improvement, administration)?

    a. How many requests by Medicaid and CHIP enrollees were received last year for disenrollment?

    b. What were the cited causes?

Grievance systems (42 CFR 438.228)

1. Please describe the process for notifying Medicaid and CHIP enrollees of any decision to deny, limit, or discontinue a request for service.

    a. What are the MCP's time frames for notification?

Practice guidelines (42 CFR 438.236 and 457.1233(c))

1. How often does your MCP receive requests from enrollees and potential enrollees for practice guidelines? How does your MCP respond to these requests?

2. When and how does your MCP disseminate practice guidelines to enrollees?

Grievance system - general requirements (42 CFR 438.402 and 457.1260)

1. What enrollee materials contain information about the complaint and grievance processes? When are enrollees presented with this information?

2. Please describe the process for handling authorization decisions that are adverse to the enrollee.

Handling of grievances and appeals (42 CFR 438.406 and 457.1260)

1. What MCP department or staff members are responsible for assisting enrollees to use the organization's complaint or grievance system, including completing forms, or taking other steps to resolve an appeal or grievance? What kind of assistance is made available to Medicaid and CHIP enrollees?

2. What are the qualifications and credentials of individuals who make decisions on grievances and appeals?

    a. How does the MCP ensure that these individuals have not been involved in any previous level of review or decision-making?

    b. How does the MCP ensure that these individuals have the appropriate clinical expertise in treating the enrollee's condition or disease, if deciding any of the following:

i. An appeal of a denial that is based on lack of medical necessity

ii. A grievance regarding denial of expedited resolution of an appeal

iii. A grievance or appeal that involves clinical issues

3. How does your MCP treat oral requests by Medicaid and CHIP enrollees to appeal actions?

4. As part of an appeal, to what extent do enrollees and their representatives have an opportunity to:

   a. Present evidence, and

   b. Examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process

Resolution and notification: Grievances and appeals (42 CFR 438.408 and 457.1260)

1. Please describe the MCP's grievance resolution process.

2. Please describe the MCP's appeal resolution process.

3. How is it determined that an enrollee's appeal requires expedited resolution?

4. What percent of appeal resolutions that are completely or partially adverse to Medicaid and CHIP enrollees are appealed to the state fair hearing process or review? Of these, what percent are overturned by the state Medicaid and CHIP agency?

Expedited resolution of appeals (42 CFR 438.410 and 457.1260)

1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? If yes, please describe this process.

   a. What are the time frames defined for this process?

2. How does the MCP notify enrollees of any denials of a request for expedited resolution?

3. Have there been any complaints by Medicaid and CHIP enrollees that their requests for expedited appeals have not been acted upon timely (e.g., within three working days). If yes, how many such complaints were received in the year under review?

Record keeping and reporting requirements (42 CFR 438.416 and 457.1260)

1. How are Medicaid and CHIP grievances and appeals registered and tracked for resolution? Is each grievance and appeal tracked through to resolution?

2. How often is Medicaid and CHIP grievance and appeal information analyzed for trends?

   a. Who receives this analysis?

   b. Does the MCP provide any information to the state relative to its grievances and appeals?

3. How long are Medicaid and CHIP grievance and appeal records retained?

4. To what extent is information on Medicaid and CHIP enrollee grievances and appeals analyzed and included as part of your MCP's Quality Assessment and Performance Improvement Program?

Continuation of benefits while the MCP or PIHP appeal and the state fair hearing are pending (42 CFR 438.420)

1. What happens to enrollee benefits once continuation of benefits has been denied by the MCP, and an appeal has been filed by the enrollee or the treating physician?

    a. Are there any mechanisms in place to continue the benefits pending the outcome of the appeal? If yes, under what circumstances?

Utilization Management Staff Interview

Instructions. MCP interview participants should include the Medical Director, utilization management directors or managers, utilization management review staff, case managers or care coordinators, and any other individuals who have information pertinent to these regulatory provisions. [Note: This interview can be combined with the Medical Director interview or the Care Coordinators and Case Managers interview.]

The utilization management interview provides an opportunity to discuss with the MCP staff responsible for tracking and managing the utilization of MCP services. Through these interviews, the reviewer(s) will assess delivery network, service authorization; the use of practice guidelines, and grievances and appeals; and management of resources across all MCP network provider sites where enrollees receive health care.

Availability of services (42 CFR 438.206)

1. How frequently does the MCP evaluate the volume and enrollee access to LTSS services? What factors are used in evaluation of the LTSS network?

    a. How does the MCP evaluate the expected utilization of institutional care in comparison with use of home and community based services (HCBS) as an alternative?

2. How frequently does the MCP evaluate the volume of and enrollee access to family plan and women's health services? What factors are sued to evaluate the network?

3. How frequently does the MCP evaluate the volume of and enrollee access to specialist health services? What factors are used to evaluate the network?

4. How frequently does the MCP evaluate the volume of and enrollee access to children's dental care? What factors are used to evaluate the network?

5. How frequently does the MCP evaluate the volume of and enrollee access to behavioral health services? What factors are used to evaluate the network?

6. How frequently does the MCP evaluate the volume of and enrollee access to family planning and women's health services? What factors are used to evaluate the network?

7. How frequently does the MCP evaluate the volume of and enrollee access to any other specific services, such as HIV and foster care services? What factors are used to evaluate the network?

Delivery network (42 CFR 438.206(b) and 457.1230(a))

1. What procedures must a Medicaid and CHIP enrollee follow if he/she wishes to receive a second opinion?

    a. For what types of services are second opinions available?

Coverage and authorization of services (42 CFR 438.210 and 457.1230(d))

1. What types of services require pre-authorization?

2. What are the MCP's time frames for processing standard and expedited requests for service authorization?

3. How does the MCP monitor its compliance with these time frames?

    a. What sources of documentation exist to provide evidence of the monitoring by the MCP?

4. How often and under what circumstances are requesting providers consulted when the MCP makes service authorization decisions?

5. To what extent does the MCP assess the consistency of authorization decisions? How does the MCP do this?

6. What is the process when a decision is being made to deny authorization for a service?

    a. Who makes the decision to deny a request to authorize a service?

7. Please describe the process for notifying the requesting provider and the enrollee of any decision to deny, limit, or discontinue authorization of services.

    a. What information is typically included in enrollee and provider notification?

    b. What are the MCP's time frames for notification?

8. To what extent if at all s inappropriate use of emergency rooms by your Medicaid and CHIP enrollees a concern for your MCP?

9. Has your MCP investigated a potential relationship between inappropriate emergency department use and enrollee access to routine and urgent care, or reviewed the most frequent diagnosis resulting in inappropriate emergency department use?

10. What was the volume of denied claims for emergency and post-stabilization services in the most recent year?

11. Does the authorization process differ between acute and primary services and LTSS, or any other providers? If yes, how?

Grievance systems (42 CFR 438.228)

1. What types of services require pre-authorization?

2. Please describe the process for notifying the requesting provider and the enrollee of any decision to deny, limit, or discontinue authorization of services.

    a. What information is typically included in enrollee and provider notification?

    b. What are the MCP's time frames for notification?

3. How does your MCP track requests for covered services that the MCP or its providers has denied?

4. What was the volume of denied request for services in the most recent year?

Application of practice guidelines (42 CFR 438.236(c) and 457.1233(c))

1. What practice guidelines have the MCP adopted?

2. To what extent are your utilization management review guidelines (criteria) consistent with these practice guidelines?

    a. How do you promote or ensure consistency?

3. Please describe how utilization management review guidelines (criteria) are modified to reflect the adoption or revision of practice guidelines.

    a. Are both sets of guidelines updated through the same process, at the same time?

Quality assessment and performance improvement program (42 CFR 438.330 and 457.1240(b))

1. What information is analyzed to detect over- and under-utilization of services?

    a. Who is involved in the analysis and review of this information?

    b. What, if any trends been identified?

    c. What are the typical follow-up actions taken when either condition is discovered?

    d. How does the MCP monitor LTSS utilization patterns? Are there any services for which specialized or more focused utilization analysis is used?

Grievance system - General requirements (42 CFR 438.402 and 457.1260)

1. Please describe the appeals process and the role of utilization management staff in the resolution process. Elaborate on the particular steps, including time frames, in which utilization management staff is involved.

2. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of an appeal? Please describe this process and its time frame.

3. Does the MCP's grievance and appeal system differ for LTSS vs. acute and primary care services? If yes, how?

Handling of grievances and appeals (42 CFR 438.406 and 457.1260)

1. What MCP department or staff is responsible for assisting enrollees in using the MCP's appeal or grievance system, including completing forms, or taking other steps to resolve an appeal or grievance?

2. What are the qualifications and credentials of individuals who make decisions on grievances and appeals?

    a. How does the MCP ensure that these individuals have not been involved in any previous level of review or decision-making?

    b. How does the MCP ensure that these individuals have the appropriate clinical expertise in treating the enrollee's condition or disease, if deciding any of the following:

        i. An appeal of a denial that is based on lack of medical necessity

        ii. A grievance regarding denial of expedited resolution of an appeal

        iii. A grievance or appeal that involves clinical issues

Expedited resolution of appeals (42 CFR 438.410 and 457.1260)

1. Is there a process in place for those instances when an enrollee's health condition requires expedited resolution of a grievance? If yes, please describe this process. What are the time frames defined for this process?

2. How does the MCP notify enrollees of any denials of a request for expedited resolution?

Continuation of benefits while the MCP or PIHP appeal and the state Fair Hearing are pending (42 CFR 438.420)

1. What happens to enrollee benefits once continuation of benefits has been denied by the MCP, and an appeal has been filed by the enrollee or the treating physician or other provider, including providers of LTSS?

    a. Are there any mechanisms in place to continue the benefits pending the outcome of the appeal and if so, under what circumstances?

    b. How are enrollees notified of this mechanism?

Medical Directors Interview

Instructions. The interview with the Medical Director provides an opportunity to assess MCP processes for authorizing services and coverage for those services. The interview will address such topics as provider involvement in the review of criteria used in the utilization management process, consistency between utilization management criteria and practice guidelines, and Quality Assessment and Performance Improvement efforts.

Coverage and authorization of services (42 CFR 438.210 and 457.1230(d))

1. How does the MCP monitor its compliance with the state's time frames for processing standard requests for service authorization?

2. What are the MCP's standards for processing expedited requests for service authorization? How does the MCP monitor its compliance with these time frames?

3. Under what circumstances are requesting providers consulted when responding to service authorization requests?

4. How does the MCP ensure consistent application of criteria used in making service authorization decisions?

5. What mechanism does the MCP use to assure that any decision to deny a service authorization request or to authorize a service in an amount, duration or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollees' condition or disease or by a professional with expertise in serving special populations (e.g. Developmental Disabilities), in special services (e.g., Vocational Rehabilitation), or with other LTSS expertise as appropriate?

6. How are employees and any contractors used by the MCP to perform service authorization and utilization management financially compensated?

    a. Are they paid in any way other than on a straight salary or per case review basis?

    b. Do their financial compensation arrangements involve the use of any financial incentives?

7. How does the MCP apply the definition of 'medically necessary services' to LTSS for activities that support age-appropriate growth and development and/or the ability to attain, maintain or regain functional capacity?

Quality assessment and performance improvement program (42 CFR 438.330 and 457.1240(b))

1. Does the MCP have any processes for reviewing claims, payment systems, encounter data, electronic health records, and medical records to assess utilization of services?

    a. Does the MCP utilize a health information exchange process?

    b. What reports on service utilization are regularly produced by these processes?

    c. What are the most recent findings with respect to over- and under-utilization?

2. How does your MCP define enrollees with "special health care needs"? How are these enrollees identified within your MCP?

3. How does your MCP assess the quality and appropriateness of care furnished to enrollees with special health care needs? Please provide examples.

4. Does the state require your MCP to address a specific topic or topics in your performance improvement projects? If yes, what types of projects are required? For each PIP, at a minimum, include how significant improvement was measured, how improvement will be/was sustained, and how beneficiary health outcomes and satisfaction will be/was measured, and how the intervention will/has improved access and/or quality of care.

    a. For duals-only MCPs, was a Medicare Advantage PIP substituted for a state-required PIP?

    b. Has CMS specified any specific PIPs? If yes, what types of projects are required? For each PIP, at a minimum, include how significant improvement was measured, how improvement will be/was sustained, and how beneficiary health outcomes and satisfaction will be/was measured, and how the intervention will/has improved access and/or quality of care.

5. Does the state require your MCP to collect and submit performance measures or to submit data to the state for it to calculate performance measures? If yes, what performance measures are specified by the state and who calculates each measure, the MCP or the state?

    a. If CMS specifies any performance measures, what performance measures are collected and submitted, if any?

    b. If the MCP provides LTSS, what LTSS performance measures are collected and submitted, including but not limited to measures of quality of life, rebalancing institutional and community-based services and community integration activities?

6. Does the state require your MCP to evaluate the impact and effectiveness of its quality assessment and performance improvement program?

    a. How does your MCP conduct its evaluation? What aspects of the program are included in the evaluation?

    b. How often does your MCP conduct its evaluation?

    c. What were the findings of the MCP's most recent self-evaluation?

    d. What action did the MCP take as a result of these findings?

    e. What is reported to the state, and how often?

7. How does the state review the impact and effectiveness of the MCP's QAPI program, including outcomes and trended results from the PIPs, reporting on performance measures, and the results of community integration for beneficiaries receiving LTSS?

    a. What is your MCP's role in the state's evaluation?

    b. What information, if any, does your MCP provide to the state?

    c. What feedback, if any, does your MCP receive from the state? How does your MCP implement the feedback?

Case Managers and Care Coordinators Interview

Instructions. Case managers and care coordinators typically are among the few MCP staff with opportunity to interact closely and directly with Medicaid and CHIP enrollees. These individuals are often responsible for guiding enrollees to the care and services available through their benefits and the provider network. These individuals play a key role in assisting enrollees in managing and maintaining their health and managing complex conditions. Interviewing these individuals will provide reviewers the opportunity to discuss topics surrounding MCP processes related to service availability, enrollee needs and special populations, and continuity and coordination of care. [Note: This interview can be combined with the Medical Director interview or the Utilization Management interview.]

Enrollee rights (42 CFR 438.100, and 42 CFR 438.206-210)

1. How are the available options for LTSS identified and presented to enrollees?

2. How are enrollees engaged in decisions about the use of LTSS?

3. How is the enrollee's right to be free from restraint or seclusion monitored for enrollees receiving LTSS?

Enrollee right to participate in decisions regarding his or her health care (42 CFR 438.100(b)(iv) and 457.1220)

1. To what extent does the MCP allow enrollees to participate in care and treatment decisions? Please describe some of the ways in which this is accomplished.

Availability of services (42 CFR 438.206)

1. How does the MCP evaluate the expected utilization of institutional care in comparison with the use of HCBS as an alternative?
2. How does the MCP evaluate availability of services for individuals with intellectual and developmental disabilities? What factors are used to evaluate the network?

3. How does the MCP evaluate availability of services for children with special health care needs? What factors are used to evaluate the network?

4. How does the MCP evaluate availability of services for individuals with behavioral health conditions? What factors are used to evaluate the network?

5. How does the MCP evaluate availability of services for dual-eligibles? What factors are used to evaluate the network?

6. How does the MCP evaluate availability of services for individuals with HIV? What factors are used to evaluate the network?

7. What methods does the MCP use to improve cultural competency?

Furnishing of services and timely access (42 CFR 438.206(c) and 457.1230(a))

1. To what extent are services offered through the MCP available to Medicaid and CHIP enrollees and others coordinating care 24 hours per day, 7 days per week when medically necessary?

2. What types of services require pre-authorization?

Coordination and continuity of care (42 CFR 438.208 and 457.1230(c))

1. Does this MCP screen Medicaid and CHIP enrollees to identify those with special health care needs? If yes, how is this implemented?

2. How are Medicaid and CHIP enrollees with special health care needs—including any individuals with special health care needs identified by your MCP and any identified by the state Medicaid agency or its agent—identified and tracked within your MCP?

3. Does this MCP assess Medicaid and CHIP enrollees with special health care needs? If yes, how are these activities conducted?

4. Does this MCP require written treatment plans to be developed for enrollees with ongoing special conditions that require a course of treatment or regular care monitoring? If yes, how is it decided which Medicaid and CHIP enrollees will receive a written treatment plan?

5. If treatment plans are required by this MCP, how does the MCP ensure that treatment plans for individuals with special health care needs address the needs identified by the assessment?

6. Please describe the treatment planning process for individuals with special health care needs and the process for determining and assuring appropriate use of specialists.

7. Within the last year, how many treatment plans have been developed?

    a. How many requests made by enrollees for review of treatment plans have been denied?

    b. What were the reasons for these denials?

    c. How many treatment plans have been denied?

    d. What were the reasons for these denials?

8. What process(es) is/are used to coordinate services for enrollees?

    a. Are their different types of care coordination mechanisms for different types of enrollees? If yes, how are these different and how do they work?

9. Who is responsible for coordinating the care of individuals with special health care needs?

10. What are the procedures for coordinating the services that the MCP furnishes to the enrollee with services the Medicaid and CHIP enrollee receives from any other MCOs, PIHPs, and PAHPs?

11. If the MCP establishes separate coordination of care for medical services, LTSS, and mental health and substance abuse services, how does the MCP ensure exchange of necessary information between providers?

12. How is post-acute care coordinated?

13. How are LTSS providers involved in person-centered assessment, person-centered care and service planning, coordination and authorization processes?

Coverage and authorization (42 CFR 438.210 and 457.1230(d))

1. What types of services require pre-authorization?

2. Are emergency back-up plans created for all enrollee's? If not, how is the need for an emergency back-up plan determined? How is the emergency back-up plan shared with all appropriate parties?

Quality assessment and performance improvement program (42 CFR 438.330 and 457.1240(b))

1. What processes does the MCP have to detect underutilization and overutilization? What activities, such as QAPI projects, has the MCP implemented to address these issues?

    a. What are the results of these activities?

2. What activities, such as QAPI projects, has the MCP implemented to assess and improve care coordination?

    a. What are the results of these activities?

Providers and Contractors Interview (as appropriate and time and resources permit)

Instructions. While interviewing providers and contractors requires additional time and resources, it is an opportunity to obtain further information about MCP performance from those health care and LTSS professionals and institutions that often serve as the first point of contact for Medicaid and CHIP members and health care providers. Provider and contractor interviews should therefore be considered as an optional component of this protocol, to be considered whenever there is a strong need for additional information and when time and resources permit. The interview participants should be selected from the provider network and should offer representative view of the breadth of the MCP's primary care, specialist, LTSS, and institutional providers. These persons can often clarify issues pertaining to communication, traversing the system, assuring enrollee rights, and delivery of care and services to the enrolled population.

There are several ways to conduct the interview. It can be arranged with a group of individual health care practitioners, a group of institution representatives, and a group of LTSS providers, or coordinated as one interview for each group or as a combined group. Geographic location of providers should be considered, and conference calls are a viable option for conducting an interview of this type, and often preferred by providers as only a brief interruption in their daily activities. For this interview to be effective, reviewers should emphasize that this is an opportunity to provide insight on the MCP's performance and not an evaluation of the care and services offered to Medicaid and CHIP enrollees.

Enrollee rights (42 CFR 438.10 and 457.1207) and Enrollee information (42 CFR 438.100 and 457.1220; and 42 CFR 438.206-210 and 457.1230(a-d))

1. When the MCP's enrollees present for services, do they appear to have a clear understanding of their rights, responsibilities, and benefits? How to obtain services?

2. Does the MCP provide you with information on where to refer enrollees who are having difficulty understanding the materials that have been provided to them by the MCP?

3. How often do you and your staff have to assist enrollees with understanding the materials provided by the MCP?

4. Does the MCP require providers to have access to oral interpreter services?

5. Does the MCP provide your office with guidance or assistance is accessing interpreter services if necessary?

Enrollee rights to receive information on available treatment options (42 CFR 438.102 and 457.1222; and 42 CFR 438.206-210 and 457.1230(a-d)); Provider-enrollee communications (42 CFR 438.100 and 457.1220; and 42 CFR 438.206-210 and 457.1230(a-d))

1. Does the MCP place any limits on your ability to counsel or advise a Medicaid and CHIP enrollee on treatment options that may be appropriate for the enrollee's condition or disease?

2. Does the MCP encourage providers to share with enrollees information on available treatment options and alternatives?

    a. Does this include options and alternatives that are within as well as those outside the scope of the enrollees benefits? If yes, how does the MCP do this?

Availability of Services: Furnishing of services (42 CFR 438.206(c) and 457.1230(a))

1. Are your hours of operation for Medicaid and CHIP enrollees different from the hours of operation for other MCP enrollees? If yes, why?

Practice guidelines (42 CFR 438.236 and 457.1233(c))

1. Are affiliated providers/contractors consulted as practice guidelines are adopted and re-evaluated?

2. How does the MCP make providers/contractors aware of practice guidelines currently in use and those under consideration for adoption?

Expedited resolution of appeals (42 CFR 438.410 and 457.1260)

1. Have there been any instances in the most recent year under review when the MCP took any punitive action against you for requesting an expedited resolution of an appeal on behalf of Medicaid and CHIP enrollees or for supporting an enrollee's appeal?

END OF WORKSHEETS FOR PROTOCOL 3

Protocol 4. Validation of Network Adequacy

A Mandatory EQR-Related Activity

ACTIVITY 1: DEFINE THE SCOPE OF THE VALIDATION

ACTIVITY 2: IDENTIFY DATA SOURCES FOR VALIDATION

ACTIVITY 3: REVIEW INFORMATION SYSTEMS UNDERLYING NETWORK ADEQUACY MONITORING

ACTIVITY 4: VALIDATE NETWORK ADEQUACY MONITORING DATA, METHODS, AND RESULTS

ACTIVITY 5: COMMUNICATE PRELIMINARY FINDINGS TO MANAGED CARE PLANS

ACTIVITY 6: SUBMIT FINDINGS TO STATE

PROTOCOL FOUR

Background

States must ensure that Medicaid and Children's Health Insurance Program (CHIP) managed care plans (MCPs) maintain provider networks that are sufficient to provide timely and accessible care to Medicaid and CHIP beneficiaries across the continuum of services. As set forth in 42 CFR 438.68, states are required to set quantitative network adequacy standards for MCPs that account for regional factors and the needs of the state's Medicaid and CHIP populations.[61]

The purpose of this protocol is to guide the external quality review organization (EQRO) in conducting the validation of network adequacy during the preceding 12 months to comply with requirements set forth in 42 CFR 438.68 and, if the state enrolls American Indians and Alaska Natives (AI/AN) in the MCO, PIHP, or PAHP, 42 CFR 438.14(b)(1).[62] This includes validating data to determine whether the network standards, as defined by the state, were met. It does not include evaluating the state's network adequacy standards. This mandatory external quality review (EQR) protocol applies to managed care organizations

[61] eCFR :: 42 CFR Part 438 -- Managed Care Network Adequacy at 42 CFR 438.68

[62] eCFR :: 42 CFR Part 438 -- Managed Care EQR Activities at 42 CFR 438.358(b)(iii)

(MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs), which are collectively referred to here as MCPs.

Regulations providing for provider-specific network adequacy standards are set forth at 42 CFR 438.68(b). The Medicaid network adequacy standards are applied to CHIP per 42 CFR 457.1218.[63] See Box 4.1 for network adequacy provisions in the managed care final rule.

Box 4.1. Network Adequacy Provisions Under 42 CFR 435.68(b) and 457.1218

- States that contract with MCPs to provide Medicaid or CHIP services must develop and enforce network adequacy standards (42 CFR 438.68(a)).
  - States must at a minimum set quantitative network adequacy standards for the following provider types, if covered under the managed care contract: primary care, adult and pediatric; obstetrics/gynecology (OB/GYN); behavioral health (mental health and substance use disorders), adult and pediatric; specialist (as designated by the state), adult and pediatric; hospital; pharmacy; and pediatric dental (42 CFR 438.68(b)(1)).
  - States that contract with MCPs to provide long-term services and supports (LTSS) must develop a quantitative network adequacy standard for LTSS provider types (42 CFR 438.68(b)(2)).
- States may elect to use a variety of quantitative standards including, but not limited to, minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation (for example, extended evening or weekend hours); and/or combinations of these quantitative measures (85 Fed. Reg. 72805 (Nov. 13, 2020)).
- In setting network adequacy standards, states must consider the diverse health care needs of their Medicaid and CHIP populations, including beneficiaries with special needs, individuals living with disabilities, people with limited English proficiency, and the characteristics of their providers (in terms of training, experience, and specialization) (42 CFR 438.68(c)).
- States must set network adequacy standards for all geographic areas covered by their contracts with MCPs. States may set network adequacy standards for the same provider type that vary based on geographic area (42 CFR 438.68(b)(3)).
- States must consider the use of telehealth if needed to ensure sufficient network adequacy when developing their network adequacy standards (42 CFR 438.68(c)(1)(ix)).
- States must require MCPs that enroll AI/AN beneficiaries to demonstrate that their networks include sufficient Indian Health Care Providers (IHCPs) so as to ensure timely access to services for AI/AN populations (42 CFR 438.14(b)).

Source: 2020 Medicaid and CHIP managed care final rule, available at https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicaid-and-childrens-health-insurance-program-chip-managed-care.

Note: Medicaid network adequacy standards under 42 CFR 438.68 are adopted for CHIP at 42 CFR 457.1218. Medicaid network and coverage requirements under 42 CFR 438.14 for AI/AN beneficiaries are adopted for CHIP at 42 CFR 457.1209.

[63] Provider-specific network adequacy standards were added to the Medicaid and CHIP regulations in November 2020 rulemaking. More information about this rulemaking is available at https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicaid-and-childrens-health-insurance-program-chip-managed-care.

State-defined network adequacy standards must be included in the state's quality strategy required under 42 CFR 340(b)(1). States must publish their quality strategies after opportunity for public comment consistent with transparency requirements in 42 CFR 438.340(c)(1) and (d). States may work with MCPs to drive improvement in network adequacy and beneficiary access to care, according to their state quality strategy goals and objectives and quality assessment and performance improvement (QAPI) programs.

MCPs that operate in multiple states must adhere to each state's set of quantitative network adequacy standards. States should annually assess whether their standards continue to align with the needs of their beneficiary populations, and update their standards as needed.

Medicaid and CHIP MCPs must conduct various activities to assess the adequacy of their networks as well as maintain provider and beneficiary data sets that allow monitoring of their networks' adequacy. States have flexibility in determining the strategies used to assess network adequacy. Examples include:

- Geomapping to determine if provider networks meet quantitative standards, such as time and distance standards
- Calculation of provider-to-enrollee ratios, by type of provider and geographic area
- Analysis of in-network and out-of-network utilization data to determine gaps in realized access (actual use of care)
- Appointment availability and accessibility studies, such as studies assessing the proportion of in-network providers accepting new patients or the average wait time for an appointment
- Telephone surveys or site visits to validate provider directory information

MCPs must share the data, analyses, and results from their network adequacy assessment activities with EQROs. The activities described below will guide the EQRO in (1) validating the data and methods used by MCPs to assess network adequacy; (2) validating the results and generating a validation rating; and (3) reporting the validation findings in the annual EQR technical report.

This protocol is organized into three phases, which includes the following validation process: (1) planning, (2) analysis, and (3) reporting. In recognition of changing practices related to the COVID-19 pandemic, each phase is designed to support activities that may be conducted on-site or remotely.

While the protocol is written as if the EQRO is validating network adequacy analyses conducted by the MCP, this protocol also applies to states that opt to conduct the network adequacy analysis using data submitted by the MCPs or using other data sources. Note that when states conduct network adequacy analyses under this protocol, the state (1) will conduct an analysis for each MCP rather than aggregated to the state level and (2) will need to share its analysis as well as the data used with the EQRO for validation. The EQRO will validate the indicators produced

by the state as if they were calculated by the MCP. In addition, consistent with validation of other EQR activities, the EQRO may contract with a third-party vendor to conduct the data validation reported in the annual EQR technical report.

Other protocols, such as Protocol 2 (Validation of Performance Measures), Protocol 3 (Review of Compliance with Medicaid and CHIP Managed Care Regulations, including availability of services), and Protocol 5 (Validation of Encounter Data Reported by the Medicaid and CHIP Managed Care Plan), may provide important information for network adequacy validation. For example, the EQRO's compliance findings around availability of services in in Protocol 3 could inform the validation of network adequacy.

Getting Started on Protocol 4

To complete this protocol, the EQRO undertakes six activities for validating network adequacy for each MCP (Figure 4.1). These six activities fall into three phases: (1) planning, which includes defining the scope of the validation (Activity 1), and identifying data sources (Activity 2); (2) analysis, which includes reviewing information systems (Activity 3), and validating data, methods and results (Activity 4); and (3) reporting, which includes communicating preliminary findings to MCPs (Activity 5), and submitting findings to the state (Activity 6).

Figure 4.1. Protocol 4 Activities

The steps associated with Activities 1 through 6 are outlined below. Two supplemental resources are available to help EQROs validate network adequacy:

- Worksheets for Protocol 4 that EQROs can use to identify network adequacy indicators and needed data sources for validation; note concerns about MCP data; guide the validation of MCP network adequacy data, data analysis, and results; and organize findings. States and

EQROs are encouraged, but not required, to use the worksheets. The worksheets are intended to help structure the way information is collected and reported by EQROs and to promote compliance with the Network Adequacy Validation protocol.

- Appendix A. Information System Capabilities Assessment, which can be used to assess the MCP's data collection, processing, and reporting systems.

The following toolkits provide additional information and resources for states and EQROs:

- "Promoting Access in Medicaid and CHIP Managed Care: A Toolkit for Ensuring Provider Network Adequacy and Service Availability," which contains additional information and resources about the validation process. This toolkit is available at https://www.medicaid.gov/medicaid/downloads/adequacy-and-access-toolkit.pdf.
- "Promoting Access in Medicaid and CHIP Managed Care: Behavioral Health Provider Network Adequacy Toolkit," which contains information focused on network adequacy and service availability standards for behavioral health. This toolkit is available at https://www.medicaid.gov/medicaid/downloads/behavior-health-provider-network-adequacy-toolkit.pdf.

TIP

Navigate to the corresponding worksheet by clicking the WORKSHEET box under each section

Activity 1: Define the Scope of the Validation of Quantitative Network Adequacy Standards

Activity 1 is intended to ensure the EQRO has a complete understanding of the network adequacy standards and methods used by the state and MCPs to monitor network adequacy. This activity guides the state and EQRO in outlining all activities that will be conducted as part of the network adequacy validation.

Step 1: Obtain Needed Information from the State

In Activity 1, Step 1, the state identifies applicable network adequacy standards, including (1) quantitative standards developed by the state under 42 CFR 438.68(b) (adopted by CHIP at 42 CFR 457.1218); and (2) the standard for MCPs to include sufficient IHCPs in their provider networks, if the state enrolls AI/AN beneficiaries in managed care. Worksheet 4.1 may be used for this purpose.

WORKSHEET 4.1

Resource for Activity 1, Step 1

Worksheet 4.1. State Network Adequacy Standards to be Validated

- Provides a template to identify all state network adequacy standards that must be addressed in the validation

At the outset of Activity 1, the state must provide the EQRO with the following information, for validation:

- **Detailed list of the state's quantitative network adequacy standards**, by provider and plan type, as specified in the state's contracts with MCPs. This should include network adequacy standards for adult and pediatric primary care providers, OB/GYNs, adult and pediatric behavioral health providers, adult and pediatric specialists, hospitals, pharmacists, pediatric dental providers, and LTSS providers, as applicable. The state should note how standards vary by MCP type, and across urban, rural, and frontier regions, and provide the criteria used to designate urban, rural, and frontier regions.
- **Description of network adequacy data and documentation** that MCPs submit to the state to demonstrate compliance with network adequacy standards, including the following:
  - A list of data and documentation that MCPs submit to the state to demonstrate compliance
  - Frequency with which MCPs must submit each type of data and documentation
  - Any formatting requirements for data and documentation, including file formats for data files
  - Any state standards for data completeness and accuracy
  - Data dictionaries and companion guides, as applicable
- **Description of the information flow from MCPs to the state**, including the role of any contractors or data intermediaries
- **EQR network adequacy validation reports from previous years**, if applicable, which can provide useful data points for determining prior approaches for monitoring and validating network adequacy, as well as suggest areas for network adequacy improvement or challenges over time
- Information about beneficiaries who are dually eligible for Medicare and Medicaid (known as dually eligible beneficiaries) and covered by a MCP
- Any other information relevant to network adequacy monitoring and validation

Step 2: Identify and Define Network Adequacy Indicators for Validation

WORKSHEET 4.2

Resource for Activity 1, Step 2

Worksheet 4.2. Network Adequacy Indicators to be Validated

- Provides a template to identify and define the network adequacy indicator(s) associated with each network adequacy standard

After identifying the quantitative standards that the EQRO will include in the network adequacy validation, the state should identify the indicators used by MCPs to assess the state's network adequacy standards. Network adequacy indicators are metrics used to measure plan compliance with state's network adequacy standards (see Box 4.2). The state may establish network adequacy indicators that vary by MCP, or are the same for all MCPs. If the state provides MCPs with guidance around constructing indicators, the state needs to establish clear definitions for each network adequacy indicator, including criteria for calculating the numerator and denominator. The state should share this guidance with the EQRO. Worksheet 4.2 can be used for this purpose.

The state and the EQRO will need to address methodological issues that impact indicator calculations. For example, if the state sets time and distance standards for MCPs, the following questions to define the indicator for this standard will need to be answered:

- Will distance be measured "as the crow flies" or using driving distances?
- Do network adequacy standards address whether providers are accessible by public transportation?
- Are travel times measured separately for private vehicles, public transit, or other means of transportation?
- How should travel time calculations address fluctuations throughout the day or seasonally?
- How, if at all, is the availability of telehealth services considered in determining whether an MCP meets the time and distance network adequacy requirements? What limits, if any, will be placed on the types and/or quantity of telehealth services that can contribute toward network adequacy requirements?

Worksheet 4.2 provides a template for the state and EQRO to identify and define the network adequacy indicator(s) associated with each network adequacy standard identified by the state in Step 1.

Box 4.2. What is the difference between network adequacy standards and indicators?

Network adequacy standards are quantitative parameters that states establish to set expectations for contracted managed care plans' provider networks. For example, a state may set a network adequacy standard that all enrollees have access to a primary care provider (PCP) within 30 miles or 30 minutes of their home.

Network adequacy indicators are metrics used to measure adherence to network adequacy standards and to determine plan compliance with state network adequacy standards. For the example given above, the network adequacy indicator may be the proportion of enrollees who have access to a PCP within 30 miles or 30 minutes of their home.

Step 3: Identify and Define Provider Types

The state may work with the EQRO to identify and define all provider types covered by each quantitative network adequacy standard to be validated under this protocol. The state and EQRO may refer to Worksheet 4.1 to see all provider types associated with each network adequacy standard. If covered under the state's managed care contracts, the validation should include adult and pediatric primary care, OB/GYN, adult and pediatric behavioral health, adult and pediatric specialist, hospital, pharmacy, pediatric dental, and LTSS providers. The state and the EQRO should also identify additional provider types (e.g., medication-assisted treatment providers for opioid use disorder), or specialists, as defined by the state, to which the state's network adequacy standards apply. The state should provide a method or criteria for categorizing provider types, and should provide a definition for each provider type. In defining provider types, the state and the EQRO should address the following questions:

- Which provider types are authorized by the state to serve as primary care providers (for example: general practitioner, family physician, internal medicine physician, OB/GYN, pediatrician, nurse practitioner, physician assistant, or other licensed practitioner as authorized by the state Medicaid and CHIP program)?
- Which specialist types (adult and pediatric) are included in the network adequacy standards?
- How does the state categorize subspecialists? For example, a radiation oncologist could be categorized as a radiologist or an oncologist.
- Are there circumstances in which providers who primarily see adult patients count toward network adequacy standards for the pediatric population? For example, the state may allow a general psychiatrist to contribute toward network adequacy standards for the pediatric population, rather than allow only child psychiatrists to contribute toward this requirement.
- Do the provider types defined in the standards align with the provider types found in the data that the EQRO will use during the validation process? For example, the EQRO should be able to crosswalk between the state-defined provider types and the provider types found in MCP encounter data.

Step 4: Establish Network Adequacy Validation Activities and Timeline

In Step 4, the state and the EQRO should establish the approach for the network adequacy validation. In this step, the EQRO establishes activities to validate the data, monitoring methods, results, and reporting from existing MCP network adequacy assessment activities. Depending on the state's network adequacy standards and the MCP's network adequacy assessment activities, the EQRO may conduct studies to validate the MCP's results. For example, access and availability studies may be appropriate to validate information in the MCP's provider directory or to assess appointment availability. The state and the EQRO should outline the activities that the EQRO will complete for the network adequacy validation, and establish a timeline for completing the network adequacy validation.

Activity 2: Identify Data Sources for Validation

In Activity 2, the EQRO will identify all data sources needed for network adequacy validation, based on the scope of the validation determined in Activity 1.

Step 1: Identify Data Sources

The EQRO will identify data needed for the validation activity (see Box 4.3). Typically, data related to both beneficiaries and providers will be needed. This could include:

- Data and documentation from MCPs, such as provider network data files or directories, beneficiary enrollment data files, claims and encounter data files, grievance and appeals data, member experience survey results, or provider and member handbooks
- Data and documentation from the state, such as board certification status
- Primary data collection to validate provider directory information or assess appointment availability and hours of operation

WORKSHEET 4.3

Resource for Activity 2, Step 1

Worksheet 4.3. Data Sources for Network Adequacy Validation

- Provides a template to identify all data sources needed for the validation

Box 4.3. Examples of Potential Data Sources for Network Adequacy Validation

- Beneficiary enrollment files
- Provider network data files or online provider directories
- Claims and encounter data
- Case management, authorization, or electronic visit verification (EVV) systems (particularly for LTSS providers)
- State board certification registries
- Grievance and appeals data
- Survey data, including member experience surveys, such as the Consumer Assessment of Health Plan Survey (CAHPS), Home and Community-Based Services (HCBS) CAHPS, National Core Indicators, and National Core Indicators-Aging and Disabilities
- Information from MCP websites, such as provider and member handbooks
- Primary data collected by the EQRO by telephone, mail, or in-person visit, such as provider information or appointment availability

Worksheet 4.3 provides a template that EQROs can use to identify all of the data sources needed for each network adequacy indicator identified by the state in Activity 1, Step 2.

Step 2: Answer Questions about Data Sources

Consulting with the state as necessary, the EQRO will answer questions about each data source, such as:

- Which variables are necessary for network adequacy validation?

- Necessary variables in provider datasets may include provider specialty and subspecialty, office address(es), languages spoken, disability access, and hours of service
- Necessary variables in beneficiary datasets may include home address, eligibility category, date of birth, sex, primary language spoken, race, ethnicity, disability status, and enrollment/termination dates

- How are the files and data formatted? Will the EQRO need to convert the files and data to other formats and, if so, what potential challenges exist and why?
- Does the state set standards for completeness and accuracy of the data?
- Should the EQRO expect to receive data dictionaries or other supplemental resources with the data?
- What challenges could the EQRO encounter in accessing and using the data and how does the challenges impact the data assessment?

Worksheet 4.3 provides a template that EQROs can use to record the pertinent information related to the data sources needed.

Activity 3: Review Information Systems Underlying Network Adequacy Monitoring

In Activity 3, the EQRO will determine if the MCP's information systems are able to collect and report accurate data related to each network adequacy indicator. The EQRO will assess the information system in three steps:

1. Review the MCP's most recently completed Information System Capacity Assessment (ISCA)
2. Assess processes for collecting network adequacy validation data not addressed in the ISCA
3. Interview MCP or other personnel to clarify findings

Step 1: Review the MCP's ISCA

The EQRO should determine whether the MCP has completed an ISCA review within the previous two years. If the MCP has completed an ISCA within the previous two years, the EQRO should review the findings. If the MCP has not conducted an ISCA within the previous two years, the EQRO must conduct one consistent with the processes discussed in Appendix A.

Based on its review of the statement of findings from the ISCA, the EQRO should understand the IT system architecture, file structure, information flow, data processing procedures, and

WORKSHEET 4.4

Resource for Activity 3, Step 1

Worksheet 4.4. Network Adequacy Data Concerns Identified in Review of ISCA

- Provides a template to describe data concerns identified in the EQRO's review of the MCP's Information System Capacity Assessment (ISCA)

completeness and accuracy of data related to current provider networks. The EQRO should review the ISCA to understand processes for maintaining and updating provider data, including how the MCP tracks providers over time, across multiple office locations, and through changes in participation in the MCP's network; how the MCP identifies providers or organizations excluded from the Medicaid and CHIP program each month (e.g., List of Excluded Individuals and Entities); and whether the MCP requires its provider network to update provider data each month. If the EQRO identifies issues that may contribute to inaccurate or incomplete network adequacy data, the EQRO should list any concerns about the data in Worksheet 4.4. The statement of findings from the ISCA includes an assessment of the utility of the MCP's information system for review of provider network adequacy. The EQRO should review this assessment and the ISCA in full to identify weaknesses in the MCP's information systems required for network adequacy validation, including where and how information systems may be vulnerable to incomplete or inaccurate data capture or processing, integration, storage, or reporting.

Step 2: Assess Processes for Collecting Network Adequacy Data Not Addressed in the ISCA

The EQRO should identify any data sources included in the network adequacy validation that were not reviewed in the ISCA. This may include primary data the EQRO will collect for the network adequacy validation (such as access and availability study data) and data from non-MCP entities (such as the state or third-party vendors), as well as any data sources from the MCP not covered in the ISCA. The EQRO should assess the integrity of the systems that collect, store, and process this data. For each data source not reviewed in the ISCA, the EQRO should consider factors such as:

WORKSHEET 4.5

Resource for Activity 3, Step 2

Worksheet 4.5. Assessment of network adequacy data sources not reviewed in the ISCA

- Provides a template to assess the integrity of the MCP's system(s) that collects, stores, and processes network adequacy data not addressed in the ISCA

- What system is used to collect and store this data?
- How are data entered (manually or electronically)?
- Which staff are involved in collecting, storing, and analyzing this data, and what is their level of training?[64]
- Are there adequate staffing resources to collect and analyze data?
- How frequently are the data collected and updated?

[64] Level of training refers to both formal and informal training that qualifies staff to collect, store, and analyze network adequacy data sources.

- What errors may occur in the process of collecting, storing, and analyzing the data? What quality assurance systems are in place to prevent and fix these errors?
- To what extent are data missing?

Worksheet 4.5 can be used to record any issues identified by the EQRO that may contribute to inaccurate or incomplete network adequacy data.

Step 3: Interview MCP or Other Personnel

After assessing the data sources needed for the network adequacy validation, the EQRO should conduct follow-up interviews with MCP personnel, as needed, to supplement its understanding of the MCP's information systems and processes. As necessary, the EQRO should follow up with personnel in other agencies or organizations with any questions about information systems and processes used in the network adequacy validation that are not maintained by the MCP.

Activity 4: Validate Network Adequacy Assessment Data, Methods, and Results

In Activity 4, the EQRO evaluates each MCP's ability to (1) collect reliable and valid network adequacy monitoring data, (2) use sound methods to assess the adequacy of its managed care networks, and (3) produce accurate results to support MCP and state network adequacy monitoring efforts. The EQRO also generates a validation rating for each network adequacy indicator for each MCP. The approach taken by the EQRO will vary based on the network adequacy methods used by MCPs, the network adequacy standards and indicators specified by the state, and the network adequacy validation scope defined by the state (Activity 1).

WORKSHEET 4.6

Resource for Activity 4, Steps 1-3

Worksheet 4.6. Assessment of MCP Network Adequacy Data, Methods, and Results

- Provides a template for reviewing the data, methods and results, and generating a validation rating for each network adequacy indicator

For Activity 4, Steps 1-3, Worksheet 4.6 providers a template that EQROs can use to assess the MCP's data, methods, and results for each network adequacy indicator. Worksheet 4.6 also guides the EQRO to generate a validation rating for each network adequacy indicator.

Step 1: Assess the Reliability and Validity of MCP Network Adequacy Data

The EQRO will determine if the data used by MCPs to monitor network adequacy are accurate and current so as to generate meaningful, actionable results. Worksheet 4.6 guides the EQRO in assessing MCP network adequacy data for each indicator. The EQRO should:

- Determine whether the required variables identified in Activity 2 are included in each data source. For each variable, the EQRO should calculate the proportion of missing data, and note any patterns in missing data
- Review the MCP's process for updating data (for example, updating provider and beneficiary information) and the frequency with which data are updated
- Assess changes in the MCP's data systems that might affect the accuracy or completeness of network adequacy monitoring data (e.g., major upgrades, consolidations within the system, acquisitions/mergers with other MCPs)

The EQRO should also compare the MCP's data from previous years against the most recent data to assess reliability, as major changes over time could reflect data quality issues. If significant changes are noted, the EQRO should consult with the MCP to determine if external factors (such as changes in populations covered or demographic changes in the overall state population) may be the cause.

If an MCP uses performance measures or encounter data in its network adequacy monitoring activities, the EQRO can use the results of Protocol 2 (Validation of Performance Measures) and/or Protocol 5 (Validation of Encounter Data Reported by the Medicaid and CHIP Managed Care Plan) to inform the EQRO's assessment of data reliability and validity.

Step 2: Assess the Methods Used by the MCP to Assess Network Adequacy

The EQRO should next review the methods used by the MCP to calculate each network adequacy indicator. For each network adequacy indicator, the EQRO should consider questions such as:

- Are the network adequacy monitoring methods selected by the MCP to calculate this indicator appropriate to the state Medicaid and CHIP population(s)? Are these methods likely to generate the data needed to calculate this indicator?
- If the MCP is sampling a subset of the Medicaid and/or CHIP provider or beneficiary population to calculate this indicator, was the sample drawn using statistically valid sampling techniques? Is the sample representative of the population? Are sample sizes for the validation sufficient to draw statistically significant conclusions?
- In calculating this indicator, does the MCP use a system for classifying provider types that follows how the state designates provider types as specialists in the MCP's contract?
- Does the MCP consider the availability of telehealth services in its assessment of network adequacy? Does the MCP's approach for addressing telehealth match the state's expectations?
- Are the methods used by the MCP to calculate this indicator rigorous and objective or could the methods be subject to manipulation?

Additionally, the EQRO may need to consider questions that apply to specific types of indicators and/or methods the MCP may use. As applicable, the EQRO should consider questions such as the following:

- Considerations for time and distance analyses:
  - How is distance measured ("as the crow flies" or using road distances)?
  - How is time measured (e.g., during low traffic or high traffic time periods, using driving distance or public transit)?
  - Does the MCP's approach match the state's expectations (provided in Activity 1, Step 2)?
- Does the MCP's approach for deriving provider-to-enrollee ratios and/or minimum percentage of contracted providers accepting new patients match the state's expectation?
- Does the MCP's approach for determining the maximum wait time for an appointment match the state's expectation?

Worksheet 4.6 guides the EQRO in evaluating the data and methods used by MCPs to assess the results generated by each MCP for each indicator.

Step 3: Validate Network Adequacy Results Submitted by the MCP

In Step 3, the EQRO should validate the calculations and results generated by the MCP for each network adequacy indicator. The EQRO should assess whether the results are valid, accurate, and reliable, and if the MCP's interpretation of data was accurate. The EQRO's approach for validating network adequacy indicators should follow the scope outlined in Activity 1. Often, the EQRO will use the data sources provided by the MCP to reproduce the MCP's calculations. As applicable, the EQRO may also conduct studies, such as provider directory validation studies and appointment availability studies, to validate the MCP's results.

Worksheet 4.6 can be used to guide the EQRO in assessing the MCP's network adequacy results and generating validation ratings that reflect the EQRO's overall confidence that the MCO used an acceptable methodology in the design, data collection, analysis and interpretation of each network adequacy indicator.

Step 4: Summarize Network Adequacy Validation Findings

Next, the EQRO will review the indicators validated in Activity 4, Steps 1-3 against the list of state network adequacy standards and indicators established in Activity 1. The EQRO will indicate whether the MCP addresses all state network adequacy indicators in its network adequacy monitoring activities, provide the validation rating for each indicator, and note any network adequacy indicators that could not be validated due to missing or incomplete data. The EQRO can use Worksheet 4.7 to summarize its findings.

WORKSHEET 4.7

Resource for Activity 4, Step 4

Worksheet 4.7. Summary of network adequacy validation findings

- Provides a template for summarizing all validation findings, including validation ratings and comments for network adequacy indicator

Activity 5: Communicate Preliminary Findings to Each MCP

In Activity 5, the EQRO will share preliminary network adequacy validation findings with each MCP, and correct omissions and errors if necessary. The EQRO should prepare a preliminary validation report for each MCP. In the report, the EQRO should document findings, provide validation ratings, identify areas of concern, and make suggestions for improvement. The EQRO should submit its preliminary findings to the MCP. The MCP may provide documentation to correct errors and omissions in the preliminary report. As needed, the EQRO may discuss the documentation with each MCP.

Activity 6: Submit Findings to State

After completing Activities 1 through 5, the EQRO should compile the results for each MCP into the annual EQR Technical Report. In the report, the EQRO will provide its assessment of each MCP's ability to (1) collect reliable and valid network adequacy monitoring data, (2) use sound methods to assess the adequacy of its managed care networks, and (3) produce accurate results to support MCP and state network adequacy monitoring efforts. EQROs are encouraged to present this information in a summary narrative format with supporting tables and graphics, where appropriate. Please see "Tips for Drafting EQR Reports" in the introduction to the protocols for further guidance about how to produce a clear and concise report. In addition, please refer to the worksheets for guidance on the content to include in the report.

The EQRO's technical report to the state should follow the state's required format, and include the following elements, along with worksheets, tools, and other supporting documentation:

- A description of the state's network adequacy standards for provider types covered by the state's MCPs, including minimum quantitative network adequacy standards, and the network adequacy indicators that were validated for each MCP (Worksheet 4.1 and Worksheet 4.2)

- A list of the data and documentation validated by the EQRO (Worksheet 4.3)
- A description of the EQRO's validation activities including:
  - The EQRO team members involved in the validation and other participants (MCP staff, vendors)
  - A summary of the validation strategy
  - Methods for collecting primary data
  - Data analysis methodology
  - Other considerations relevant to the network adequacy validation process
- Findings on the MCP's information systems capabilities and data integration, including documentation of the timing of the state's most recent ISCA and a description of what documentation was reviewed by the EQRO to support the validation of network adequacy (Worksheet 4.6)
- Analyses and conclusions for each network adequacy validation activity for each MCP. The EQRO should compile data across MCPs to create data tables with summary statistics for each MCP that include actual results and validation ratings (and analysis of patterns across MCPs), using the criteria established by the state in Activity 1 (Worksheet 4.7)
- Recommendations for improving the reliability and validity of each MCP's process for monitoring network adequacy, including implications for the MCP's data systems, methods, and staffing (e.g., programming and analytic capacity) (Worksheet 4.8)

Resources for Activity 6

Information gathered in Activities 1 through 4 using the following worksheets may be helpful when preparing the final validation report:

Worksheet 4.1. State Network Adequacy Standards to be Validated
- Lists all state network adequacy standards that must be addressed in the validation

Worksheet 4.2. Network Adequacy Indicators to be Validated
- Lists and defines the network adequacy indicator(s) associated with each network adequacy standard

Worksheet 4.3. Data Sources for Network Adequacy Validation
- Lists all data sources included in the validation

Worksheet 4.6. Assessment of MCP Network Adequacy Data, Methods, and Results
- Provides a template for reviewing the data, methods and results for each network adequacy indicator

Worksheet 4.7. Summary of Network Adequacy Validation Findings
- Provides validation ratings and comments for network adequacy indicator

Worksheet 4.8. Recommendations to Improve MCP Assessment of Network Adequacy
- Provides a template for summarizing EQRO recommendations from past EQR technical reports and EQRO recommendations based on the current validation process

When possible, the validation report should identify recommendations from the previous year's report submitted to the state, and discuss progress made on these recommendations over the past year based on information gathered during the validation process (Worksheet 4.8).

END OF PROTOCOL 4

Worksheets For Protocol 4: Network Adequacy Validation Tools

Instructions. Use these or similar worksheets to identify the network adequacy indicators to be validated, document and describe the data sources used for validation, assess the underlying data structures and considerations, validate network adequacy data elements, and compare the network adequacy findings to state network adequacy standards. This tool includes the following worksheets cross-walked to the applicable activity and step. Examples are provided for the first four worksheets for illustrative purposes.

Worksheet name	Protocol activity and step
Worksheet 4.1. State Network Adequacy Standards to be Validated	Activity 1. Step 2. Obtain Needed Information from the State
Worksheet 4.2. Network Adequacy Indicators to be Validated	Activity 1. Step 2. Identify and Define Network Adequacy Indicators for Validation
Worksheet 4.3 Data Sources for Network Adequacy Validation	Activity 2. Step 1. Identify Data Sources
Worksheet 4.4. Network Adequacy Data Concerns Identified in Review of ISCA	Activity 3. Step 1. Review the MCP's ISCA
Worksheet 4.5. Assessment of Network Adequacy Data Sources not Reviewed in the ISCA	Activity 3. Step 2. Assess Processes for Collecting Network Adequacy Data Not Addressed in the ISCA
Worksheet 4.6. Assessment of MCP Network Adequacy Data, Methods, and Results	Activity 4. Step 1. Assess the Reliability and Validity of MCP Network Adequacy Data Activity 4. Step 2. Assess the Methods Used by the MCP to Assess Network Adequacy Activity 4. Step 3. Validate Network Adequacy Results Submitted by the MCP
Worksheet 4.7. Summary of Network Adequacy Validation findings	Activity 4. Step 4. Summarize Network Adequacy Validation Findings
Worksheet 4.8. Recommendations to Improve MCP Assessment of Network Adequacy	Activity 6. Submit Findings to the State

For each MCP, please complete the following information:

MCP name	
MCP contact name and title	
Mailing address	
Phone/fax numbers	
Email address	
Plan type	□ MCO □ PIHP □ PAHP □ LTSS □ Other: specify _____ If PIHP or PAHP, type: _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 4.1. State Network Adequacy Standards to be Validated

Instructions: Worksheet 4.1 guides the state and the EQRO to identify the network adequacy standards that the EQRO will need to validate. In the table below, the EQRO should list the quantitative network adequacy standards to be validated under this protocol. If covered under the state's managed care contracts, the validation standards should include adult and pediatric primary care, OB/GYN, adult and pediatric behavioral health, adult and pediatric specialist, hospital, pharmacy, pediatric dental, and LTSS providers. The validation standards should also include additional provider types (e.g., medication-assisted treatment providers for opioid use disorder), or specialists, as defined by the state, that follow the state's network adequacy standards. The state and the EQRO should add rows as necessary to the table to capture all state network adequacy standards that will be validated. Definitions for this activity include:

- **Network adequacy standard:** A quantitative parameter that states establish to set expectations for contracted managed care plans' provider networks. For example, a state may set a network adequacy standard that all enrollees have access to a primary care provider (PCP) within 30 miles or 30 minutes of their home.
- **Applicable provider types**: All provider types to which the network adequacy standard applies.
- **Applicable plan types**: All plan types (such as Medicaid, CHIP, LTSS, and dental plans) to which the network adequacy standard applies.
- **Applicable regions**: All regions to which the network adequacy standard applies. Typically, regions are categorized as urban, rural and frontier. In Activity 1, Step 1, the state and EQRO should clarify how regions are defined. When standards differ by region (for example, if the state's distance standard between a beneficiary home and primary care provider is 30 miles in urban areas and 50 miles in rural areas), they should be listed in separate rows in the table below.
- **Data and documentation submitted by MCPs**: All data and documentation MCPs must submit to demonstrate compliance with the network adequacy standard. In parentheses, please note the frequency with which this data and documentation is submitted (e.g., annually, quarterly, monthly).

Network adequacy standard	Applicable provider types	Applicable plan types	Applicable regions	Data and documentation submitted by MCPs (frequency)
Enrollees must have access to a primary care provider office within 30 minutes or 30 miles of their residence	*Primary care (family medicine physicians, internal medicine physicians, OBGYNs, pediatricians, nurse practitioners, physician assistants)*	*Medicaid, CHIP*	*Statewide*	*Beneficiary enrollment files (monthly)* *Provider network data files (quarterly)*

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 4.2. Network Adequacy Indicators to be Validated

Instructions: Worksheet 4.2 guides the state and the EQRO to define the network adequacy indicators that the EQRO will need to validate. To start, the EQRO should fill in the first column of the table below with the network adequacy standards identified in Activity 1, Step 2 (Worksheet 4.1). The state and the EQRO should then identify and define the indicator(s) that will be validated, listing each indicator in its own row and adding rows as necessary. A separate worksheet should be completed to define the indicators that will be validated for each MCP, taking into account the standards that apply to each plan type. Definitions for this activity include:

- **Network adequacy standard:** A quantitative parameter that states establish to set expectations for contracted managed care plans' provider networks. For example, a state may set a network adequacy standard that all enrollees have access to a primary care provider (PCP) within 30 miles or 30 minutes of their home.
- **Network adequacy indicator**: The metric(s) used to assess adherence to the quantitative network adequacy standard required by the state. For example, the network adequacy indicator for a network adequacy standard that all enrollees have access to a primary care provider (PCP) within 30 miles or 30 minutes of their home could be the proportion of enrollees who have access to a primary care provider within 30 miles or 30 minutes from their home.
- **Definition of network adequacy indicator:** A clear description of the network adequacy indicator, including criteria for calculating the numerator and denominator. The definition should address specific methodological issues that impact indicator calculations. For example, for time and distance indicators, the definition should specify whether distance is measured "as the crow flies" or using driving distances. The definition should also identify the provider types to which the indicator applies.

Managed Care Plan (MCP) name: *Alpha Plan*

Network adequacy standard	Network adequacy indicator	Definition of network adequacy indicator
Beneficiaries must have access to a primary care provider office within 30 minutes or 30 miles of their residence	*Proportion of beneficiaries who have a primary care provider accepting new Medicaid patients within 30 minutes or 30 miles of their residence*	*Numerator: Number of beneficiaries for which one or more of the following is true:* • *An in-network provider office is a 30-minute drive or less from their residence (according to mapping software)* • *An in-network provider office is 30 miles or less by road from of their home (according to mapping software)* *Denominator: All Medicaid and CHIP beneficiaries except those enrolled only in LTSS plans*

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Worksheet 4.3. Data Sources for Network Adequacy Validation

Instructions: For each network adequacy indicator identified in Activity 1, Step 2 (Worksheet 4.2), Worksheet 4.3 lists the network adequacy indicators used to measure the MCPs' compliance with the network adequacy standards established by the state and guides the EQRO to identify all data sources needed to validate a network adequacy indicator. To start, the EQRO should fill in the first column of the table below with the network adequacy indicators identified in Worksheet 4.2, adding rows as necessary. If multiple data sources will be used to validate a given indicator, each data source should be listed in a separate row. The EQRO should then fill in the remaining columns with information about the data source. Definitions for this activity include:

- **Network adequacy indicator**: The metric(s) used to assess adherence to the quantitative network adequacy standard required by the state. For example, the network adequacy indicator may be that enrollees have access to a primary care provider within 30 miles or 30 minutes from their home. The table below should include all network adequacy indicators identified in Worksheet 4.2.
- **Data source:** The type of data needed to validate a network adequacy indicator. When multiple data sources are used to validate a given indicator, each data source should be listed in a separate row. For example, if validation of time and distance indicators requires both provider network and beneficiary enrollment files, each data source should be listed separately. The year(s) of data should also be listed.
- **Data format and software:** File format for the data source and any digital software needed to access or analyze this file format. Additionally, the EQRO should note if it will need to convert this data to other file formats, and if so, any potential challenges that may occur.
- **Variables for network adequacy validation:** All variables within the data source that are needed to complete the validation activity. The EQRO should consider how to utilize different variables for beneficiary datasets and provider datasets.
- **State standards for data accuracy, timeliness, and completion**: If applicable, any standards set by the state related to data accuracy and completeness. Typically, this applies to data that MCPs collect and submit to the state.
- **Challenges and notes:** Any potential challenges the EQRO could encounter in accessing and using the data source, and any additional information that provides context for data validation of the given indicator. If applicable, this column could include hyperlink(s) to the data source or related materials to facilitate validation of the given indicator.

Managed Care Plan (MCP) name: *Alpha Plan*

Network adequacy indicator	Data source and year(s) of data	Data format and analysis software; note if conversion required	Variables for network adequacy validation	State standards for accuracy, timeliness, and completion	Challenges and notes
Proportion of beneficiaries who have a primary care provider office within 30 minutes or 30 miles of their residence	*Beneficiary enrollment files*	*Comma Separated Value (CSV)*	*Beneficiary address, beneficiary date of birth, beneficiary plan type*	*State requires MCPs to submit updated and accurate beneficiary enrollment files monthly*	*State and MCP have noted that in urban regions a significant proportion of beneficiaries rely on public transit, rather than driving*

Network adequacy indicator	Data source and year(s) of data	Data format and analysis software; note if conversion required	Variables for network adequacy validation	State standards for accuracy, timeliness, and completion	Challenges and notes
Proportion of beneficiaries who have a primary care provider office within 30 minutes or 30 miles of their residence	*Provider network data files*	*Comma Separated Value (CSV)*	*Provider address, provider type*	*State requires MCPs to submitted updated and accurate provider network data files quarterly. The state flags and rejects data in which provider type is not specified.*	*State and MCP have noted challenges keeping provider network data up-to-date; provider network data also does not include information about accommodations for beneficiaries with physical disabilities or low English proficiency*

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Worksheet 4.4. Network Adequacy Data Concerns Identified in Review of ISCA

Instructions: Worksheet 4.4 guides the EQRO in identifying any data concerns it has identified in its review of an MCP's Information System Capacity Assessment (ISCA). The EQRO should first determine whether the MCP has completed an ISCA review within the past two years. If the MCP has not conducted an ISCA within the previous two years, the EQRO must conduct one consistent with the processes discussed in Appendix A. If the MCP has completed an ISCA review within the past two years, the EQRO should review the findings and identify any concerns related to data sources that will be used in the network adequacy validation.

The EQRO should fill in the first column of the table below with data sources identified in Activity 2, Step 1 (Worksheet 4.3) that are covered in the ISCA. If the EQRO identifies concerns related to a given data source in its review of ISCA findings, the EQRO should fill in the remaining columns to describe the concern and potential workarounds. If no data concerns are identified for a given data source, the EQRO should enter "Not identified" in the second column.

Managed Care Plan (MCP) name: *Alpha Plan*

Data source	Data concern	Type (check boxes)						Potential solutions or workarounds
		Data capture	Data processing	Data integration	Data storage	Data reporting	Other	
Provider network data files	*Provider network data files may be inaccurate due to providers entering and leaving networks, or changes in provider information, such as address*	X				X		*The EQRO will validate a sample of providers through phone calls or on-site visits to determine if the provider still participates in the network, if the location is accurate, and if the provider is accepting new Medicaid patients.*

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Worksheet 4.5. Assessment of Network Adequacy Data Sources not Reviewed in the ISCA

Instructions: Worksheet 4.5 guides the EQRO in assessing the integrity of any systems that collect, store, and process network adequacy data not addressed in the ISCA. The EQRO should identify any data source(s) identified in Activity 2, Step 1 (Worksheet 4.3) that were not reviewed in the ISCA. This may include MCP data sources not covered in the ISCA, data from non-MCP entities, and primary data the EQRO plans to collect for the purpose of the network adequacy validation. For each data source, the EQRO should complete the table below to assess the integrity of the system that collects, stores, and processes the data. The EQRO should conduct follow-up interviews as needed to supplement its understanding of the information systems and processes.

Managed Care Plan (MCP) name: _____

Name of data source	
What system is used to collect this data?	
What system is used to store this data?	
How frequently are the data collected and updated?	
What software systems and/or programming languages are used to analyze this data?	
Which staff are involved in collecting and storing this data, and what is their level of training?	
Are there adequate staffing resources to collect and analyze data? Specifically, does the MCP employ enough data analysts and do they have adequate time to perform necessary analytics?	
Which staff are involved in analyzing and reporting this data, and what is their level of training?	
What errors may occur in the process of collecting, storing, and analyzing the data?	
What systems are in place to prevent and fix errors that occur in the process of collecting, storing, and analyzing the data?	
What proportion of the data are missing or incomplete on key data elements?	
What systems are in place to prevent missing or incomplete data?	
Data concerns relevant to network adequacy validation	
Potential solutions or workarounds to address data concerns	

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Worksheet 4.6. Assessment of MCP Network Adequacy Data, Methods, and Results

Instructions: Worksheet 4.6 guides the EQRO in evaluating and assessing the data and methods used by MCPs to calculate results generated for each network adequacy indicator. This worksheet also guides the EQRO in generating a validation rating that reflects the EQRO's overall confidence that an acceptable methodology was used for all phases of design, data collection, analysis and interpretation of the network adequacy indicator.

The EQRO should fill in the table below **for each network adequacy indicator** to be validated. The EQRO should respond to the questions below, and insert comments to explain "No" and "Not Applicable" responses. If an item is partially met, select "No" and explain in comments. For example, if data sources are available for some but not all indicators or for some but not all years, select "No" and explain in comments. If an item is "Not Applicable," please explain in comments.

Managed Care Plan (MCP) name: _____

Network Adequacy Indicator: _____

Question	Yes	No	Not Applicable	Comments
Assessment of data collection procedures				
Were all data sources (and year[s] of data) needed to calculate this indicator submitted by the MCP to the EQRO?				
For each data source, were all variables needed to calculate this indicator included?				
Are there any patterns in missing data that may affect the calculation of this indicator? (Note: This assessment should be based on a systematic assessment of the proportion of missing data for each variable.)				
Do the MCP's data enable valid, reliable, and timely calculations of this indicator?				
Did the MCP's data collection instruments and systems allow for consistent and accurate data collection for this indicator over the time periods studied?				
During the time period included in the reporting cycle, have there been any changes in the MCP's data systems that might affect the accuracy or completeness of network adequacy data used to calculate this indicator (e.g., major upgrades, consolidations within the system, acquisitions/mergers with other MCPs)?				

Question	Yes	No	Not Applicable	Comments
If encounter or utilization data were used to calculate this indicator, did providers submit data for all encounters?				
If LTSS data were used to calculate this indicator, were all relevant LTSS provider services included (for example, through claims and encounter data, authorization systems, case management systems, or electronic visit verification [EVV] systems)?				
If access and availability studies were conducted to calculate this indicator, does the MCP include all phone calls made in the denominator? This means phone calls that do not reach a provider office may be excluded from the denominator.				
If access and availability studies were conducted to calculate this indicator, does the MCP have processes for addressing potential roadblocks in identification, such as lack of a Medicaid or CHIP ID or medical record number needed to speak with provider offices?				
Assessment of MCP Network Adequacy Methods				
Are the methods selected by the MCP to calculate this indicator appropriate for the state				
Are the methods selected by the MCP to calculate this indicator appropriate to the state Medicaid and CHIP population(s)?				
Are the methods selected by the MCP adequate to generate the data needed to calculate this indicator?				
In calculating this indicator, does the MCP use a system for classifying provider types that matches the state's expectations and follows how the state defines a specialist?				
If applicable, does the MCP's approach for addressing telehealth match the state's expectations?				

Question	Yes	No	Not Applicable	Comments
If the MCP is sampling a subset of the Medicaid and/or CHIP population to calculate this indicator, did the sampling frame contain a complete, recent, and accurate list of the target population? A sampling frame is the list from which the sample is drawn. It includes the universe of members of the target population, typically Medicaid and CHIP beneficiaries and providers. The completeness, currency, and accuracy of the sampling frame are key to the representativeness of the sample.				
If the MCP is sampling a subset of the Medicaid and/or CHIP population to calculate this indicator, is the sample representative of the population?				
If the MCP is sampling a subset of the Medicaid and/or CHIP population to calculate this indicator, are sample sizes large enough to draw statistically significant conclusions?				
In calculating this indicator, were valid sampling techniques used to protect against bias? Specify the type of sampling used in the “comments” field.				
If applicable to this indicator, does the MCP’s approach for measuring distance (e.g., “as the crow flies” or using road distances) match the state’s expectation?				
If applicable to this indicator, does the MCP’s approach for measuring time (e.g., during low traffic or high traffic time periods, using driving distance or public transit) match the state’s expectation?				
If applicable to this indicator, does the MCP’s approach to deriving provider-to-enrollee ratios or percentage of contracted providers accepting new patients match the state’s expectation?				
If applicable to this indicator, does the MCP’s approach for determining the maximum wait time for an appointment match the state’s expectation?				
Are the methods used to calculate this indicator rigorous and objective?				

Question	Yes	No	Not Applicable	Comments
Are the methods used to calculate this indicator unlikely to be subject to manipulation? If "no," please describe in the "comments" field.				
Assessment of MCP network adequacy results				
In calculating this indicator, did the MCP produce valid results—that is, did the MCP measure what they intended to measure?				
In calculating this indicator, did the MCP produce accurate results—that is, did the MCP's calculated values reflect the true values?				
In calculating this indicator, did the MCP produce reliable results—that is, were the MCP's results reproducible and consistent?				
In calculating this indicator, did the MCP accurately interpret its results?				
Comments				
Please note any recommendations for improving the data collection procedures to calculate this indicator.				
Please note any recommendations for improving the sampling methods to calculate this indicator.				
Please note any recommendations for improving the analysis to calculate this indicator.				
Please note any recommendations for improving the results to calculate this indicator.				

Calculate validation score:

A. Total number of "Yes" responses	
B. Total number of "No" responses	
Score = A / (A + B) x 100	

Determine validation rating:

The "validation rating" refers to the EQRO's overall confidence that acceptable methodology was used for all phases of design, data collection, analysis, and interpretation of the network adequacy indicator.

Validation score	Validation rating
90.0% or greater	High confidence
51.0% to 89.9%	Moderate confidence
10.0% to 49.9%	Low confidence
Less than 10%	No confidence

Summary:

Managed Care Plan (MCP) name:
Indicator:
Validation rating: ☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence
Comments

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 4.7. Summary of Network Adequacy Validation Findings

Instructions: Worksheet 4.7 guides the EQRO in summarizing its validation findings. The EQRO should complete this worksheet separately for each MCP. To start, the EQRO should fill in the first column of the table below with the network adequacy indicators identified in Activity 1, Step 2 (Worksheet 4.2). The EQRO should then note whether the MCP addressed the network adequacy indicator in its network adequacy assessment activities. For indicators addressed by the MCP, the EQRO should provide the validation rating generated in Activity 4, Step 3 (Worksheet 4.6), noting if any indicators could not be validated due to missing data or other issues. The EQRO may provide any additional context needed in the "comments" field. The EQRO should add additional rows as needed to include all network adequacy indicators. Definitions for this worksheet include:

- **Network adequacy indicator**: The metric(s) used to assess adherence to the quantitative network adequacy standard required by the state. For example, the network adequacy indicator may be the proportion of enrollees who have access to a primary care provider within 30 miles or 30 minutes from their home, or provider-to-enrollee ratio. The table below should include all network adequacy indicators identified in Activity 1, Step 2 (Worksheet 4.2).
- **Validation rating:** The rating, calculated in Activity 4, Step 3 (Worksheet 4.6) that refers to the EQRO's overall confidence that acceptable methodology was used for all phases of design, data collection, data analysis, and interpretation of network adequacy monitoring activities.

Managed Care Plan (MCP) name: _____

Network adequacy indicator	Did the MCP address this indicator in its network adequacy monitoring activities?	Validation rating	Comments
	☐ Addressed ☐ Missing	☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence ☐ Could not be validated	
	☐ Addressed ☐ Missing	☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence ☐ Could not be validated	
	☐ Addressed ☐ Missing	☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence ☐ Could not be validated	
	☐ Addressed ☐ Missing	☐ High confidence ☐ Moderate confidence ☐ Low confidence ☐ No confidence ☐ Could not be validated	
	☐ Addressed ☐ Missing	☐ High confidence ☐ Moderate confidence ☐ Low confidence	

Network adequacy indicator	Did the MCP address this indicator in its network adequacy monitoring activities?	Validation rating	Comments
		☐ No confidence ☐ Could not be validated	

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 4.8. Recommendations to Improve MCP Assessment of Network Adequacy

Instructions: Worksheet 4.8 provides a template for the EQRO to refer back to EQRO recommendations from past EQR technical reports (where applicable), review MCP progress in responding to those recommendations, and provide recommendations based on the current network adequacy validation cycle. The recommendations should be specific and actionable to support improvement of the MCP's assessment of network adequacy.

Managed Care Plan (MCP) name:
Prior Recommendation Year (if applicable):
EQRO Prior Recommendations (if applicable):
Summary of MCP Response to Prior Recommendations (if applicable):
EQRO Assessment of Degree to which MCP Effectively Addressed the Recommendations (if applicable):
Current Recommendation Year:
EQRO Current Recommendations for MCP Assessment of Network Adequacy:

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

END OF WORKSHEETS FOR PROTOCOL 4

Protocol 5. Validation of Encounter Data Reported by the Medicaid and CHIP Managed Care Plan

An optional EQR-related activity

ACTIVITY 1: REVIEW STATE REQUIREMENTS

ACTIVITY 2: REVIEW THE MCP'S CAPABILITY

ACTIVITY 3: ANALYZE ELECTRONIC ENCOUNTER DATA

ACTIVITY 4: REVIEW MEDICAL RECORDS

ACTIVITY 5: SUBMIT FINDINGS

PROTOCOL FIVE

Background

Encounter data are the information related to the receipt of any item or service by an enrollee in a managed care plan (MCP). It is often thought of as the managed care equivalent of fee-for-service (FFS) claims. Encounter data reflect that a provider rendered a specific service under a managed care delivery system, regardless of if or how the MCP ultimately reimbursed the provider. They contain substantially the same information included on claim forms (e.g., UB-04 or CMS 1500), although not necessarily in the same format. However, because some managed care providers and/or services may be paid via capitation or episodes of care, rather than based on a claim submitted for individual services rendered, encounter data may be less complete or accurate than claim data. As payment methodologies have begun to incorporate value-based payment elements (such as bundled payment or episode payment), collecting complete and accurate encounter data has become even more crucial.

Since 1999, CMS has required states to submit complete and accurate enrollment and utilization data, including FFS claims and encounter records, through the Medicaid Statistical Information System (MSIS). In 2011, CMS began working with state agencies and other stakeholders to build a new data infrastructure to replace MSIS. The Transformed Medicaid Statistical Information System (known as T-MSIS) is intended to modernize the way states submit data about beneficiaries, providers, MCPs, FFS claims, third-party liability, and encounters to CMS. States must

comply with the T-MSIS requirements and all associated guidance for all managed care data submitted to CMS.[65]

The availability of accurate and complete encounter data is important to the effective operation and oversight of MCPs that serve enrollees covered by Medicaid and the Children's Health Insurance Program (CHIP) (see Box 5.1).

Box 5.1 State Uses of Encounter Data

- Develop capitation rates
- Perform risk adjustment
- Measure quality
- Implement alternative payment methods
- Conduct program integrity
- Engage in policy development

Federal regulations at 42 CFR Part 438 include several provisions related to encounter data.

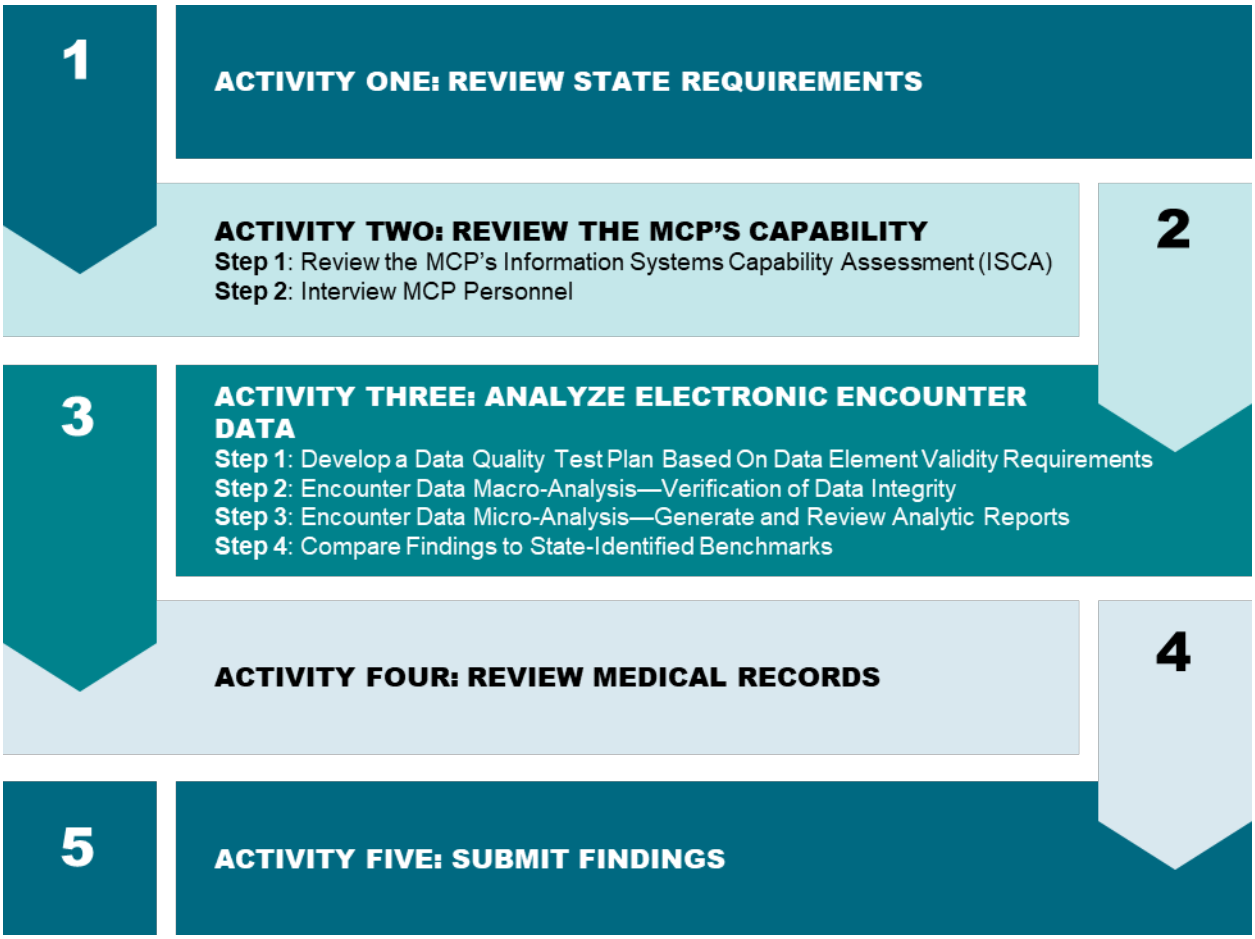
- All providers must submit claims and/or encounters to states for all services regardless of the method by which a plan pays its providers (e.g., FFS, capitated, basis, or sub-capitation). (42 CFR 438.818(a))
- States must review and validate encounter data on initial receipt from their MCPs, and again when they submit it to CMS. (42 CFR 438.818(a)(2))
- States must submit complete, accurate, and timely encounter data to CMS in a standardized format (i.e., T-MSIS). (42 CFR 438.818(a)(3))
- CMS may impose penalties on states for noncompliance by withholding Federal Financial Participation (FFP) funds. (42 CFR 438.818(c))
- This protocol provides guidance to EQROs on validating the accuracy and completeness of encounter data submitted by MCPs.

Getting Started on Protocol 5

To complete this protocol, the EQRO undertakes five activities for each MCP (Figure 5.1).

[65] More information about T-MSIS requirements is available at https://www.medicaid.gov/medicaid/data-systems/macbis/transformed-medicaid-statistical-information-system-t-msis/index.html.

Figure 5.1. Protocol 5 Activities



Two supplemental resources are available to help EQROs validate encounter data:

- Worksheets for Protocol 5. Encounter Data Tables, a set of worksheets that can be used to document acceptable error rates and data element validity requirements, findings from the review of individual encounter records, a comparison of findings to state-identified benchmarks, results from the EQRO's validation of medical records, and a suggested format for reporting encounter data validation information in the EQR technical report. Format for Reporting Encounter Data Validation Information in the EQR Technical Report
- Appendix A. Information System Capabilities Assessment, which is used to assess the MCP's data collection, processing, and reporting systems

In addition, it may be helpful to refer to the CMS Encounter Data Toolkit, which contains additional information and resources about the validation process. This toolkit is available at https://www.medicaid.gov/medicaid/downloads/medicaid-encounter-data-toolkit.pdf.

The remainder of this protocol outlines the steps associated with Activities 1 through 5.

TIP

Navigate to the corresponding worksheet by clicking the **WORKSHEET** box under each section

Activity 1: Review State Requirements

Activity 1 is intended to ensure the EQRO has a complete understanding of a state's requirements for each MCP's encounter data. Before initiating Activity 1, EQROs should request all available encounter data guidance from states, including encounter reporting requirements and standards, data dictionary, edit checks, and other documents. At the outset of Activity 1, the state should provide the EQRO with at least the following information:

WORKSHEET 5.1

WORKSHEET 5.2

Resource for Activity 1

Worksheet 5.1. Specification of Acceptable Error Rates and Identified Areas of Concern

- Provides guidance for the EQRO's review of a state's specific requirements for reporting encounters

Worksheet 5.2. Data Element Validity Requirements

- Provides a template for the EQRO to document the state's specific requirements for validating each data element by type of service

1. **Specific requirements regarding the MCPs' collection and submission of encounters.** Some states may formalize these requirements in contractual language or companion guides. The state should provide the EQRO with a detailed list of all requirements, by plan and plan type
2. **Requirements regarding the types of encounters that must be validated** (e.g., inpatient hospital, professional, home health). The state may find it difficult to integrate some types of encounters (e.g., non-emergency transportation or atypical providers) into its data systems. Whenever possible, the state should direct the EQRO to alternative sources to validate this information. Note that under this protocol, a state could direct the EQRO to validate all of an MCP's encounter data or a subset of an MCP's encounters. If the state chooses to validate a subset of the encounter data based on provider type, it must validate all encounters for the selected provider type across all MCPs. If the state chooses to validate encounter data for a subset of MCPs, it must validate all encounters for the subset of MCPs
3. Standards for the submitted data, including the following:
    - An operational definition of an "encounter," such as adjudication status, and other relevant details
    - Types of encounters MCPs must report (e.g., inpatient hospital, outpatient, professional, home health)
    - Format in which encounters must be submitted (837 standard transaction, proprietary)

- Objective standards to which encounter data will be compared (e.g., number of beneficiaries with at least one encounter)

4. **State standards for encounter data completeness and accuracy**. The state should clearly specify acceptable rates of accuracy and completeness for each data element for each field for each encounter type, which may depend on the intended use of the encounter data. Although initial error rates may be higher, each MCP's targeted error rate should be below 5 percent for each time period examined. The state should align its own standards with those required to satisfy T-MSIS requirements
5. **Data dictionary and companion guides**. States often cite data dictionaries or companion guides in managed care contract language for reference to accountability and standards for encounter data. Those may be updated on a more regular basis than the contracts themselves. For states that employ a fiscal intermediary, the intermediary may be the best source of this information
6. **Description of the information flow from the MCP to the state**, including the role of any contractors or data intermediaries. States that use separate organizations for medical and behavioral health should include details about how the data are collected and integrated into a single system, as well as challenges the EQRO may face in handling these data
7. **A list and description of automated edits or checks performed on the data** when received into the state system (Medicaid Management Information System or data warehouse). This should include information about how the system handles encounters that fail an edit check. For example, does the system reject an entire file if one encounter is rejected?
8. **The timeliness requirements for data submissions** (e.g., how far from the original date of service the record must be submitted), and standards for timeliness, as applicable and as laid out by the state in contract documents. States are increasingly able to process high volumes of records on a daily basis, while some prefer a monthly submission from plans. States also may have various tolerance levels for what percentage of records must meet particular timeliness standards
9. **Any EQR validation reports from previous years.** Previous reports can provide useful data points for determining how much progress MCPs have made in improving data quality and completeness, as well as giving a state picture of improvement or challenges over time
10. **Any other information relevant to encounter data validation**. States may find they use other documentation or context in their own analyses of their MCP's encounter data. If supplementary information will provide relevant context to encounter validation, such as a list of excluded providers, it should be provided to the EQRO

Activity 2: Review the MCP's Capability

Activity 2 is intended to evaluate an MCP's ability to collect complete and accurate encounter data. Before assessing the output produced by the MCP's information system, the EQRO should

determine whether the system is able to collect and report high quality encounter data. To do so, the EQRO should assess the information system in two steps (described in more detail below):

1. Review the MCP's most recently completed Information System Capacity Assessment (ISCA)
2. Interview MCP personnel to clarify ISCA findings as necessary

Step 1: Review the MCP's ISCA

The EQRO should determine whether the MCP has completed an ISCA review within the past two years.[66] If a recent ISCA has been completed, the EQRO should review the findings. If the MCP has not conducted an ISCA within the previous two years, the EQRO must conduct one consistent with the processes discussed in Appendix A.

The EQRO should review the MCP's ISCA to identify weaknesses in the MCP's information systems. This assessment determines where and how information systems may be vulnerable to incomplete or inaccurate data capture or processing, integration, storage, or reporting. Based on the findings from the ISCA, the EQRO should understand the following:

1. IT system architecture, file structure, information flow, and data processing procedures
2. Specific programming language used by the system (e.g., SQL)[67]
3. Process by which the MCP modifies its source code to address changes in state reporting requirements (Note: The EQRO should obtain all source code from the MCP)
4. Other claims/encounter processing issues
    - How the system handles voids, adjustments, crossovers, and records not requiring payments, such as for sub-capitated arrangements

WORKSHEET A.1

WORKSHEET A.2

WORKSHEET 5.1

Resource for Activity 2, Step 1

Worksheet 5.1. Specification of Acceptable Error Rates and Identified Areas of Concern

- Provides guidance for the EQRO's review of a state's specific requirements for reporting encounters

Appendix A guides the information systems review. The appendix includes two worksheets:

- ISCA Worksheet A.1 is the tool used for the assessment
- ISCA Worksheet A.2 is used by the EQRO to assess the adequacy of MCP policies and procedures based on the information collected in Worksheet A.1

[66] There is no statutory or regulatory requirement for the frequency with which ISCAs should be conducted. Each state must determine the maximum interval between assessments of MCP information systems, balancing the cost to the state and burden on the MCP with the need to ensure that changes to the MCP's information systems are assessed frequently enough to support accurate performance measurement.

[67] SQL is programming language for storing, manipulating, and retrieving data in databases.

- Whether the system verifies encounters at both header and detail levels[68]
- Whether there are processes in place to identify "orphan" header or detail records[69]

5. Completeness of data
    - Whether there any service types (e.g., non-emergency transportation or behavioral health) not in the system
6. Written policies and procedures for edits and audits
7. Claims/encounter system demonstration
    - Whether the system permits working with the data in a "test" environment
8. Processes for merging and/or transferring data
9. Processes for encounter data intake, logging, adjudication, and denial
10. Audits performed to assure data quality and accuracy and processing timeliness
11. Maintenance and updating of provider data, including how the MCP identifies providers or organizations excluded from the Medicaid program each month (e.g., List of Excluded Individuals and Entities), and whether the MCP requires its provider network to update provider data each month
12. Processing of enrollment data, including a description of how the system identifies beneficiaries as information changes over time (e.g., how the system handles name and address changes)
13. Specific claims and encounter verification procedures
14. Frequency of information updates (e.g., how often does the MCP update its provider table?)
15. Management of enrollment and disenrollment information

During the review of ISCA findings, the EQRO may identify encounter data errors by MCPs (see Box 5.2). If the EQRO identifies issues that may contribute to inaccurate or incomplete encounter data, the EQRO should list any concerns about the encounter data in Column 4 of Worksheet 5.1. Specification of Acceptable Error Rates and Identified Areas of Concern for each encounter type listed.

[68] The detail-level on an encounter refers to information included on the individual lines contained within the encounter (such as charges or procedure codes for multiple services provided within a single visit); the header-level refers to information provided at the claim level (such as beneficiary ID, provider ID, date of service, and diagnoses).

[69] An orphan encounter is one in which there are one or more detail records without an associated header record, or vice versa.

Box 5.2 Potential Causes of Encounter Data Errors by MCPs

- Non-standard codes or forms
- Inadequate front-end data edits
- Lack of provider contractual requirements that tie payment to data submission
- Use of default dates of service or provider identifiers
- Failure to collect key demographic data elements
- Out of date or incomplete reference tables
- Failure to collect Medicare crossover claims
- Inconsistent use of adjusted and void claims

Step 2: Interview MCP Personnel

After reviewing the findings from the ISCA, the EQRO should conduct follow-up interviews with MCP personnel as needed to supplement the information in the ISCA and ensure its understanding of the MCP's information systems and processes. The EQRO should refer to ISCA components that the MCP uses to produce performance measures, including enrollment, medical, pharmacy, provider, lab, and other ancillary or supplemental data sources.

Activity 3: Analyze Electronic Encounter Data

Activity 3 is the core function used to determine the validity of the encounter data. When the EQRO has completed the steps within this activity, it should know whether the data are complete, of high quality, and can be used for analysis of quality, access, program integrity monitoring, among other critical state activities. If the EQRO cannot confirm the quality of the data after completing this activity, it should not proceed to Activity 4, the Medical Record Review. Instead, the EQRO should work closely with the state or plans to determine underlying problems or acquire additional information to determine the quality and usefulness of the data submitted. Difficulties completing this analysis may need to be summarized for the state as indicating serious data quality issues.

The EQRO should use the information obtained from these analyses, the ISCA tool, follow-up interviews, and the results of state edits to assess the completeness and accuracy of the MCP's encounter data. The results of Activity 3 will inform the development of a long-term monitoring strategy for assessing the quality of the encounter data. As the data evolve over time, the EQRO will be able to design targeted validation strategies to identify problem areas requiring resource intensive medical record review.

Under this activity, the EQRO should carry out the following Steps 1 through 4.

Step 1: Develop a Data Quality Test Plan Based On Data Element Validity Requirements

The EQRO should use the information obtained from Activities 1 and 2 (including the ISCA review and follow-up interviews with MCP staff) to develop a data quality test plan. The plan should:

- Account for front-end edits already built into the MCP's data system so that it focuses on issues that the MCP may have inadvertently missed or allowed for other reasons
- Specify the areas to be tested and the expected results

To be of greatest use to states and other stakeholders, the EQRO should develop a plan that addresses the following questions:

The general magnitude of missing encounter data. The EQRO should use information from the MCP about encounters that fail front-end edits and the reasons for these failures to determine whether, and how much, encounter data is missing. The EQRO should compare these results with normative data on encounters for similar populations for this purpose. Examples of the use of benchmarks for assessing encounter data completeness are available in the Encounter Data Toolkit, available at https://www.medicaid.gov/medicaid/downloads/medicaid-encounter-data-toolkit.pdf

1. **Types of encounters that may be missing.** MCPs that pay for "bundled" services (e.g., prenatal care) or that capitate providers (e.g., for primary care) may not receive complete encounter information from these providers. The EQRO should apply specific knowledge about the MCP's contractual relationships with providers to identify specific areas to look for missing services. The EQRO should obtain information from the MCP on the use of bundled payment and capitation to inform its plan
2. **Overall data quality issues.** The EQRO should identify specific data quality problems such as inability to process or retain certain fields, or limited coding specificity on the encounter data record
3. **MCP data submission issues.** The EQRO should identify problems the MCP has compiling its encounter data and submitting the data files to the state

Step 2: Encounter Data Macro-Analysis—Verification of Data Integrity

Steps 2 and 3 of Activity 3 are closely related. When the EQRO reviews the data for accuracy and completeness, it conducts both macro- and micro-analyses. Step 2 describes the macro-analysis, while Step 3 describes the micro-analysis.

WORKSHEET 5.3

Resource for Activity 3, Step 2

Worksheet 5.3. Evaluation of Submitted Fields

- Provide a template for the EQRO to document its findings for each data element

In Step 2, the EQRO should:

- Analyze and interpret data in specific fields
- Check the data for volume and consistency

Without duplicating the state's edit checks, the EQRO should analyze and interpret data in submitted fields. In addition:

1. Is there information in the field, and is that information of the type requested?
    - The EQRO should check each field to determine whether its values are of the type and size found in the state's data dictionary, or in nationally recognized standards. For example, if CPT®-4 codes are requested, the field should have five digits. If the state's Medicaid and CHIP beneficiary ID is requested, the field should contain the correct number of letters and characters
2. Are the values valid and in the correct format?
    - To what extent are the values in the field valid? For instance, if ICD-10 diagnosis codes have been requested, are the values in the diagnosis field valid for that standard?
    - Do critical fields contain non-missing values in the correct format and specificity (e.g., maximum number of characters in a diagnosis) and that values are consistent across fields?
3. Are the data available?
    - Are all required data elements reported?
    - Do the data exist for all service types?
    - When viewed by date of service, are there gaps in the data?
4. Do the data meet basic consistency expectations?
    - Is beneficiary enrollment consistent over time?
    - Are the number of encounters consistent over time?
    - When broken out by population subgroups or service types, does consistency persist?

5. Are the state's identifiers (IDs) accurately incorporated into the MCP's information system?
    - The EQRO should compare the encounter data file to the state's eligibility file and check for accuracy of the IDs and other eligibility information (e.g., age, sex, and eligibility category). In addition, the EQRO should determine whether there are encounter data for the expected proportion of beneficiaries in comparison to utilization norms for similar populations
6. Is the information for each critical field within required ranges and is the volume of data consistent with the MCP's enrollment? For example, can the following types of questions be answered with the data:
    - What is the rate of emergency department utilization per 1,000 member months?
    - What percentage of beneficiaries have at least one encounter during the year?

Note: The EQRO should automate these analyses and perform them as a standard data review process. The EQRO should perform these analyses for each service type (e.g., inpatient hospital, outpatient, professional, home health, durable medical equipment) and for each data field within a service type.

Step 3: Encounter Data Micro-Analysis—Generate and Review Analytic Reports

1. In Step 3, the EQRO should move beyond analyses focused on data integrity and that are field-specific to analyses that cross fields and provide a broader view of whether the data can be used for meaningful analyses. Often data elements may meet basic expectations, but until multiple fields are used together for analysis, some data quality issues may not be detected. Examples of analytic reports that can detect broader data quality issues are:

WORKSHEET 5.3

Resource for Activity 3, Step 3

Worksheet 5.3. Evaluation of Submitted Fields

- Provide a template for the EQRO to document its findings for each data element

- Reasonability tests
    - The EQRO should develop frequency distributions of the values and compare them to normative data from similar populations to determine whether the values make sense. For example,
    - If "place-of-service" is a required field, the values should be distributed across a range of values (e.g., IP hospital, OP hospital, ED, or office)
    - The number of enrollees, the number of encounters, and counts and totals for various eligibility categories or demographic subgroups, diagnoses, or types of service
    - Frequency distributions on specific fields, as well as on the variables created explicitly for data validation purposes (e.g., beneficiary age from date of birth)

- Distributions on subsets of data, especially where there are specific concerns about data validity. For example, if the EQRO finds a low rate of utilization for outpatient services, it could analyze the data by provider zip code to determine whether the files are missing specific zip codes, causing the system to reject records. By taking a deeper dive into the data, the EQRO could detect a different problem than originally expected
- Univariate statistics (e.g., means, medians, quartiles, and modes) as appropriate. The EQRO should check the output of these reports for reasonableness and to detect specific problems such as entire categories of data missing from the regular data submissions

- Analyses by dates of service versus adjudication dates
  - Analyzing the data by dates of service and by adjudication dates can detect issues in consistency over time. Inconsistent processing can indicate other problems within the MCP's IS system, which may impact data validity. After establishing the length of time between service and adjudication dates, the EQRO should compare them with standards or benchmarks for data submission and processing
- Checks by provider types
  - The EQRO should review the data by provider type to identify missing provider types and examine fluctuations in patient visits by provider type for specified time periods. The EQRO should compare the distribution of encounters by provider type to normative information. The EQRO should also examine diagnosis or procedure codes by provider type to ensure that the relationship between provider specialty and the services rendered is consistent
- Relational analyses by service type or episodes of care
  - The relationship between ancillary services (e.g., labs, x-rays, etc.) and visits
  - The relationship between outpatient visits and the number of prescriptions dispensed
  - The relationship between primary and specialty care visits
  - Outpatient services associated with inpatient admissions
  - Grouped services expected in particular types of visit or episodes of care
  - Other relationships between service types previously identified as problematic through the ISCA, front-end edits, or other EQRO validation activities.
- Analyses broken out by demographic group or subpopulation
  - If not addressed already in the MCP's front-end edits, the EQRO should conduct analyses that take a beneficiary's age and gender into account. For example, the EQRO could verify that a gender-specific diagnosis (e.g., endometriosis) or procedure (e.g., caesarean delivery) is consistent with the beneficiary's age and gender derived from the encounter header record or the beneficiary's enrollment record

- Analytic questions
    - The EQRO should use information gathered in previous steps to select a question or series of questions it might answer using the encounter data as another step in determining quality and usability. For instance, the EQRO could take a particular measure of interest to the state and replicate it across all MCPs or within MCPs, such as the number of beneficiaries per primary care provider.

The EQRO should conduct these analyses on the encounter data and compare the results to external benchmark information (Step 4). As part of the review, the EQRO should display the data quality findings graphically to identify issues for further investigation and to communicate the results of the data quality review. The EQRO should generate these reports for each MCP and on the entire encounter data set for all MCPs to account for problems associated with small numbers of encounters for individual MCPs. For examples of these types of displays, see Section 5 of the CMS Encounter Data Toolkit.[70]

Step 4: Compare Findings to State-Identified Benchmarks

In this step, the EQRO compares the encounter data submitted by each MCP to benchmarks identified by the state. The EQRO will need to identify and document these benchmarks. The benchmarks can be obtained from various sources, including:

WORKSHEET 5.4

Resource for Activity 3, Step 4

Worksheet 5.4. Benchmark Utilization Rates

- Provides a template for the EQRO to compare findings to state-identified benchmarks

- Aggregate encounter data from all Medicaid or CHIP MCPs in the state
- Historical FFS or PCCM data
- Other comparable states
- The CMS Encounter Data Toolkit
- Other benchmarks, such as MCP financial reports, commercial MCPs, national standards, HEDIS®, or the Child and Adult Core Set measures[71]

The EQRO should understand which differences from comparison data require further investigation. For example, emergency room utilization might be lower in managed care than in FFS. However, large swings in utilization from one time period to the next, or differences from the benchmark that are not explained by delivery system differences may indicate incomplete or

[70] The CMS Encounter Data Toolkit is available at https://www.medicaid.gov/medicaid/downloads/medicaid-encounter-data-toolkit.pdf.

[71] HEDIS® benchmarks are published annually by NCQA in The State of Healthcare Quality Report, available at http://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality. Child and Adult Core Set benchmarks are available at https://www.medicaid.gov/medicaid/quality-of-care/index.html.

erroneous encounter data, rather than a difference in provider practice patterns. The EQRO should vet its assumptions about changes in utilization with the MCPs and the state to determine what follow-up analyses might be required. For example, unusual changes in utilization and outcomes may occur after a natural disaster (such as a hurricane). The EQRO should discuss anomalous findings with the state to assess underlying factors that may utilization or outcomes.

Activity 4: Review Medical Records

The purpose of Activity 4 is to confirm the findings from the analysis of encounter data performed in Activity 3, using retrospective reviews of patient medical records. This activity makes the following assumptions about the record review:

1. Reviews performed under the guidance of this protocol and activity should be independent of record reviews performed for all other purposes, including those performed to validate performance measures, for program integrity, etc.
2. The state will determine the timing and frequency of all medical record reviews
3. Once the state has determined a review of medical records is appropriate, the EQRO will draw a sample of records for validation on a regular and periodic basis, as directed by the state agency

WORKSHEET 5.5

WORKSHEET 5.6

Resources for Activity 4

Worksheet 5.5. Medical Record Review for Encounter Data Validation

- The Event Validation Table indicates whether an encounter record matches the medical record, and vice versa
- The Data Field Validation Table indicates whether codes or other data fields in the encounter record match the medical record, and vice versa

Worksheet 5.6. Medical Record Review Results Summary Sheet

- Summarizes the results of the medical record review, including the error rate and reasons for errors

EQROs should approach the validation of encounters from medical records as if they are research questions with clear hypotheses, well-defined sampling methodology, and predetermined error tolerances. Questions under consideration for medical record review generally fall into the following categories:

1. Questions of Description
    - Are all of the diagnosis codes in the patient's medical record on the associated encounter?
    - Are all of the procedure codes in the patient's medical record on the associated encounter?
    - Does the Date of Birth (DOB) listed in the beneficiary's medical record match the DOB found on the encounter header?
2. Questions of Relationship
    - Are there differences in the number of diagnoses reported for women compared to men?

- Are there differences in the distribution of Evaluation & Management (E&M) procedure codes by age group?
- Are there differences in the utilization of specific procedure codes by geographic area (e.g., county)?

3. Questions of Comparison
   - Are there differences in the average number of diagnoses coded on the encounter records compared to those found on FFS or PCCM claims?
   - Are there differences in the distribution of E&M procedure codes (i.e., 99201 – 99205) on the encounter records compared to those found on FFS or PCCM claims?
   - Are there differences in the distribution of Place of Service codes on the encounter records compared to those found on FFS or PCCM claims?

EQROs should limit each medical record review to a specific encounter type (e.g., inpatient hospital admissions, physician office visits). The EQRO should ensure that in narrowing the scope of the review, it does not overlook service types that are vulnerable to undercounting (such as prenatal and postpartum visits).

EQROs should determine the sample size for the medical record review using standard sampling methodology. The sample size will depend in part on the minimum error rate the EQRO must detect and the number of subpopulations for which validation is conducted. Note that it is not appropriate to substitute a record that is missing. Substitution may be allowed if a medical record is out of the office for legal review. Box 5.3 provides sampling guidance for medical record reviews.

Box 5.3 Sampling Guidance for Medical Record Review

- See Appendix B for an overview of sampling approaches and guidance for calculating sample sizes
- Set sample sizes for medical record review sufficient to estimate the error rate for each type of encounter within each population, with equal precision for each time period under review
- It may be appropriate to allow the substitution of a medical record if it is out of the office for legal review. However, it is not appropriate to substitute a record that is missing
- A statistician or other staff with expertise in sample design and implementation should advise the state and/or EQRO on the appropriate sampling strategy for the medical record review

Once the sample of medical records is selected, the EQRO needs to request the medical records from providers, compare the content of the encounter records and medical records, and document findings. The state should provide written guidance to the EQRO about the procedures for conducting the medical record review, including the reporting requirements, the data elements chosen for validation, and the error categories used. The EQRO should employ experienced clinical coders to review codes based on the diagnoses stated by the provider in the patient's medical record.

To obtain medical records for review, the EQRO should give each provider a list with each patient's name, age, and sex, the provider's name, and the target dates of service. This information should be sufficient for the provider to identify the beneficiary and locate the correct record. Guidelines should describe exactly how to document the findings of medical record review and should include:

- Directions for reviewing medical records
- Instructions for evaluating conflicting documents
- Instructions on what to do when no code can be readily assigned
- Use of optional codes
- Definitions of what constitutes an "error"
- Lists and locations of approved reference materials
- Whom to consult for additional assistance

In defining what constitutes an error, the state should consider the following:

- Designate certain errors as "critical" depending on the intended use of the data. These designations may evolve over time as encounter data issues change. For example, the initial stages of analysis may focus on diagnosis (ICD-10) and procedure (CPT®) codes rather than provider specialty or place of service codes. The latter two fields may be of little value if the former fields are inaccurate
- Distinguish error "tiers" (e.g., critical, serious, moderate), which may permit use of encounter data that may be incomplete or have some inaccuracies

Activity 5: Submit Findings

After the completion of Activities 1 through 4, the EQRO should create data tables that display summary statistics for the information obtained from each MCP. Summarizing the information in tables makes it easier to evaluate the findings and highlight patterns in the accuracy and completeness of the data. The EQRO should draft a narrative to accompany the tables, highlighting individual MCP issues and providing recommendations to each MCP and the state about improving the quality of the encounter data.

WORKSHEET 5.7

Resource for Activity 5

Worksheet 5.7. Suggested Format for Reporting Encounter Data Validation Information in the EQR Technical Report

- Provides a template for reporting results from the encounter data validation activity in the EQR technical report

In its findings and recommendations, the EQRO should assess the MCP's ability to provide the state with encounter data that meets the quality standards for submission to the state for use in T-MSIS. The EQRO should also assess the MCP's ability to produce reliable and valid performance measures as specified in the managed care quality strategy.

END OF PROTOCOL 5

Worksheets for Protocol 5: Encounter Data Tables

Instructions. Use these or similar worksheets as a guide when validating encounter data. The encounter data worksheets 5.1 through 5.4 are intended to help document acceptable error rates and data element validity requirements, findings from the review of individual encounter records, and comparison of findings to state-identified benchmarks. Worksheet 5.5. Medical Record Review for Encounter Data Validation is intended to help record results from the EQRO's validation of medical records. Worksheet 5.6. Medical Record Review Results Summary Sheet summarizes the results of the medical record review, including the error rate and reasons for errors.

Worksheet Name	Protocol Activity and Step
Worksheet 5.1. Specification of Acceptable Error Rates and Identified Areas of Concern Worksheet 5.2. Data Element Validity Requirements	Activity 1. Step 1. Review the MCPs' ISCA
Worksheet 5.1. Specification of Acceptable Error Rates and Identified Areas of Concern ISCA Worksheet A.1. ISCA Tool ISCA Worksheet A.2. ISCA Worksheet & Interview Guide	Activity 2. Step 1. Review the MCP's Capability
Worksheet 5.3 Evaluation of Submitted Fields Worksheet 5.4. Benchmark Utilization Rates	Activity 3. Analyze Electronic Encounter Data
Worksheet 5.5. Medical Record Review for Encounter Data Validation Worksheet 5.6. Medical Record Review Summary Sheet	Activity 4. Step 1. Obtain and Review Medical Records and Document Findings
Worksheet 5.7. Suggested Format for Reporting Encounter Data Validation Information in the EQR Technical Report	Activity 5. Submit Findings

Worksheet 5.1. Specification of Acceptable Error Rates and Identified Areas of Concern

Instructions. Worksheet 5.1 provides guidance for the EQRO's review of a state's specific requirements for reporting encounters. The EQRO should add rows as necessary to include all service types used by the state. Definitions for this activity are as follows:

- Encounter Data Error Types
  - **Missing.** A service rendered for which there is no encounter record
  - **Surplus.** An encounter submitted for a service that was never rendered, or which duplicates another record
  - **Erroneous.** Services rendered where there is an error in the encounter record
- **Acceptable Error Rate.** For each type of service (e.g., inpatient) and error (e.g., missing), the EQRO should document the state's acceptable error rate. In Worksheet 5.1, the acceptable error rate column expresses this rate as the percentage of missing, surplus, or erroneous records the state will accept from the MCP. Files with an error rate exceeding the thresholds are unacceptable. For example, a state might set error thresholds for office visits at less than 10 percent for missing encounters, less than 2 percent for surplus encounters, and less than 5 percent for encounters with erroneous information. If the state expresses its error tolerance in a different way, the EQRO should adjust the acceptable error rate accordingly.
- **Areas of Concern.** Based on the ISCA and other information, the EQRO should identify errors that it reasonably expects might occur. The EQRO could derive this information from work it performs in Protocol 2, Validation of Performance Measures Reported by the MCP. It should use the information to guide subsequent reviews.

Service type	Error type	Acceptable error rate	Area of concern (Yes/No/Describe)
Office visit – includes all services, except dental and mental health / substance abuse	Missing Surplus Erroneous	< % < % < %	
Office visit – includes mental health / substance abuse services only	Missing Surplus Erroneous	< % < % < %	
Office visit – includes dental services only	Missing Surplus Erroneous	< % < % < %	
Inpatient admission – includes all IP services, except mental health / substance abuse services	Missing Surplus Erroneous	< % < % < %	
Inpatient admission – includes mental health / substance abuse services only	Missing Surplus Erroneous	< % < % < %	
Other types of encounters (e.g., emergency department, lab / x-ray, pharmacy, physical therapy)	Missing Surplus Erroneous	< % < % < %	

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Worksheet 5.2. Data Element Validity Requirements

Instructions. The EQRO should document clearly the state's specific requirements for validating each data element by type of service. The EQRO should then evaluate each file received to validate the specific data elements. The EQRO should add rows as necessary to incorporate all data elements for which the state identifies specific validation requirements. Definitions for this activity include:

- **Expectation.** The EQRO should use this column to describe the general requirement(s) for validating each data element.
- **Validation Criteria.** The EQRO should use this column to document the validation threshold for each data element. Typically, the column will include a quantitative expression of the description in the Expectation column. Examples are shown in Worksheet 5.2.

Service type:		
Data element	**Expectation**	**Examples of validation criteria**
Enrollee ID	A valid member ID (e.g., Medicaid ID Number; SSN) as documented in the state's eligibility file.	98% valid.
Date of service (FDOS; LDOS)	Dates of service should be distributed across the entire period analyzed. Look for large month-to-month increases or decreases. Also, look for months with encounters that may be missing entirely.	Calculate the average number of encounters per month over the period specified in the study. In general, month-to-month differences should be relatively small. Document any outliers and request an explanation from the MCP.
Unit of service (Quantity)	This field should generally include the units billed for each type of medical service (e.g., 2 units ≥ 23 minutes through 37 minutes).	X% non-zero. < Y% should be 1 if CPT® code in range 99200-99215, 99241-99291.
Procedure code	Should include valid CPT® and HCPCS values, or another state-approved code.	At least 98% of the values in this field should be valid (i.e., non-zero, not blank, and not 8-or-filled) and in the expected format.
Revenue code (Hospital)	If the facility uses a UB04 claim form, this field should always be populated on inpatient encounters.	At least 98% of the values for this field on inpatient claims should be valid and in the expected format.

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Worksheet 5.3. Evaluation of Submitted Fields

Instructions. As the EQRO reviews encounter records, it should document its findings for each data element on Worksheet 5.3 or a similar form. To complete Worksheet 5.3 or similar tool, ask the following questions:

1. Is there information in the field, and is the information of the type (e.g., numeric) and format (e.g., MM/DD/YYYY) required?

    - The EQRO should check each data element to determine whether its values are of the type and size specified in the state's data dictionary. For example, if CPT®-4 codes are required, the field should have 5 characters. If the state's Medicaid and CHIP beneficiary ID is required, the field should include the specified number of alpha, numeric, or alphanumeric characters.

2. Compared to a generally accepted external standard, are the values in the specified field valid? For example, do the values in the field PROC-CODE match those found in the ICD-10-CM tables?

	Field is populated		Correct type		Correct size		Value is valid	
Required field	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
Member ID								
Plan ID								
Billing provider ID								
Rendering provider ID								
Primary diagnosis code								
Primary procedure code								
First date of service								
Last date of service								
Quantity (units)								
Add rows as needed								

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Worksheet 5.4. Benchmark Utilization Rates

Instructions. The EQRO should use this worksheet to compare its findings to state-identified benchmarks. Revise the column headings to reflect the specific benchmarks identified by the state. EQROs should add measures as specified by state validation requirements. CMS suggests that eligibility measures, if included, should align with the eligibility group code in T-MSIS.

Measure	MCP rate	FFS/PCCM rate	Comparable state(s) rate(s)	Other comparable rate (specify)
Inpatient discharges				
Inpatient LOS				
Overall				
By high-volume MS-DRGs				
By eligibility category/cohort				
Ambulatory surgeries				
Total number of surgeries				
By high-volume CPTs® or ambulatory surgery categories				
Total surgeries (per 1,000 members)				
By high-volume CPTs® or ambulatory surgery categories				
Providers				
Primary care physicians				
Specialists				
Other (e.g., mental health providers)				
Enrollees				
Total number of enrollees				
By eligibility category				
By age, gender categories				
Service utilization				
Total number of service users				
By eligibility category				
By age, gender categories				
Visits				
Total number of visits				
Average visits per enrollee				
Average visits per user				
By visit type (e.g., well-child)				

Measure	MCP rate	FFS/PCCM rate	Comparable state(s) rate(s)	Other comparable rate (specify)
Other service types (e.g., Rx)				
Total number by service type				
Encounters by enrollee/service type				
Encounters by enrollee/service type				

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Worksheet 5.5. Medical Record Review for Encounter Data Validation

Instructions. Complete Worksheet 5.5 for each record in the sample. Transfer results from the Event Validation and the Data Field Validation tables to Worksheet 5.6. Medical Record Review Results Summary Sheet.

Reviewer name:		**Review completion date:**	
Data element	**Field value**	**Data element**	**Field value**
Medical record ID number		Practice name	
Patient name		Practice TIN	
Patient ID number		Rendering provider name	
Patient gender		Rendering provider PIN	
Patient date of birth		Primary diagnosis	
First date of service		Principal procedure	
Last date of service			

Event Validation Table

Line number	**Procedure**	**Event noted on encounter record**	**Event noted in medical record**	**Match**	**No match**
1					
…					
…					
…					
N					

Note: Include one line for each procedure in the record for selected date.

If no match is found (i.e., the event is missing from either the medical record or the encounter record), record the results on the Medical Record Review Results Summary Sheet below, and stop.

If the event is present on both the medical and encounter records, proceed to validation of the specified data fields.

Required Review: (Check One)

[ ] Office visit: Includes all services, except dental and mental health/substance abuse

[ ] Office visit: Includes mental health/substance abuse services only

[ ] Office visit: Includes dental services only

[ ] IP admission: Includes all IP services, except mental health/substance abuse services

[ ] IP admission: Includes mental health/substance abuse services only

[ ] Other types of encounters utilized by the state (e.g., lab/x-ray; physical therapy)

[ ] Specify other service type: _____

Data Field Validation Table

Diagnosis codes and descriptors					
Encounter line #	**Encounter Dx code**	**Dx description**	**Medical record Dx code**	**Match**	**No match**
1					
…					
N					
Procedure codes and descriptors					
Encounter line #	**Encounter procedure code**	**Procedure description**	**Medical record procedure code**	**Match**	**No match**
1					
…					
N					
Revenue codes and descriptors					
Encounter line #	**Encounter revenue code**	**Revenue description**	**Medical record revenue code**	**Match**	**No match**
1					
…					
N					

Note: The EQRO should edit this table to include all data elements under review.

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Worksheet 5.6. Medical Record Review Results Summary Sheet

Research question:

_____
_____
_____

Sample size: _____

Sampling methodology: _____

Please summarize how the MCP addresses medical record review auditing or accuracy checks:

_____
_____

Record of substitutions (list substitutions and reasons):

Original Record	Replacement Record	Replacement Reason
1.		
2.		
3.		

Results:

Record numbers reviewed	Event noted on encounter record	Event recorded in medical record	Match? (Yes / No)	Notes / Comments
1				
2				
3				
…				
N				

Error rate (total records with errors/total records in sample): _____

Reviewer summary of findings (including reasons for errors):

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Worksheet 5.7. Suggested Format for Reporting Encounter Data Validation Information in the EQR Technical Report

Instructions. Use Worksheet 5.7 as a framework to report findings from the encounter data validation activities in Protocol 5 by MCP.

For each MCP, please complete the following information:

MCP name	
MCP contact name and title	
Mailing address	
Phone/fax numbers	
Email address	
EQRO interview date	
Type of delivery system (check all that apply)	□ Staff model □ Network □ IPA
Plan type	□ MCO □ PIHP □ PAHP □ PCCM □ LTSS □ Other: specify _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP

Note: CHIP= Children's Health Insurance Program; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCP= Managed Care Plan; MCO = Managed Care Organization; PAHP= Prepaid Ambulatory Health Plan; PIHP = Prepaid Inpatient Health Plan; PCCM = Primary Case Management.

Encounter Type	Records Received and Reviewed	Total Elements Possible	Total Matched Elements	Percentage of Matched Elements
Inpatient				
Outpatient				
Office visit				
Total				

Inpatient Encounter Type	Diagnosis Codes	Procedure Codes	Revenue Codes	Total
Match				
No Match				
Total Elements				
Match Percent				

Outpatient Encounter Type	Diagnosis Codes	Procedure Codes	Revenue Codes	Total
Match				

Outpatient Encounter Type	Diagnosis Codes	Procedure Codes	Revenue Codes	Total
No Match				
Total Elements				
Match Percent				

Office Visit Encounter Type	Diagnosis Codes	Procedure Codes	Revenue Codes	Total
Match				
No Match				
Total Elements				
Match Percent				

No Match for Diagnosis Code Element			
Encounter Type	Total Elements	Lack of Medical Record Documentation	Incorrect Principal Diagnosis (Inpatient) or Incorrect Diagnosis Codes
Inpatient			
Outpatient			
Office Visit			
Total			

No Match for Procedure Code Element			
Encounter Type	Total Elements	Lack of Medical Record Documentation	Incorrect Principal Diagnosis (Inpatient) or Incorrect Diagnosis Codes
Inpatient			
Outpatient			
Office Visit			
Total			

No Match for Revenue Code Element			
Encounter Type	**Total Elements**	**Lack of Medical Record Documentation**	**Incorrect Principal Diagnosis (Inpatient) or Incorrect Diagnosis Codes**
Inpatient			
Outpatient			
Total			

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END OF WORKSHEETS FOR PROTOCOL 5

Protocol 6. Administration or Validation of Quality of Care Surveys

AN OPTIONAL EQR-RELATED ACTIVITY

PROTOCOL SIX

SECTION I. ADMINISTERING A SURVEY
ACTIVITY 1: IDENTIFY THE SURVEY PURPOSE, OBJECTIVES, AND AUDIENCE
ACTIVITY 2: DEVELOP A WORK PLAN
ACTIVITY 3: SELECT THE SURVEY INSTRUMENT
ACTIVITY 4: DEVELOP THE SAMPLING PLAN
ACTIVITY 5: DEVELOP A STRATEGY TO MAXIMIZE RESPONSE
ACTIVITY 6: DEVELOP A QUALITY ASSURANCE PLAN
ACTIVITY 7: IMPLEMENT THE SURVEY ACCORDING TO THE WORK PLAN
ACTIVITY 8: PREPARE AND ANALYZE SURVEY DATA AND PRESENT RESULTS IN A FINAL REPORT
SECTION II. VALIDATING A SURVEY
ACTIVITY 1: REVIEW THE SURVEY PURPOSE, OBJECTIVES, AND AUDIENCE
ACTIVITY 2: REVIEW THE WORK PLAN
ACTIVITY 3: REVIEW THE RELIABILITY AND VALIDITY OF THE SURVEY INSTRUMENT
ACTIVITY 4: REVIEW THE SAMPLING PLAN
ACTIVITY 5: REVIEW THE ADEQUACY OF THE RESPONSE RATE
ACTIVITY 6: REVIEW THE QUALITY ASSURANCE PLAN
ACTIVITY 7: REVIEW THE SURVEY IMPLEMENTATION
ACTIVITY 8: REVIEW THE SURVEY DATA ANALYSIS AND FINAL REPORT

Background

Surveys are an important resource for assessing the experience of managed care enrollees and providers. Information derived from surveys can help states and managed care plans (MCPs) create a person-centered health care environment for those enrolled in Medicaid and the Children's Health Insurance Program (CHIP). Enrollee surveys can be used to assess experience with their health plan and its providers, and the quality of care they receive. Provider surveys can be used to assess the characteristics of providers and practices that serve Medicaid

and CHIP enrollees, their accessibility and availability, and their experience with the Medicaid and CHIP programs.

This protocol provides guidance for administering and validating consumer or provider surveys. These surveys may be administered by states or MCPs (or their vendors) and validated by an external quality review organization (EQRO) or administered by the EQRO on behalf of a state or MCP. Because this protocol may be used for a variety of purposes, it does not specify one survey instrument, sampling method, or analytical approach.

An overarching goal of this protocol is to provide guidance about designing and conducting surveys that produce valid and reliable results. In this context, validity refers to surveys that measure what they were intended to measure. Reliability refers to the internal consistency of a survey and the reproducibility of survey results when administered under different conditions (e.g., by different people or at different times). Please refer to the Technical Appendix at the end of this protocol for further discussion about potential sources of survey error that can affect the overall quality of a survey.

Getting Started on Protocol 6

This protocol includes eight activities related to administering and validating a survey (Figure 6.1). When an EQRO validates a survey, the activities in 6.1 focus on ensuring the survey was administered correctly. Although the focus of the EQR-related activity will differ depending on whether the EQRO's role is to administer or validate a survey, these eight activities are common to both roles.

Figure 6.1. Protocol 6 Activities

Note: These activities pertain to survey implementation. Survey validation activities involve reviewing the adequacy of survey implementation.

Two supplemental resources are available to help EQROs administer and validate a survey:

- Worksheets for Protocol 6. Survey Administration and Validation Tools, which can be used to guide the EQRO's activities as follows:
    - For survey administration: Use the worksheets to track and document steps performed in designing and implementing the survey. In the "Comments" column, document decisions or findings
    - For survey validation: Use the worksheets to track and document steps performed in validating the survey. In the "Comments" column, document the outcome of validation activities, including sources reviewed. The worksheets can also be used as an outline for the final report to the state. Expand the tool to include other activities or findings as needed
- Appendix B. Sampling Approaches for EQR Data Collection Activities, which provides an overview of sampling methods

Section I of this protocol describes the activities associated with administering a survey. Section II describes the activities associated with validating a survey.

Section I. Administering a Survey

Activity I.1: Identify the Survey Purpose, Objectives, and Audience

The first step in developing a survey is to identify the survey purpose, objectives, and audience (Worksheet 6.1). The EQRO should develop a clear understanding of how a state will use the survey results, including what the state wants to learn from the survey and what it plans to do with the results (see Box 6.1).

WORKSHEET 6.1

Resource for Activity 1

Worksheet 6.1. Survey Purpose, Objectives, and Audience

- Provides a set of questions to assess the clarity of the survey purpose, objectives, and audience

The state should also specify the audience for the findings, since the survey content, analysis plan, and report format will vary based on the audience. Such audiences and uses could include the following:

- **Enrollees and their families.** Increasingly, consumers rely on survey information to inform their choice of health care options. To support this use, the survey design must allow for comparisons among MCPs, potentially controlling for or stratifying enrollee characteristics
- **MCPs and providers.** To promote value-based purchasing in Medicaid and CHIP, information on the quality of care provided by MCPs and providers can be used to identify higher- and lower-performing plans and practices and support quality improvement initiatives
- **State policymakers.** With increasing recognition of the link between better care, better health, and more affordable care, information on enrollee experiences in managed care, barriers to care, and the role of social determinants can be used to develop initiatives to reduce disparities and improve outcomes

Box 6.1 Examples of Survey Uses

- Monitor and evaluate access, timeliness, and quality of care provided to Medicaid and CHIP enrollees
- Inform value-based purchasing and quality improvement initiatives
- Provide information to help Medicaid and CHIP enrollees make informed choices among MCPs

Next, the state should specify survey domains that align with the intended use of the survey results. For example, if the survey results will be used to help enrollees choose a health plan, specific measurement domains might include experience with the primary care provider, access to specialty care, and treatment planning, among others.

Finally, the state should specify the unit of analysis, including populations or subpopulations of interest. Depending on the purpose of the survey, the unit of analysis could be the entire managed care population in the state or it could be targeted to subpopulations, for example,

individual MCPs, provider groups, children with chronic conditions, new Medicaid enrollees, or individuals recently disenrolled from an MCP. This information is used to develop the sampling approach, instrument design, and analysis plan.

Activity I.2: Develop a Work Plan

WORKSHEET 6.2

Resource for Activity 2

Worksheet 6.2. Work Plan

- Provides a set of questions to assess the work plan

After determining the intended use of the survey in collaboration with the state, the EQRO should prepare a work plan that will govern the implementation of the survey (including the project management plan, schedule, and reporting requirements). Key issues to address in the work plan are summarized in Worksheet 6.2. Refer to Activity I.6 for examples of typical weekly data collection schedules. The EQRO should obtain state approval of the work plan before implementing the survey and then administer the survey in accordance with the approved work plan.

Activity I.3: Select the Survey Instrument

WORKSHEET 6.3

Resource for Activity 3

Worksheet 6.3. Survey Instrument

- Provides a set of questions to assess the selection of the survey instrument

The state's choice of a survey instrument should be consistent with the purpose of the data collection, unit of analysis, and goal of collecting valid and reliable data (Worksheet 6.3). This protocol describes three options for selecting the survey instrument:

- Option 1. Use an existing validated survey instrument
- Option 2. Adapt an existing survey instrument with additional state-specific questions
- Option 3. Develop a new survey instrument

The state may choose among the three options independently or in consultation with the EQRO. However, there often are trade-offs in selecting an instrument. Use of an existing instrument may provide the greatest assurance of validity and reliability but omit certain key domains of interest. In contrast, development of a new survey instrument may provide the closest alignment with the intended use of the survey results but validity and reliability may be untested. Thus, another option is to adapt an existing survey instrument by adding state-specific questions to address gaps in survey content. These three options are summarized in more detail below.

- Option 1. Use an Existing Validated Survey Instrument
  - Use of an existing well-validated instrument offers several benefits such as:
  - Readily accessible
  - Cost efficient

- Minimal development and testing hours
- Often translated into Spanish or other languages
- Available benchmark data that can be used for context and comparisons
- Potential for rapid launch of data collection to investigate time-sensitive issues

The state or EQRO can select from a variety of existing survey instruments. Table 6.1 provides examples of instruments that have been used to gather (1) beneficiary feedback about experiences with health care, and (2) provider feedback on organizational issues.

Table 6.1. Examples of Existing Validated Survey Instruments

Example	Description
Beneficiary surveys	
CAHPS®	• Developed by AHRQ in collaboration with the CAHPS® Consortium, the CAHPS® survey instruments and reporting formats have undergone rigorous testing for reliability and validity • States frequently use the CAHPS® surveys to assess enrollees' experiences with managed care; versions include a Health Plan Survey; Clinician & Group Survey; Hospital Survey; and Cancer Care Survey. An overview is available at https://www.ahrq.gov/cahps/index.html • Includes surveys for Child and Adult Medicaid and CHIP enrollees available at https://www.ahrq.gov/cahps/surveys-guidance/hp/index.html • Allows for the addition of supplemental questions; see https://www.ahrq.gov/cahps/surveys-guidance/item-sets/search.html • National and regional benchmarks are available; information about the CAHPS database is available at https://www.ahrq.gov/cahps/cahps-database/index.html • Note that there are two versions of CAHPS (AHRQ and NCQA); more information about the differences between the two versions is available at https://www.ahrq.gov/cahps/surveys-guidance/hp/about/NCQAs-CAHPS-HP-Survey.html • A CAHPS Health Plan survey fielding guide is available at https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/hp/fielding-the-survey-hp50-2013.pdf
CAHPS Behavioral Health Care Surveys	• Two CAHPS products are available to assess patient experience with behavioral health, mental health, or substance use services: (1) supplemental items for the CAHPS Health Plan Survey and Clinician & Group Survey and (2) CAHPS Experience of Care and Health Outcomes (ECHO) Survey • More information about CAHPS mental health surveys is available at https://www.ahrq.gov/cahps/surveys-guidance/echo/index.html

Example	Description
Long-term Services and Supports (LTSS) Surveys	• Standardized instruments for measuring experiences with LTSS and home and community-based services (HCBS) include the HCBS CAHPS, National Core Indicators, and National Core Indicators-Aging and Disabilities • More information about HCBS CAHPS is available at https://www.medicaid.gov/medicaid/quality-of-care/quality-of-care-performance-measurement/cahps-home-and-community-based-services-survey/index.html • More information about National Core Indicators is available at https://www.nationalcoreindicators.org/ • More information about National Core Indicators-Aging and Disabilities is available at http://www.advancingstates.org/initiatives/national-core-indicators-aging-and-disabilities
Provider and practice surveys	
Patient Centered Medical Home Assessment (PCMH-A)	• Standardized practice-level survey instrument • Designed to help practices monitor their progress as they transition to a medical home care model and identify areas for improvement • More information is available at http://www.safetynetmedicalhome.org/sites/default/files/PCMH-A.pdf • A modified PCMH-A survey was developed for the Comprehensive Primary Care Initiative (PCPI) evaluation; for more information see https://innovation.cms.gov/Files/reports/cpci-evalrpt2.pdf
Staff Experience Survey	• Developed by the University of Chicago to assess staff experience across multiple domains: access to care and communication with patients, tracking data, electronic medical record, care management, quality improvement, work satisfaction, work environment, work activities, and demographics • Survey instrument is available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3752653/

Even when using an existing instrument, the EQRO should review the instrument's reliability and validity based on published or unpublished documentation (see Box 6.2). For example, existing validated survey instruments may not have been validated in a Medicaid or CHIP population or not tested in languages other than English. Selecting instruments not validated in the target population may not yield valid or reliable results for that population. When using an existing survey instrument, the EQRO should document findings related to reliability and validity testing of the survey instrument, preferably in a comparable population.

Box 6.2 Validity and Reliability

Validity refers to the degree to which the survey is measuring what was intended to be measured and is made up of two components:

- Face validity refers to the degree to which the survey is measuring what was intended to be measured
- Content validity refers to whether the survey questions accurately represent the concept or subject matter being measured

Reliability refers to:

- Internal consistency of a survey
- Reproducibility of survey results when administered under different conditions (such as by different people or at different times)

- Option 2. Adapt an Existing Survey
    - Another option is to adapt an existing survey by adding or deleting items, modifying questions, or using only certain groups of questions relevant to the state's survey objectives. Modifying an existing questionnaire provides the state with the flexibility to add or change the survey content while providing many of the advantages of using a pre-existing questionnaire. However, adding, deleting, or modifying questions may undermine the validity and reliability of the questions, as well as the survey overall. Validated questionnaires are tested "as a whole," and modifications can change the focus and purpose of the questionnaire.
    - Some surveys, such as the CAHPS® Medicaid Health Plan Survey, provide optional supplemental questions the state can consider using to customize the questionnaire. This has the advantage of providing a validated instrument that allows comparisons, while accommodating special questions of particular interest to the state or MCPs.
    - When the EQRO adapts an existing questionnaire, it should consult with an expert in survey design about incorporating the modification and conducting appropriate tests for reliability and validity. Any new translations should also be tested.
- Option 3. Develop a New Survey Instrument
    - The state or EQRO may also decide to develop a new survey instrument when the survey purpose requires answers to questions not measured by existing instruments. A well-designed instrument can capture information of interest and relevance to the questions under study.

Box 6.3 includes best practices in questionnaire and design that states or EQROs should follow. If possible, the state or EQRO should involve a survey design expert to address issues associated with respondent burden, comprehension, and readability.

Box 6.3. Best Practices in Questionnaire Design

- Questions are worded clearly and briefly, and in an unbiased manner so respondents can readily understand key terms and concepts
- Questions request information that respondents can reasonably be expected to report
- Question response categories are appropriate, mutually exclusive, and reasonably exhaustive given the intent of the questions
- Questions are accompanied by clear, concise instructions and probes so that respondents will know exactly what is expected of them
- All questions can be easily understood by someone with a sixth-grade reading level

In addition, the state or EQRO should work with a survey design expert to assess face and content validity and conduct a pretest of the instrument for reliability. Although assessment of the validity and reliability of new surveys can be costly and time consuming, such testing is key to identifying methodological flaws that could make the results suspect.

Face and content validity can be assessed by conducting cognitive interviews or convening one or more focus groups that include targeted survey respondents or individuals with subject matter expertise. A factor analysis could also be conducted to verify that the individual items that comprise a scale are measuring the domain of interest. Reliability can be assessed using the test-retest method in which the survey is administered to the same group at two different times. A correlation coefficient is calculated and indicates the reproducibility of results. Correlation coefficients with r-values at or above 0.70 indicate good reliability. However, even with high reliability, a new survey instrument will have limited benchmarks for comparison of results.

Activity I.4: Develop the Sampling Plan

The EQRO should develop a sampling plan that represents all eligible enrollees within the MCP (Worksheet 6.4). Refer to Appendix B. Sampling Approaches for EQR Data Collection Activities for an overview of sampling approaches that can be used for drawing a survey sample. In general, the sampling plan should incorporate information from the five steps described below.

WORKSHEET 6.4

Resource for Activity 4

Worksheet 6.4. Sampling Plan

- Provides a set of questions to assess the sampling plan

Appendix B. Sampling Approaches for EQR Data Collection Activities

- Provides an overview of sampling approaches and guidance for determining sample sizes for EQR data collection activities

Step 1: Define the Study Population

The EQRO must first define the population to be studied (for example, all Medicaid or CHIP beneficiaries enrolled in an MCP or all children with chronic conditions) and then determine which data source(s) to use to construct a list of all units in the study population (this list is referred to as the sampling frame). The sampling frame will be used to draw the sample for data collection. The sampling frame should include all the information necessary to determine whether units in the population are eligible for the study

(e.g., dates of Medicaid coverage and MCP enrollment) and any information that would be used for stratification by subgroup (e.g., age, gender, zip code of residence).

Step 2: Determine the Type of Sampling to be Used

There are two basic types of sampling methods.

- **Probability (or random) sampling methods** leave selection of population units to chance and not to convenience or preference on the part of the individuals conducting the study or otherwise participating in the study. Probability sampling removes systematic bias in the selected sample due to observed and unobserved differences in the sampling units
- **Non-probability sampling methods** are used when subjects are scarce or hard to sample (no sampling frame) and/or the study relies on volunteers. The sample is based on the choice of those administering the survey rather than chance; therefore, some bias can be expected

Probability sampling is preferable to non-probability sampling when feasible because it removes systematic bias from the sample. For more information on commonly used types of probability and non-probability sampling methods, see Appendix B.

Step 3: Determine the Number of Units to Sample

The number of units selected in the sample depends on several factors, including the level of precision required to achieve statistically valid results, the expected number of respondents (i.e., the response rate), and other constraints on the financial and personnel resources available to administer the survey. Samples with a larger number of units will provide a higher level of precision, but may be more expensive to collect data from and present more of a burden on financial and personnel resources.

For the CAHPS® Medicaid Health Plan Survey, the target number of completed surveys is 411 per health plan. The recommended initial sample sizes are 1,350 for the Medicaid Adult Version and 1,650 for the Medicaid Child Version. For other surveys, the EQRO should consider contacting a sampling statistician to conduct a statistical power analysis to help determine the optimal number of units to sample to meet precision targets while accounting for financial and personnel burden.

Given the interdependence between sample size, response rate, and precision, a goal is to achieve the highest response rate possible. See Activity I.5 for strategies to maximize survey response.

Step 4: Select the Sample

In this step, the EQRO determines how the sample will be selected. For probability sampling methods, the sample can be drawn using statistical software packages. For non-probability samples, the sample is selected by the EQRO based on convenience or perceived representativeness of the study population. The sampling plan should clearly explain the

sampling methods, and describe the procedures used to minimize bias. For more information on selecting the sample, see Appendix B.

Activity I.5: Develop a Strategy to Maximize Response

The EQRO should develop a strategy for maximizing survey response that includes a plan for both locating and contacting the sample members.

WORKSHEET 6.5

Resource for Activity 5

Worksheet 6.5. Strategy to Maximize Response

- Provides a set of questions to assess the strategy for locating sample members and specific data needed to administer the survey

Step 1: Maximize Completeness of Sample Information Before Survey Launch

Before the survey is implemented, the EQRO should identify the specific data it needs to locate sample members and develop a strategy for ensuring the locating information is complete. The following information is frequently used to locate sample members in Medicaid surveys:

- First and last name
- Address
- Home and cell phone numbers
- E-mail address
- Date of birth
- Primary language
- Preferred language
- Name of MCP
- Length of enrollment

These data elements should be used for the purpose of contacting sample members and should be kept separate from the survey data to protect the confidentiality of the sample members' survey responses and protected health information (PHI). The survey data provided by the sample member should be identified by a unique, numeric identification number, not by name or other identifying characteristic.

The EQRO should collect complete contact information and consider that some information may be verified through the state's eligibility files or the MCPs' enrollee files. The EQRO may also need to establish a data use agreement with the state or MCP for the protection and handling of PHI. The EQRO should also expect missing data in the state data files and document its plans to locate and contact respondents, including sending names in the sample file to a telephone number look-up vendor or using a change-of-address database vendor.

Step 2: Design a Data Collection Strategy that Maximizes Response

The EQRO should design a data collection strategy that maximizes response and fits within the available budget and schedule. The data collection strategies described below represent best practices in the field of survey research and are frequently used to maximize survey response.[72] The EQRO should design a data collection plan that uses some or all of the strategies described below:

1. **Advance letter.** Including an introductory letter before starting data collection lends legitimacy to the survey. A good letter emphasizes survey sponsorship (e.g., on state government letterhead signed by the agency director), describes the purpose of the survey, includes a statement about sample member confidentiality, provides information on how the sample member was selected for the survey, and describes benefits to the sample member as a result of participation (and emphasizes there is no penalty for not responding). In addition, the letter should be personalized and addressed to the respondent by name
2. **Multiple and varied call attempts.** Best practices to increase survey response include the use of varied contact attempts. This can include multiple contact attempts at different times of the day, mailing a reminder postcard or second survey if conducting a self-administered paper survey, making a follow-up phone call to non-respondents to a mail survey, or conducting repeat calls in a telephone survey. The EQRO should track and follow up on the number of respondents that could not be contacted or failed to respond
3. **Multi-mode surveys.** Combining two or more modes of data collection (such as mail and phone) in a single survey effort can lead to higher response rates than single-mode surveys. This is because multi-mode surveys may:
    - Lower costs by beginning data collection in a cost-effective mode
    - Allow the data collection to continue for longer periods
    - Increase the timeliness of response (for example, results from a web-based survey can be received faster than results by mail)
    - Limit coverage error by offering the survey by mail or web if the population of interest may not have consistent telephone service. In addition, as more households have access to the internet, using email and text messaging (with respondent permission) has become an increasingly common method to contact respondents. Box 6.4 provides additional information about integrating web-based outreach in data collection.
4. **Multiple languages.** The state and MCPs should have information about each beneficiary's primary and/or preferred language. If this information is not readily available, the EQRO

[72] For more information about best practices see: (1) Dillman, Don A., Jolene D. Smyth, Leah Melani Christian. Internet, Mail and Mixed-Mode Surveys: The Tailored Design Method (4th ed.), 2014. (2) Groves, R.M. Non response rates and nonresponse bias in household surveys. Public Opinion Quarterly, vol. 70, no. 5, Special Issue 2006, pp. 646–675.

might include a sentence in the advance letter translated into the most common languages in the area, inviting the individual to call for more information or to request a specific translation

Box 6.4. Integrating Web-Based Outreach in Data Collection

- Send the advance letter by email in place of, or in addition to, first class mail
- Send the reminder postcard by email in place of, or in addition to first class mail
- Include a hyperlink to an online version of the survey in the advance letter or advance email
- Begin data collection with an online survey and follow-up with non-respondents by mail and/or telephone
- When deciding which mode(s) to use, always consider the population's access to and preferences for each mode

The strategies should be tailored to the survey population. In particular, the EQRO should customize strategies for provider surveys. While the design and contact strategies listed above also are effective when surveying health care professionals (such as physicians, nurses, and practice staff), health care professionals historically are a difficult population to reach. A meta-analysis[73] of 154 surveys of health care professionals found statistically significant improvements in response rates when using mail-based data collection (compared to the web-based mode) and when monetary incentives were offered (compared to those that did not offer a monetary incentive or offered a non-monetary incentive). In addition, surveys with one or two follow-up attempts yielded higher response rates than studies with three or more follow-ups.

Step 3: Specify the Method Used to Calculate the Response Rate

The sampling plan should specify the method that will be used to calculate the response rate. The EQRO should use a standard methodology to calculate the response rate. The American Association of Public Opinion Research (AAPOR) provides a list of standard definitions, which is available at https://www-archive.aapor.org/AAPOR_Main/media/publications/Standard-Definitions20169theditionfinal.pdf.

The sampling plan should also note target response rates for similar surveys, which can be used as a benchmark to assess the adequacy of the response rate after the survey is implemented, such other surveys conducted by the state or by other states, or other types of surveys implementing the same methodology.

Step 4: Include a Plan for a Non-Response Analysis

Finally, after the survey is complete, a non-response analysis should be conducted, as discussed in Activity I.8. The sampling plan should describe the approach that will be taken to a non-

[73] Young Ik Cho, Timothy P. Johnson, and Jonathan B. VanGeest. Enhancing Surveys of Health Care Professionals: A Meta-Analysis of Techniques to Improve Response. Evaluation & the Health Professions, vol. 36, no. 3, pp. 382-407, August 2013.

response analysis to assess whether there are differences between respondents and non-respondents.

Activity I.6: Develop a Quality Assurance Plan

The EQRO should develop a quality assurance plan that contains quality checks for all phases of the data collection effort (Worksheet 6.6). The quality assurance plan should describe the checks to be performed and the processes used to implement the checks (see Box 6.5). The quality checks should cover the sampling and locating processes, be customized by data collection mode, and specify data quality controls.

WORKSHEET 6.6

Resource for Activity 6

Worksheet 6.6. Quality Assurance Plan

- Provides a set of quality check questions to assess the quality assurance plan

Box 6.5. Tips for Quality Assurance Checks

The quality assurance plan should describe each quality check and clearly identify:

- What checks are being performed
- How the checks are performed
- Who performs the checks
- Frequency of the checks
- Percentage of survey records that are to be checked
- Corrective actions required if an issue is identified
- How the issue was resolved

Activity I.7: Implement the Survey According to the Work Plan

The EQRO should implement the survey according to the weekly data collection schedule laid out in the work plan (see Activity I.2 and Worksheet 6.7). Although there is no set time frame for data collection, on average, data collection activities range from 10 to 14 weeks. Three sample data collection schedules by week are included in Table 6.2. Any deviations from the work plan should be documented and the reasons for those deviations should be explained.

WORKSHEET 6.7

Resource for Activity 7

Worksheet 6.7. Survey Implementation According to the Work Plan

- Provides a set of questions to assess survey implementation

Table 6.2. Sample Data Collection Schedules by Week

Data Collection Week	Mail-only protocol	Telephone-only Protocol	Mixed-mode Example: Mail with Telephone Follow-up
1	Mail initial survey with cover letter to sample members	Mail advance letters and begin telephone contact to sample members	Mail initial survey with cover letter to sample members
2	Mail optional postcard and receipt returned surveys	Mail optional postcard and continue telephone follow-up	Mail optional postcard and receipt returned surveys
3	Receipt returned surveys	Continue telephone follow-up (weeks 3–10)	Receipt returned surveys
4	Mail second survey with cover letter to non-respondents		Mail second survey with cover letter to non-respondents
5	Receipt returned surveys (weeks 5–10)		Receipt returned surveys
6			Telephone follow up to non-respondents and receipt returned surveys (weeks 6–12)
7			
8			
9			
10	**End data collection**	**End data collection**	
11			
12			**End data collection**

Activity I.8: Prepare and Analyze Survey Data and Present Results in a Final Report

Once the surveys have been completed and returned, the EQRO must prepare the data for analysis. This may include post-processing procedures (e.g., cleaning and editing, creating weights, and conducting a nonresponse analysis). Then the EQRO proceeds with the data analysis in accordance with the work plan and prepares the final report (Worksheet 6.8).

WORKSHEET 6.8

Resource for Activity 8

Worksheet 6.8. Survey Data Analysis and Final Report

- Provides a set of questions to assess the data analysis and final report

Step 1: Implement Post-Processing Procedures

Consistent with the quality assurance plan (Activity I.6), the EQRO should implement procedures to handle responses that fail edit checks, address missing data, and remove data from surveys determined to be unusable. The EQRO should specify the criteria used to remove

surveys or data from the final analytic file (including the threshold used to determine a completed case). The EQRO should document the reasons for all exclusions or adjustments of data used for the analysis.

Step 2: Calculate the Sampling Weights

When a sample is selected in such a way that there are different probabilities of selection for different units, sampling weights must be constructed and used for any analyses conducted with data collected from the sample. The weights take into account the sample design and nonresponse of sampled units. The weighted results, therefore, are representative of the population not just the units that responded to the survey.

The sampling weight is equal to one over the probability of selection for a unit. For example, if the probability of selection is 0.25 for a unit, the sampling weight is 1/0.25 = 4. In probability sampling, the sampling weights are used to make inferences to the study population. The sampling weights would also need to be adjusted to account for nonresponse if there is considerable nonresponse during data collection. The EQRO should consult a sampling statistician to help calculate the sampling weights.

Step 3: Conduct a Non-Response Analysis

The response rate is only one indicator of survey quality. Another indicator is the extent to which non-respondents may differ from respondents on the key variables in the survey sample. Because significant differences may bias the survey estimates, it is important to conduct a nonresponse analysis to assess the representativeness of the survey respondents.

Before beginning the data analysis, the EQRO should compare the characteristics of respondents and non-respondents using means and frequency distributions. The analysis should rely on information available in the sample frame (such as information found in state Medicaid eligibility files). Tests of statistical significance (e.g., t-tests and chi-square tests) should be performed to determine whether the differences are statistically significant. If there are substantial differences between respondents and non-respondents, the EQRO should consult a statistician to assess what types of adjustments might be necessary to account for potential bias in the survey responses.

Step 4: Analyze Survey Data

Following the analysis plan laid out in the work plan and approved by the state, the EQRO should generate means or frequency distributions for each survey question and calculate statistics. The analysis should include a description of the population characteristics, performance on the outcome measures included in the survey (such as access, timeliness, and quality of care or experience of care).

In addition, the EQRO should examine differences in survey results among MCPs, between MCPs and the FFS or PCCM population (if applicable), or between MCPs in the state and nationally or regionally (if benchmarks are available). The EQRO could also analyze and report on variations among subpopulations within each MCP. For example, the state may be interested in whether responses differ significantly across geographic locations, racial/ethnic groups, socioeconomic groups, or other identifiable subgroups. For recurring surveys with trendable results, the EQRO could examine changes over time on key metrics.

Results should be weighted, account for the complex sample design in computing variances (if applicable), and take into consideration the adequacy of sample sizes to support the analyses.

Some surveys include open-ended, qualitative responses related to experience or satisfaction. In such cases, the open-ended responses should be reviewed, coded into categories if feasible, and synthesized for analysis. Such information can enrich the quantitative data analysis and provide a "voice" to illustrate the numerical findings.

Step 5: Prepare and Submit a Final Report

The EQRO should prepare and submit reports in the agreed format, which may include:

- Survey purpose and objectives
- Survey implementation procedures, including challenges encountered, lessons learned, and recommendations for improving future efforts
- Overview of analytic findings, including subgroup analyses and tests of statistical significance
- Methodologically appropriate, comparative information about MCP performance
- A detailed assessment of each MCP's strengths and weaknesses with respect to access, quality, and/or timeliness of health care furnished to enrollees
- Conclusions drawn from the data

Results from the survey should always be presented for groups and not for individual respondents. Statistical graphs should accompany narrative text to aid comparison and interpretation. For example, bar graphs and comparison charts, such as those recommended by CAHPS®, convey important information about the performance of each MCP and indicate meaningful differences among MCPs.

The EQRO should submit a draft report and provide the state with an opportunity to review and comment on the draft report. The EQRO should then revise the draft and submit a final report that incorporates state comments. Other deliverables may include a raw data file and analysis files, as well as public reports, presentations, or web sites developed for public reporting.

Section II. Validating a Survey

Protocol 6 also contains guidance for EQROs charged with validating a survey conducted by a state, MCP, or a vendor hired by the state or MCP.[74] The activities described in this section focus on reviewing the survey design and implementation for validity, reliability, and methodological rigor. They do not include collecting additional survey data from survey respondents to verify their responses or test for survey validity and reliability.

The EQRO should use the Worksheets for Protocol 6 or a similar tool to guide the validation process. The EQRO should identify the documentation it used to review the survey procedures and note its findings for each activity. In addition, the EQRO should note the absence of documentation for a particular activity as it may be relevant to the survey validation.

Upon completion of the validation activities, the EQRO should synthesize all of the validation findings from Activities II.1 through II.8 based on the findings documented in the Worksheets for Protocol 6. The EQRO should submit a final validation report that assesses the overall quality of the survey, and in particular, the extent to which the survey achieved its purpose and objectives. Key elements of this assessment are whether the survey findings can be generalized to the population from which the sample was drawn and whether the data quality and completeness can support the survey's intended uses.

Although survey validation is an optional EQR-related activity, CMS recommends that surveys be validated when states intend to use survey results for such decisions as consumer health plan selection, health plan or provider payment, or performance incentives (e.g., auto-assignment).

Activity II.1: Review the Survey Purpose, Objectives, and Audience

To understand and evaluate the adequacy of the survey to meet its intended uses, the EQRO should seek information from written sources or through interviews about the survey's purpose, objectives, and audience. See Activity I.1 for more information about defining the survey purpose, objectives, and audience.

WORKSHEET 6.1

Resource for Activity 1

Worksheet 6.1. Survey Purpose, Objectives, and Audience

- Provides a set of questions to assess the clarity of the survey purpose, objectives, and audience

[74] Many states and MCPs contract with survey vendors certified by the National Committee for Quality Assurance (NCQA) to conduct CAHPS® 5.0H surveys following a standardized and validated protocol. A list of approved vendors is available at https://www.ncqa.org/programs/data-and-information-technology/hit-and-data-certification/cahps-5-1h-survey-certification/vendor-directory/.

Activity II.2: Review the Work Plan

To understand the survey implementation plan, the EQRO should review the work plan, including the project management plan, schedule, reporting requirements, data preparation plan, data analysis plan, and security protocols and procedures. The work plan provides a foundation for understanding the rigor of the overall survey approach; deviations from the work plan may signal concerns related to the effectiveness of survey implementation. See Activity I.2 for more information about developing a work plan.

WORKSHEET 6.2

Resource for Activity 2

Worksheet 6.2. Work Plan

- Provides a set of questions to assess the work plan

Activity II.3: Review the Reliability and Validity of the Survey Instrument

As discussed in Activity I.3, there are three options for selecting a survey instrument:

1. Use an existing validated survey instrument
2. Adapt an existing survey instrument with additional state-specific questions
3. Develop a new survey instrument

WORKSHEET 6.3

Resource for Activity 2

Worksheet 6.3. Survey Instrument

- Provides a set of questions to assess the selection of the survey instrument

Each of these approaches involves trade-offs. For example, use of an existing validated survey instrument increases assurances about the instrument's validity and reliability, but the instrument may have gaps in survey content for the specific survey purpose. Development of a new survey instrument may result in more targeted content for the specific survey purpose, but require more effort to ensure validity and reliability of the instrument. As part of this validation activity, the EQRO is charged with assessing the extent to which there is sufficient documentation of the validity and reliability of the selected survey instrument.

The EQRO should not conduct independent validity and reliability testing of the survey instrument; however, it should note whether such testing was done. The EQRO should consider the adequacy of the survey's reliability and validity testing in determining whether to rely on the survey findings to inform the EQRO's analysis and evaluation of access, quality, and timeliness of health care. See Activity I.3 for more information about assessing the validity and reliability of survey instruments.

Activity II.4: Review the Sampling Plan

The EQRO should assess the sample plan documentation for the following:

WORKSHEET 6.4

Resource for Activity 4

Worksheet 6.4. Sampling Plan

- Provides a set of questions to assess the sampling plan

Appendix B. Sampling Approaches for EQR Data Collection Activities

- Provides an overview of sampling approaches and guidance for determining sample sizes for EQR data collection activities

1. Clear definition of the study population. The EQRO should document whether there was a clear definition of the study population
2. Appropriate specifications for the sample frame. The EQRO should assess whether the sampling frame was clearly described and appropriate to the survey objectives
3. Quality of the sampling frame. The EQRO should assess whether the sampling frame is free from bias. The sampling frame should include all members of the population to be studied, and not omit any members of the population
4. Type of sampling method used. The EQRO should evaluate whether the sampling method used was appropriate to the survey's purpose (e.g., use of probability versus non-probability methods). For more information, see Appendix B
5. Adequacy of the sample size. The EQRO should determine whether the sample size was appropriate for the survey. Two factors influence the determination of the appropriate sample size for a survey: (1) the acceptable margin of error, and (2) the confidence levels
6. Procedures for sample selection. The EQRO should review the sample selection procedures including reviewing the statistical program or other process used to generate the sample. The EQRO should determine the extent to which the selection of sample members was conducted to protect against bias

The level of detail involved in this review requires that the EQRO use professional statisticians. The EQRO must evaluate whether the sample selected was sufficiently representative of the study population for the EQRO to have confidence in the survey findings. See Activity I.4 for more information about developing a sampling plan.

Activity II.5: Review the Adequacy of the Response Rate

In this activity, the EQRO should review the methods used to maximize the response rate, as well as the methods used to calculate the response rate. In addition, the EQRO should assess potential sources of non-response and bias, and the extent to which the response rate weakens or strengthens the generalizability of the survey findings.

WORKSHEET 6.5

Resource for Activity 5

Worksheet 6.5. Strategy to Maximize Response

- Provides a set of questions to assess the strategy for locating sample members and specific data needed to administer the survey

The EQRO should determine whether a standard methodology was used to calculate the response rate. The American Association of Public Opinion Research (AAPOR) provides a list of standard definitions and response rate calculators on its website at http://www.aapor.org/Standards-Ethics/Standard-Definitions-(1).aspx. To provide context for the assessment of the adequacy of the response rate, the EQRO should consider benchmarking the response rate against those achieved by similar surveys. As discussed in Activity I.8, a nonresponse analysis can provide insights into the representativeness of the survey when response rates are low.

See Activity I.5 for more information on strategies to maximize response.

Activity II.6: Review the Quality Assurance Plan

The EQRO should review the quality assurance plan to ensure that it contains quality checks for all phases of the data collection effort. Specific areas for focus include checks during the sampling and locating processes, customization by data collection mode, and specification of data quality controls. In addition, the EQRO should be sure that the plan specifies how the checks will be implemented. See Activity I.6 for more information on the quality assurance plan.

WORKSHEET 6.6

Resource for Activity 6

Worksheet 6.6. Quality Assurance Plan

- Provides a set of quality check questions to assess the quality assurance plan

Activity II.7: Review the Survey Implementation

The EQRO should review documentation regarding the survey implementation and assess whether implementation conformed to the work plan. The EQRO should specifically consider the following:

WORKSHEET 6.7

Resource for Activity 7

Worksheet 6.7. Survey Implementation According to the Work Plan

- Provides a set of questions to assess survey implementation

- Adherence to the sampling plan
- How the survey questionnaire was administered, including formatting and distribution of mailed surveys or scripting and training of telephone interviewers
- Changes to the survey schedule
- Evidence of implementation of the quality assurance checks
- Problems detected and corrections implemented during the survey process
- Confidentiality procedures followed
- Data collection, data entry, and data quality control methods used, including reports of missing data, data that failed edit checks, and incomplete or unusable surveys

See Activity I.7 for more information on survey implementation.

Activity II.8: Review the Survey Data Analysis and Final Report

The EQRO should review how the survey data were analyzed, including the statistical procedures used and comparisons made. The EQRO should assess whether the analysis was appropriate to the survey purpose, whether appropriate statistical tests were applied, and how well the survey findings were supported by the data. In its final validation report, the EQRO should document its conclusions and provide written findings on:

WORKSHEET 6.8

Resource for Activity 8

Worksheet 6.8. Survey Data Analysis and Final Report

- Provides a set of questions to assess the data analysis and final report

- The survey's technical strengths and weaknesses
- Appropriateness of analysis methods (e.g., data quality, sample sizes, weighting and adjustment for complex sample design if applicable, significance testing)
- Appropriateness of presentation approaches (such as text, tables, figures)
- Appropriateness of conclusions drawn from the survey data
- The limitations and generalizability of survey findings

See Activity I.8 for more information about the presentation of survey findings.

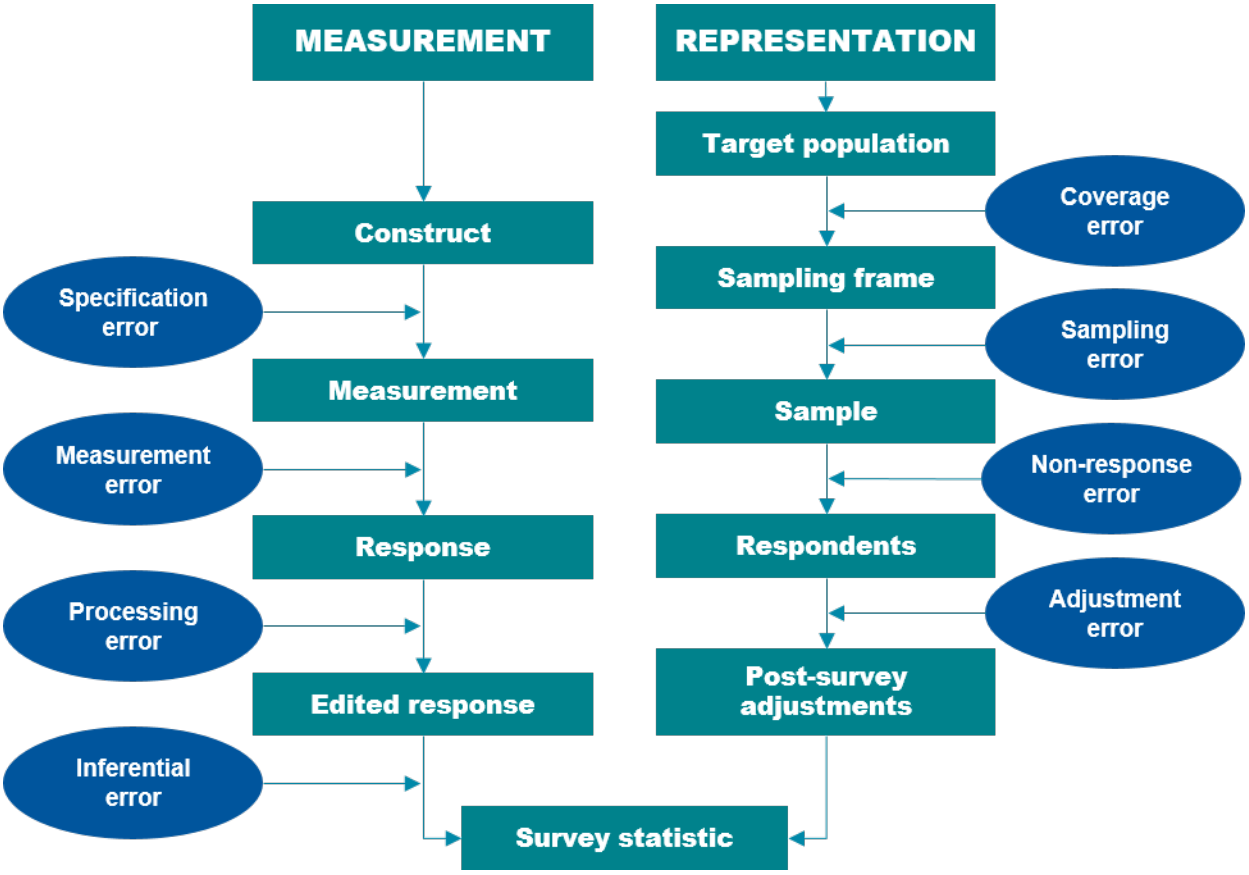
Technical Appendix for Protocol 6: Understanding Potential Sources of Survey Error

Survey results are used increasingly for "high-stakes" activities such as consumer health plan selection, health plan or provider payment, or performance incentives (e.g., auto-assignment). As a result, there is increasing scrutiny on the quality and integrity of surveys to support such initiatives. States and MCPs cannot afford "errors" in a survey, as the consequences may be substantial from a beneficiary, provider, health plan, and state perspective.

This appendix provides additional information on how to assess the overall quality of the survey effort using a Total Survey Error (TSE) paradigm. The TSE paradigm identifies potential sources of survey error and examines the accumulation of all errors that arise in the design, collection, processing, and analysis of survey data. It is important to note that in the TSE paradigm, errors are sources of uncertainty, a deviation of a survey response from its underlying true value. Errors are not mistakes.

The TSE paradigm is included in Figure 6.2. Table 6.3 describes which errors may arise in the process and steps that EQROs (or survey vendors) can take to remedy the errors. This information can inform the administration and validation of surveys to improve overall survey quality.

Figure 6.2. The Total Survey Error Paradigm: Understanding Potential Sources of Error in Surveys



Source: Adapted from Groves, R.M. et al, Survey Methodology, Hoboken, NJ, John Wiley & Sons, 2004.

Table 6.3. Mapping Common Sources of Survey Error to Data Collection Activities and Remedies to Minimize Error

Activity	Common Errors	Definition	Remedies
1	Specification error	Sometimes called validity, are we measuring what we say we are measuring?	• Use validated scales, pretesting, cognitive testing, focus groups
2	Measurement error	When an answer to a question is inaccurate, imprecise, or cannot be compared to other respondents' answers due to the questionnaire, respondent, interviewer, or mode	Design survey using best practices: • Programming checks • Validated scales • Multiple languages • Multiple modes to participate
3	Coverage error	When who/the group you want to study differs from who is available to study	• Offer multiple modes to participate • Use dual frame samples

Activity	Common Errors	Definition	Remedies
3	Sampling error	When the survey includes only a subset of the target population. This error cannot be avoided unless a census is conducted	• Conduct power calculations • Create sampling weights • Conduct all analyses using weights
4	Nonresponse error	When people in the survey sample do not respond and are different from those who do respond in a way that is important to the study. There is Unit nonresponse (sample members who do not respond to the survey) and Item nonresponse (sample members who skip or refuse specific questions)	• Use proven contact strategies, such as advance letters and vary modes for nonresponse follow up • Institute range checks • Monitor skip patterns and missing data through frequency reviews • Conduct critical item retrieval • Conduct nonresponse bias analysis • Make nonresponse adjustments
5	Processing error	Problems that occur when preparing "raw" datasets set for analysis, such as inconsistent coding, treatment of outliers, or deriving new variables	• Develop cleaning and coding specifications • Perform double entry, adjudication, data review
6	Adjustment error	Mistakes in efforts to improve the quality of the survey estimates as a result of coverage, sampling, and non-response errors	• Use post-survey adjustments such as weighting and imputation
6	Inferential error	Making opinionated statements, drawing incorrect conclusions, or going beyond the limits of the design	• Prepare comprehensive quality assurance plans • Develop rigorous data analysis plans

Source: Adapted from Groves, R.M. et al, Survey Methodology, Hoboken, NJ, John Wiley & Sons, 2004.

END OF PROTOCOL 6

Worksheets for Protocol 6: Survey Administration and Validation Tools

Instructions. Use these or similar worksheets as a guide when administering or validating a survey. Each numbered worksheet corresponds to an activity in the protocol. For each question, please check "Yes," "No," or "Not applicable." If the answer is "No" or "Not applicable," please explain in the "Comments" column. Add "Comments" for any question as needed.

- For survey administration: Use the worksheets to track and document steps performed in designing and implementing the survey. In the "Comments" column, document decisions or findings
- For survey validation: Use the worksheets to track and document steps performed in validating the survey. In the "Comments" column, document the outcome of validation activities, including sources reviewed. The worksheets can also be used as an outline for the final report to the state. Expand the tool to include other activities or findings as needed

This tool includes the following worksheets and the applicable activity and step:

Worksheet Name	Protocol Activity and Step
Section I. Administering the Survey Section II. Validating the Survey	
Worksheet 6.1. Survey Purpose, Objectives, and Audience	Section I. Activity 1. Define the Survey Purpose, Objectives, and Audience Section II. Activity 1. Review the Survey Purpose, Objectives, and Audience
Worksheet 6.2. Work Plan	Section I. Activity 2. Develop the Work Plan Section II. Activity 2. Review the Work Plan
Worksheet 6.3. Survey Instrument	Section I. Activity 3. Select the Survey Instrument Section II. Activity 3. Review the Validity and Reliability of the Survey Instrument
Worksheet 6.4. Sampling Plan	Section I. Activity 4. Develop the Sampling Plan Section II. Activity 4. Review the Sampling Plan
Worksheet 6.5 Strategy to Maximize Response	Section I. Activity 5. Develop a Strategy to Maximize Response Section II. Activity 5. Review the Adequacy of the Response Rate
Worksheet 6.6. Quality Assurance Plan	Section I. Activity 6. Develop a Quality Assurance Plan Section II. Activity 6. Review the Quality Assurance Plan
Worksheet 6.7. Survey Implementation According to the Work Plan	Section I. Activity 7. Implement the Survey According to the Work Plan Section II. Activity 7. Review the Survey Implementation
Worksheet 6.8. Survey Data Analysis and Final Report	Section I. Activity 8. Prepare and Analyze Survey Data and Present Results in a Final Report Section II. Activity 8. Review the Survey Data Analysis and Final Report

Worksheet 6.1. Survey Purpose, Objectives, and Audience

Survey purpose, objectives, and audience: _____

Assess the clarity of the survey purpose and audience by answering the following questions. Insert comments to explain "No" and "Not applicable" responses.

Question	Yes	No	Not applicable	Comments
Was there a clear, written statement of the survey purpose that addresses access, timeliness, and/or quality of care?				
Was the unit of analysis clearly stated?				
Did the unit of analysis include individual MCPs?				
Was there a clear and measurable written study objective?				
Was the audience for and intended use of the survey findings identified?				
Overall validation assessment: In the comments section, note any recommendations for improving the survey purpose, objective, and audience				

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 6.2. Work Plan

Date of work plan: _____

Assess the adequacy of the work plan by answering the following questions. Insert comments to explain "No" and "Not applicable" responses. (Note: Validation of the work plan occurs in conjunction with Activity 5, Review Survey Implementation According to the Work Plan.)

Question	Yes	No	Not applicable	Comments
Did the work plan include a project management plan (including key staff and roles)?				
Did the work plan include a project schedule (including timelines and deliverable dates)?				
Did the work plan specify project reporting requirements (including the number, format, and content of the reports)? • The work plan should include a description of any reports that the EQRO will be responsible to publicly release, if this is part of the EQRO's scope of work				
Did the work plan include a data preparation plan, such as production of data files, data file format, and delivery?				
Did the work plan include a data analysis plan (including the use of a statistician as appropriate)? • The EQRO should use a statistician to develop an analysis plan that supports the survey purpose and objectives and is consistent with the intended use of results • If feasible, the EQRO should provide the state with a mock-up of the analysis before administering the survey. This will assure the survey analysis will be consistent with the intended use of results				
Did the work plan include data security protocols and procedures for assuring the confidentiality of data in compliance with HIPAA?				
Overall validation assessment: In the comments section, note any recommendations for improving the work plan				

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 6.3. Survey Instrument

Name of survey instrument_____

Assess the selection of the survey instrument by answering the following questions. Insert comments to explain "No" and "Not applicable" responses. Complete a separate worksheet for each survey instrument.

Question	Yes	No	Not applicable	Comments
Was the selected survey instrument appropriate for the purpose of the survey and the unit of analysis?				
Were new items developed for the survey?				
If new items were developed, was a test of validity and reliability conducted for the new items?				
Was the overall survey instrument tested for face validity and content validity and found to be valid?				
Was the overall survey instrument tested for reliability and found to be reliable?				
Was testing performed for the specific target population (e.g., Medicaid or CHIP) and languages?				
Overall validation assessment: In the comments section, note any recommendations for improving the selection of the survey instrument				

Worksheet 6.4. Sampling Plan

Assess the sampling plan by answering the following questions. Insert comments to explain “No” and “Not applicable” responses.

Question	Yes	No	Not applicable	Comments
Was the study population clearly defined?				
Was the sampling frame clearly defined and appropriate based on the survey objectives?				
Was the sampling frame free from bias?				
Was the sampling method appropriate to the survey purpose?				
Was the sample size sufficient for the intended use of the survey (acceptable margin of error, level of certainty required)?				
Were the procedures used to select the sample appropriate and protected against bias?				
Overall validation assessment: In the comments section, note any recommendations for improving the sampling plan				

Worksheet 6.5. Strategy to Maximize Response

Assess the strategy for locating sample members and specific data needed to administer the survey by answering the following questions. Insert comments to explain "No" and "Not applicable" responses.

Question	Yes	No	Not applicable	Comments
Was locating of sample members conducted to ensure complete contact information? Locating is a technique used to improve response rates by locating and contacting sample members. This includes verified collection of data, such as first and last name, home address, email address, phone number(s), date of birth, language preference, etc.				
Were any of the following strategies included to maximize response: • Advance letter • Multiple and varied call attempts • Multi-mode surveys • Multiple languages				
Were strategies customized to the study population (e.g., providers versus beneficiaries)?				
Was the method specified for calculating the response rate, and if so, was the method in accordance with industry standards?				
Was a plan included to conduct a non-response analysis?				
Overall validation assessment: In the comments section, note any recommendations for improving the response strategy				

Worksheet 6.6. Quality Assurance Plan

Date of Quality Assurance Plan: _____

Assess the quality assurance plan by indicating whether the following quality checks were included in the plan. Insert comments to explain "No" and "Not applicable" responses. (Note: The assessment of whether the plan was implemented appropriately is included in Worksheet 6.7.)

Question	Yes	No	Not applicable	Comments
Sampling. Did the plan include a check to ensure the sample was constructed as specified in the sampling plan?				
Locating. Did the plan include a check that initial contact was made for every sample member?				
Mail data collection. Were the following quality checks included in the plan? • Was the survey reviewed for respondent reading level (surveys should be written at a 6th grade reading level to ensure most respondents are able to read and understand the content) • Were specifications and procedures developed for formatting, reproducing, and distributing the survey questionnaire? • Were contents of the mailing packet, such as the cover letter and questionnaire, reviewed for accuracy, print smearing, fading, and misalignment? • Were the returned mail surveys data entry reviewed for accuracy?				
Telephone data collection. Were the following quality checks included in the plan? • Were interviewer training and telephone scripts reviewed for accuracy? • Were telephone interviews monitored to confirm that interviewers read questions verbatim and accurately captured responses?				
Web-based data collection. Did the plan include a check that the web-based instrument programming and content was tested for accuracy?				
Data quality controls. Did the plan include procedures to handle responses that fail edit checks, treatment of missing data, and determination of usable/complete surveys? (Note: The plan should establish a pre-determined number of questions that must be answered by the respondent to be considered a usable case.)				
Overall validation assessment: In the comments section, note any recommendations for improving the quality assurance plan				

Worksheet 6.7. Survey Implementation According to the Work Plan

Assess the implementation of the survey by answering the following questions. Insert comments to explain "No" and "Not applicable" responses.

Question	Yes	No	Not applicable	Comments
Was the weekly data collection plan implemented as described in the work plan?				
If deviations from the data collection plan occurred, were the reasons for the deviations explained?				
Were quality assurance checks implemented as specified in the quality assurance plan (see Worksheet 6.6)? If deviations occurred, please explain in the Comments column • Was the sampling plan verified to ensure the sample was constructed as specified? • Was initial contact made for every sample member? • Were specified quality checks made in accordance with the data collection mode (mail, telephone, web-based, or mixed mode)? • Were procedures developed to handle responses that fail edit checks, treatment of missing data, and removal of surveys or data determined to be unusable?				
Overall validation assessment: In the comments section, note any recommendations for improving the implementation of the survey				

Worksheet 6.8. Survey Data Analysis and Final Report

Assess the data analysis and final report by answering the following questions. Insert comments to explain "No" and "Not applicable" responses.

Question	Yes	No	Not applicable	Comments
Were post-processing procedures implemented to address the following: • Responses that failed edit checks • Missing data • Removal of surveys or data determined to be unusable				
Were weights created as appropriate for analyzing survey responses and generalizing results to the study population?				
Was a nonresponse analysis conducted to determine if survey respondents differ from respondents on key variables important to the findings?				
Were survey data analyzed following the analysis plan laid out in the work plan?				
Did the final report include a comprehensive overview of survey purpose/objective, implementation, and substantive findings?				
Overall validation assessment: In the comments section, note any recommendations for improving the data analysis and final report				

END OF WORKSHEETS FOR PROTOCOL 6

Protocol 7. Calculation of Additional Performance Measures

AN OPTIONAL EQR-RELATED ACTIVITY

ACTIVITY 1: PREPARE FOR MEASUREMENT

ACTIVITY 2: CALCULATE MEASURES

ACTIVITY 3: REPORT RESULTS

PROTOCOL SEVEN

Background

One purpose of quality measurement is to evaluate the degree to which evidence-based treatment guidelines are followed, where indicated, and to assess the results of care. The use of quality measurement helps strengthen accountability and support performance improvement initiatives at numerous levels. Performance measures can be used to demonstrate a variety of activities and health care outcomes for particular populations. For example, states use performance measures to monitor the performance of individual managed care plans (MCPs) at a point in time, to track their performance over time, to compare performance among MCPs, and to inform the selection and evaluation of quality improvement activities.

Federal regulations at 42 CFR 438.330(c) require states to specify standard performance measures for MCPs to include in their comprehensive quality assessment and performance improvement (QAPI) programs.[75] Each year, the MCPs must: (1) measure and report to the state standard performance measures specified by the state; (2) submit specified data to the state which enables the state to calculate the standard performance measures; or (3) a combination of these approaches. Validation of the performance measures specified by the state for inclusion in MCPs' QAPI programs is a mandatory external quality review (EQR)-related activity (see 42 CFR 438.358(b)(1)(ii)), as described in Protocol 2. Validation of Performance Measures Reported by the Managed Care Plan.

Federal regulations at 42 CFR 438.358(c)(3) specify that the external quality review organization (EQRO) may calculate performance measures in addition to

[75] More information about QAPI and performance measures is available at 42 CFR 438.330(b)(2). CHIP regulations at 42 C.RF.R 457.1240(b).cross-reference QAPI and performance measure regulations.

those specified by the state for inclusion in MCPs' QAPI programs. Calculation of these additional performance measures are an optional EQR-related activity.

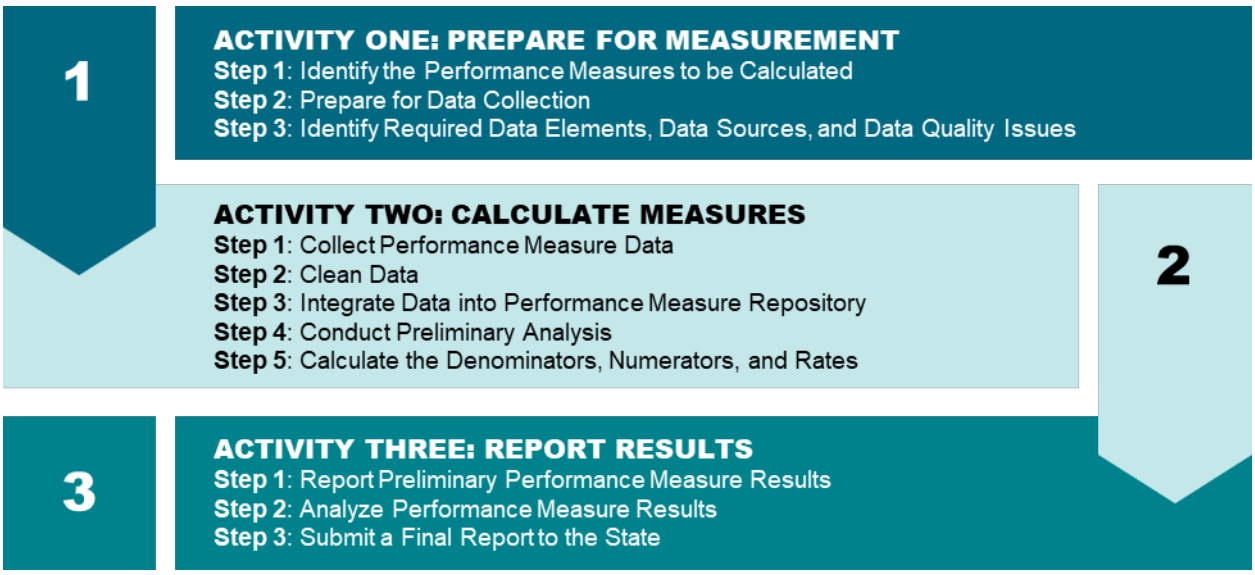
In many cases, states and MCPs use measures included in the CMS Child and Adult Core Set measures to monitor and track quality of care in Medicaid and CHIP.[76] While use of these measures by states is voluntary, CMS encourages states to adopt and use the Child and Adult Core Set measures to support their managed care quality measurement and improvement initiatives. Many Core Set measures are part of the Healthcare Effectiveness Data and Information Set (HEDIS®), and have national and regional benchmarks.

This protocol provides guidance to states on the calculation of additional (non-QAPI) performance measures to monitor the care provided by MCPs to enrollees covered by Medicaid and CHIP.

Getting Started on Protocol 7

Protocol 7 consists of three activities: preparation for measurement, calculation, and reporting (Figure 7.1). For each activity, the protocol specifies the steps to be performed and the outcomes to be achieved. The remainder of this protocol outlines the steps associated with these activities.

Figure 7.1. Protocol 7 Activities



[76] More information about the Child Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html. More information about the Adult Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html.

Two supplemental resources are available to help EQROs calculate additional performance measures:

- Worksheets for Protocol 7. Performance Measure Calculation Tools, which can be used to identify the performance measures to be calculated, document the technical specifications for each measure, develop a master list of data elements, indicate the data sources and any known data quality issues, and specify the file format for the transmission of the required data elements
- Appendix A. Information System Capabilities Assessment, which is used to assess the MCP's data collection, processing, and reporting systems

Activity 1: Prepare for Measurement

Step 1: Identify the Performance Measures to be Calculated

The state should provide the EQRO with a list of performance measures to be calculated along with technical specifications for their calculation. The EQRO must understand the state's specifications for each performance measure (e.g., sampling guidelines, data sources, measurement period, instructions for calculating numerators and denominators), as well as the state's requirements for benchmarking, analysis, and reporting.

WORKSHEET 7.1

WORKSHEET 7.2

Resources for Activity 1, Step 1

Worksheet 7.1. List of Performance Measures to be Calculated

- Provides a template for identifying the measures the EQRO will calculate for the state, including the source, how frequently to calculate each measure, and when each measure is due to the state

Worksheet 7.2. Companion Performance Measurement Tool

- Provides a template for documenting additional information about measures in Worksheet 7.1, including technical specifications, benchmarks, performance standards, or other information about state requirements

The EQRO must also understand the state's requirements for the timing and format of the performance measure report. The EQRO should create a list of performance measures to be calculated to document the measures required by the state and the reporting frequency and timeline for each measure (Worksheet 7.1). For each performance measure listed in Worksheet 7.1, the EQRO should complete a companion performance measurement worksheet that contains the technical specifications for the measure, benchmarks, performance standards, and other information needed to analyze the performance measure according to the state's

requirements (Worksheet 7.2). The EQRO may need to request clarification from the state, measure steward, or other expert if the measure specifications are unclear.

Step 2: Prepare for Data Collection

The EQRO should send an introductory communication to the MCP outlining the purpose, process, and timeline for its performance measure calculation activities. In addition, the EQRO should request a contact within the MCP to schedule activities and provide requested documents and other information.

The EQRO should inform the MCP that it may be necessary to interview MCP or vendor staff with responsibility for data collection or performance measurement. The information provided by the MCP should inform the EQRO of the location of the required data, which organization (state, EQRO, or MCP) will need to collect and integrate specific data elements, and how to access the data. Information obtained from MCP staff may improve the efficiency and accuracy of the EQRO's effort to collect and integrate the data necessary for calculating performance measures.

During this step, the EQRO should also review or conduct an Information Systems Capabilities Assessment (ISCA) for each MCP to:

- Understand data sources, flows, and integration processes used by the MCP
- Identify where the EQRO needs to work with outside data sources to obtain additional data
- Determine which data elements are integrated by the MCP and which data elements the EQRO must integrate

Appendix A contains the ICSA tool and instructions for completing the ISCA. For more information on how the EQRO should conduct or review an existing ICSA as part of its performance measurement activities, please refer to Protocol 2, Activity 1, Step 2, Assess the Integrity of the MCP's Information System.

If data will be collected from other sources such as state public health registries, vital records, hospital discharge abstract databases, or behavioral health vendors under contract to the state, the EQRO should establish contact with the organizations responsible for these data sources.

Step 3: Identify Required Data Elements, Data Sources, and Data Quality Issues

Next, the EQRO should prepare a master list of data elements (Worksheet 7.3) and identify available data sources for each required data element, noting any completeness or integration issues for each element (Worksheet 7.4).

WORKSHEET 7.3

WORKSHEET 7.4

Resources for Activity 1, Step 3

Worksheet 7.3. Data Element Master Checklist

- Provides a template for identifying the data elements needed to calculate each performance measure

Worksheet 7.4. Data Availability and Data Quality

- Provides a template for documenting data availability and data quality issues (e.g., completeness and integration)

Data sources may include those maintained by an MCP in a data repository, such as claims or enrollment data. Data sources may also include sources external to the MCP, such as a state registry, provider medical record, MCP vendor, or state vendor. The EQRO should document data capture or integration issues for the required data elements, such as an inability to capture individual prenatal care services when the MCP pays for maternity care using a global fee. As another example, the EQRO may identify issues associated with data sources external to the MCP, such as difficulty accessing confidential information about mental health services that the state contracts with another organization to manage, incomplete data in a voluntary state registry, or challenges in obtaining vital records required for data linkage.

Activity 2: Calculate Measures

Step 1: Collect Performance Measure Data

After the required data elements and data sources have been identified, the EQRO will request the data needed to calculate the performance measures from the MCP or other data suppliers. For each data source, the EQRO should specify how the data are to be transmitted to the EQRO, including appropriate privacy and security safeguards. To ensure accurate and complete data for measure calculation, the EQRO should develop a file format that specifies the content and structure of the data file along with definitions of all data fields (Worksheet 7.5).

WORKSHEET 7.5

Resource for Activity 2, Step 1

Worksheet 7.5. Illustrative File Format for Transmission of Claims Data

- Provides a template for constructing an electronic data shell or file format including definitions for all data fields

The EQRO should construct file formats that are customized to each data supplier. The file format for obtaining data from the MCP data repository will likely include all data elements that originate from claims/encounter, eligibility, and provider transaction systems. (In some cases, the data will be available in a state data repository and the file format should reflect the state system

structure.) A file format used to obtain vital records or immunization registry data would contain different data fields and definitions applicable to those sources.

If the EQRO needs to conduct medical record review, it should develop the following resources:

- Abstraction tools
- Training for personnel conducting the medical record abstraction
- Quality assurance procedures to assess the accuracy and reliability of the medical record abstraction
- Electronic data entry edits for abstracted medical record information

If the MCP or other entity is performing medical record review and supplying those data to the EQRO, the EQRO should refer to Protocol 2 to validate the abstracted medical record information.

Step 2: Clean Data

As the EQRO receives data, it should evaluate each incoming data stream to ensure that the number of bits received is equal to the number sent. After entering the data into its repository, the EQRO should clean the data using electronic edits. Examples of edits include the following:

- Valid procedure codes (e.g., active code, required number of digits)
- Valid diagnosis codes (e.g., active code, required number of digits)
- Internal consistency of diagnosis and procedure codes (e.g., consistent with the enrollee's age or gender, or the practitioner's specialty)
- Correct field size and type (e.g., alpha, numeric, date)
- Valid date ranges (e.g., "to" date is later than "from" date; dates occur during the appropriate timeframe for the measure)
- Valid practitioners (e.g., active provider)
- Valid enrollees (e.g., eligible on date of service)

Data that pass the edit should be integrated in the EQRO's performance measure repository (see Step 3). When data fail an edit, the EQRO should contact the supplier and request the data be corrected and resubmitted. The EQRO should document the nature and extent of failures, including information about whether it received corrected information. This documentation is necessary for the EQRO to understand the accuracy and completeness of the data underlying the performance measures it will calculate.

Step 3: Integrate Data into Performance Measure Repository

The EQRO may receive data from multiple MCPs, multiple sources within each MCP, and other organizations, such as a statewide registry or other state vendors responsible for delivering specific benefits like pharmacy or mental health services. To calculate performance measures, the data must be integrated across the various data sources so that all services provided to a specific enrollee can be associated with that enrollee. The ISCA, reviewed in Activity 1, Step 3, will provide information about the adequacy of data integration within each MCP.

During this step, the EQRO will also assess the integration of data from non-MCP data suppliers, such as the state's encounter data repository or other vendors. This may include administering relevant portions of the ISCA to these other suppliers. The EQRO must determine which portions of the ISCA are relevant depending on the specific data elements the supplier provides and the degree of data integration the supplier must perform. The assessment includes assessing the reliability of data transmissions within and from each data supplier. The EQRO may have different degrees of access to these data suppliers and must work with them, to the extent possible, to understand the data flows and procedures used to ensure data integrity. For each data supplier, the EQRO may need to:

- Examine the details of the data supplier's processes to accurately and completely transfer data from the transaction files (i.e., enrollment, provider, encounter/claims) into its data repository, if any
- Examine samples of data to assess completeness and accuracy
- Investigate the data supplier's processes to consolidate multiple files (sometimes referred to as deduplicating or "de-duping" of files), and to extract required information from its data repository
- Compare actual results of file consolidations or extracts to those that should have resulted according to documented algorithms or specifications
- Review procedures for consolidating data from vendors in ways that ensure the accurate, timely, and complete integration of the data
- Review computer program reports or documentation that reflect these vendor coordination activities, and spot check to verify that no data necessary to performance measure reporting are lost or inappropriately modified during transfer
- Assess the extent to which proper linkage mechanisms have been employed to join data from all necessary sources (e.g., identifying an enrollee with a given disease/condition)

To ensure proper data integration within its own data repository, the EQRO must undertake the following activities:

- Write program logic or source code for each measure that identifies, tracks, and links enrollment within and across product lines (Medicaid and CHIP), by age and sex, as well as

through possible periods of enrollment and disenrollment, which complies with the specifications of each performance measure

- Conduct tests of data to assess completeness, integration, and integrity, and to ensure there is no double-counting of services reported through different data systems or suppliers
- Assure that all enrollees who were eligible to receive the specified services were included in the initial population from which the final denominator was produced. The eligible population will include both enrollees who received the services and those who did not. This same activity applies to provider groups or other relevant populations identified in the specifications of each performance measure

Step 4: Conduct Preliminary Analysis

The EQRO will assess the completeness, accuracy, and reasonableness of the data in its repository, and work with the MCP and other data suppliers until the data are satisfactory. Referring to the ISCA conducted for the MCP and other data suppliers, the EQRO will have identified areas of potential weakness. These should be considered in conducting analyses of missing data, data quality, and supplier data issues.

Missing Data. The EQRO will analyze its repository for evidence of missing data. To determine completeness, the EQRO should compare its data with data from the state, from prior years, and from similar populations. Based on findings from the ISCA, the EQRO may pursue specific concerns such as missing beneficiaries; missing providers, provider locations, or provider types; and missing services or service types. Knowledge of the data suppliers' contractual relationships with providers from the ISCA as well as knowledge of the expected magnitude of reporting will help identify specific areas to investigate for missing data. The EQRO should be aware of instances when the MCP was unable to submit data, when submitted data failed edits, and when data were not resubmitted.

Other Data Quality Issues. The EQRO should analyze the data it has received to identify data quality problems such as inability to process or retain certain fields. Some MCPs may lack the capacity to capture or maintain all the data elements that are required for submission, such as secondary diagnoses or procedure codes or some coding specificity.

Supplier Data Issues. Using the edit checks from Activity 2, Step 2, the EQRO should identify problems in how data suppliers compiled and submitted their data to the EQRO.

Significant issues may affect the feasibility of calculating valid and reliable performance measures. Before proceeding to Step 5, the EQRO should report significant issues to the state and determine whether the data are suitable for calculating selected measures.

Step 5: Calculate the Denominators, Numerators, and Rates

Following the specifications provided by the state, the EQRO calculates performance measures from its data repository. To do this, the EQRO must purchase or write and test source code to properly apply all specifications to identify the denominator population. The EQRO must apply specified continuous enrollment and other eligibility criteria and implement exclusions from the denominator.

Once the EQRO has identified all eligible beneficiaries in the denominator for a measure, it must apply the specifications to identify cases that qualify for inclusion in the numerator. Where sampling is required such as for medical record review, the EQRO must follow the specifications for selecting an appropriate sample. The EQRO should follow the medical record review process outlined in Activity 2, Step 1 regardless of when in the measure calculation process the medical record review takes place.

Activity 3: Report Results

Step 1: Report Preliminary Performance Measure Results

Before sharing performance measure results with the state, the EQRO should share its preliminary findings with the MCPs to obtain their feedback about the accuracy of the results. The report should include, at a minimum, the following elements for each performance measure:

- Data source(s)
- Method (administrative, medical record review, hybrid)
- Denominator
- Sample size (if relevant)
- Administrative numerator events (if relevant)
- Medical record numerator events (if relevant)
- Calculated rate
- Deviations from the measure specifications (if relevant)

To enable the MCP to understand and interpret the results, the report may also analyze MCP performance in relation to external benchmarks or prior-year performance.

The EQRO should invite the MCP to offer comments and documentation to support correction of any factual errors or to clarify results. The EQRO should provide a reasonable period of time for the MCP to provide its comments. The EQRO should then recalculate measures based on the comments, if necessary, and revise its findings where appropriate.

Step 2: Analyze Performance Measure Results

Using the final calculations from Activity 3 Step 1, the EQRO should conduct all analyses required by the state. The results should be presented in a format prescribed by the state, or if the state has not prescribed a format, in a way that facilitates the state's intended use of the performance measures. Decisions about the format include the balance between text, tables, and graphics, as well as the level of detail. In addition, the EQRO should determine whether the data should be analyzed for each MCP individually, or whether individual MCP results should also be compared to results for other MCPs or in relation to external benchmarks.

Step 3: Submit a Final Report to the State

The EQRO will submit a final report containing the performance measure results, analyses, and recommendations in the format prescribed by the state and in the time frame required. The content of the final report should include the following elements:

- A summary of the EQRO's performance measurement activities, including documentation of the activities performed
- Work papers and detailed results of key steps of the measure calculation process, MCP-specific performance measure rates, and accompanying analyses
- Discussion of areas of MCP strength and opportunities for improvement in both data management and performance
- Recommendations for improving MCP performance

The EQRO should submit a draft report on performance measure results to the state (separate from the EQR technical report) and revise the final report based on feedback from the state.

END OF PROTOCOL 7

Worksheets for Protocol 7: Performance Measure Calculation Tools

Instructions. Use these or similar worksheets to identify the performance measures to be calculated, document the technical specifications for each measure, develop a master list of data elements, indicate the data source and any known data quality issues, and specify the file format for the transmission of the required data elements. This tool includes the following worksheets crosswalked to the applicable Activity and Step:

Worksheet Name	Protocol Activity and Step
Worksheet 7.1. List of Performance Measures to be Calculated	Activity 1. Step 1. Define the Scope of the Validation
Worksheet 7.2. Companion Performance Measurement Tool	Activity 1. Step. 1. Define the Scope of the Validation Activity 1. Step 3. Conduct Detailed Review of Measures Activity 2. Step 4. Complete the Detailed Review of Measures
Worksheet 7.3. Data Element Master Checklist	Activity 1. Step 4. Initiate Review of Medical Record Data Collection Activity 3. Post-Site Visit Activities
Worksheet 7.4. Data Availability and Data Quality	Activity 2. Step 5. Prepare for the MCP Site Visit
Worksheet 7.5. Illustrative File Format for Transmission of Claims Data	Activity 2. Step 1. Review Information Systems Underlying Performance Measurement

For each MCP, please complete the following information:

MCP name	
MCP contact name and title	
Mailing address	
Phone/fax numbers	
Email address	
EQRO interview date	
Type of delivery system (check all that apply)	□ Staff model □ Network □ IPA
Plan type	□ MCO □ PIHP □ PAHP □ PCCM □ LTSS □ Other: specify _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP

Acronyms: CHIP = Children's Health Insurance Program; EQR = External Quality Review; EQRO = External Quality Review Organization; IPA = Independent Practice Association; LTSS = Long-Term Services and Supports; MCO = Managed Care Organization; MCP= Managed Care Plan; PAHP= Prepaid Ambulatory Health Plan; PCCM = Primary Care Case Management; PIHP = Prepaid Inpatient Health Plan; PIP = Performance Improvement Project.

Worksheet 7.1. List of Performance Measures to be Calculated

This worksheet is used to identify the measures to be calculated, including the measure source, how frequently the measure is reported, and the reporting deadline. Complete the worksheet for each measure to be calculated, and adapt as needed. Please note if you use the HEDIS® or Child/Adult Core Set specifications. Also note if the measure is homegrown.

NQF # (if applicable)	Measure Steward	Performance measure	Measure source	Reporting frequency	Reporting deadline

The list below is illustrative of the information to be included in the worksheet. Please include National Quality Forum (NQF) number (if applicable), and measure steward.

NQF # (if applicable)	Measure Steward	Performance measure	Measure source	Reporting frequency	Reporting deadline
0038	NCQA	Childhood Immunization Status (CIS-CH)	HEDIS® MY 2020/ Child Core Set	Annual	June 30th
1407	NCQA	Immunizations for Adolescents (IMA-CH)	HEDIS® MY 2020/ Child Core Set	Annual	June 30th
1392	NCQA	Well-Child Visits in the First 30 Months of Life (W30-CH)	HEDIS® MY 2020/ Child Core Set	Annual	June 30th

Worksheet 7.2. Companion Performance Measurement Tool

This worksheet is used to document the technical specifications and benchmarks for each measure to be calculated. Complete the worksheet for each measure listed in Worksheet 7.1, and adapt as needed.

Measure Name and Description _____

Characteristics	Measure specifications
Measure purpose (check all that apply)	☐ QI or PIP ☐ Demonstration/waiver program (e.g., 1115 demonstration) ☐ Pay for performance/Value-based purchasing ☐ Public reporting ☐ Other (specify) _____
Data collection method (check one)	☐ Administrative ☐ Medical Record Review ☐ Hybrid (administrative supplemented by medical record review) ☐ Survey ☐ Other (specify) _____
Sampling method (if applicable)	Specifications for sample size, sampling method and replacement methods: _____
Age	Lower age limit: _____ Upper age limit: _____
Sex (check one)	☐ Males only ☐ Females only ☐ Males and females
Continuous enrollment	☐ No ☐ Yes (specify) _____
Index event (e.g., birthday; discharge; prescription; diagnosis; procedure)	☐ No ☐ Yes (specify) _____
Denominator elements and data sources (e.g., member ID, age, gender, enrollment and disenrollment dates, diagnoses, procedures)	A list of each data element needed to establish eligibility for the denominator: _____ For each denominator element, the allowable data source(s): _____
Numerator elements and data sources (e.g., procedure codes, diagnosis codes, pharmacy codes, lab results, dates of service)	A list of each data element needed to establish eligibility for the numerator: _____ For each numerator element, the allowable data source(s): _____
Denominator	Denominator statement: _____ Inclusions/exclusions: _____ Denominator time window: _____

Characteristics	Measure specifications
Numerator	Numerator statement: _____ Inclusions/exclusions: _____ Numerator time window: _____
Rate calculation	Formula for calculation of rate: _____
Benchmark(s) (check all that apply)	☐ State-level (specify): _____ ☐ Regional (specify): _____ ☐ National (specify): _____ ☐ Other (specify): _____ Source(s): _____
Other analysis requirements (e.g., change from prior year or comparison to state average or best in state, including statistical tests)	List required analyses: _____

Worksheet 7.3. Data Element Master Checklist

This checklist is used to develop a master list of data elements needed to calculate each performance measure. Indicate whether each data element is required to calculate the measure, and adapt as needed.

	Performance Measure 1	Performance Measure 2	Performance Measure 3	Performance Measure 4	Performance Measure 5
Denominator data elements:					
Date of birth					
Sex					
Enrollment date					
Disenrollment date					
Diagnosis code					
Procedure code					
Service date					
Provider ID					
Numerator data elements:					
Diagnosis code					
Procedure code					
Pharmacy code					
Lab order					
Lab result					

Worksheet 7.4. Data Availability and Data Quality

This worksheet is used to document the data availability and data quality issues for each data element required to calculate the denominator and numerator for each measure in Worksheet 7.1.

	Available data source(s)?	In data repository?	Identified data quality issues (e.g., data completeness, integration issues)
Denominator data elements:			
Date of birth		☐ Yes ☐ No	
Sex		☐ Yes ☐ No	
Enrollment date		☐ Yes ☐ No	
Disenrollment date		☐ Yes ☐ No	
Diagnosis code		☐ Yes ☐ No	
Procedure code		☐ Yes ☐ No	
Service date		☐ Yes ☐ No	
Provider ID		☐ Yes ☐ No	
[INSERT other denominator data elements]		☐ Yes ☐ No	
Numerator data elements:			
Diagnosis code		☐ Yes ☐ No	
Procedure code		☐ Yes ☐ No	
Pharmacy code		☐ Yes ☐ No	
Lab order		☐ Yes ☐ No	
Lab result		☐ Yes ☐ No	
[INSERT other numerator data elements]		☐ Yes ☐ No	

Worksheet 7.5. Illustrative File Format for Transmission of Claims Data

This worksheet provides a template for constructing an electronic data shell or file format, including definitions for all data fields. Complete this template for each data field in the claims file, and adapt as needed.

Field #	Data Field	Applies to UB	Phys	Rx	Type/Format	Req/Opt	Comments
1	Row Type	X	X	X	Char(1)	Required	1=UB, 2=Phys, 3=Rx
2	Claim Status	X	X	X	Char(1)	Required	P=Paid, D=Denied Denied claims are highly desirable for accurate performance measurement
3	Recipient ID	X	X	X	Varchar(50)	Required	Medicaid or CHIP identifier supplied by the State for the member. Native or encrypted. If encrypted, separate encryption key must be provided.
4	Claim Number	X	X	X	Varchar(80)	Required	Required if source is not sending final-only versions of claims
5	Prior Version Claim Number	X	X	X	Varchar(80)	Required	Required if source is not sending final-only versions of claims
6	Claim Received Date	X	X	X	yyyymmdd	Required	Required if source is not sending final-only versions of claims
7	Claim Paid Date	X	X	X	yyyymmdd	Required	Required if source is not sending final-only versions of claims
8	Billing Provider ID	X	X	X	Varchar(30)	Required	Any internal identifier for the billing provider. Must be unique to one clinician or entity. Must exist on the provider file. If supplying for Rx, use pharmacy provider ID.
9	Principal Diagnosis	X	X		Varchar(5)	Required	No periods, left justified
10	Diagnosis 2	X	X		Varchar(5)	Required	No periods, left justified
11	Diagnosis 3	X	X		Varchar(5)	Required	No periods, left justified

END OF WORKSHEETS FOR PROTOCOL 7

PROTOCOL EIGHT

Protocol 8. Implementation of Additional Performance Improvement Projects

An Optional EQR-Related Activity

ACTIVITY 1: SELECT THE PIP TOPIC

ACTIVITY 2: DEFINE THE PIP AIM STATEMENT

ACTIVITY 3: IDENTIFY THE PIP POPULATION

ACTIVITY 4: USE SOUND SAMPLING METHODS

ACTIVITY 5: SELECT THE PIP VARIABLES

ACTIVITY 6: COLLECT VALID AND RELIABLE DATA

ACTIVITY 7: ANALYZE DATA AND INTERPRET RESULTS

ACTIVITY 8: REVIEW IMPROVEMENT STRATEGIES

ACTIVITY 9: ASSESS WHETHER SIGNIFICANT AND SUSTAINED IMPROVEMENT OCCURRED

Background

Federal regulations at 42 CFR 438.330(b)(1) and 457.1240(b) require that Medicaid and CHIP managed care plans (MCPs) conduct performance improvement projects (PIPs) that focus on both clinical and nonclinical areas as part of a comprehensive quality assessment and performance improvement (QAPI) program.[77] Validation of the PIPs conducted by MCPs as a part of their QAPI programs is a mandatory external quality review (EQR)-related activity, as described in Protocol 1. Validation of Performance Improvement Projects.

In addition, Federal regulations at 42 CFR 438.358(c)(4) and 457.1250(a) specify that the external quality review organization (EQRO) may conduct PIPs in addition to those performed by the MCPs as a part of their QAPI programs. These additional PIPs are an optional EQR-related activity. These PIPs can be conducted in conjunction with CMS and state quality improvement priorities or to align with national quality improvement initiatives.

[77] At a minimum, a single PIP that focuses on both clinical and non-clinical aspects of care may satisfy this requirement. Otherwise, a state must require at least two PIPs, one clinical and one non-clinical.

These activities are eligible for enhanced Federal financial participation at a 75 percent rate (1) when conducted by a qualified EQRO on an MCO, (2) when the EQR-related activities are completed using methodologies consistent with the protocols contained within this document, and (3) when the state receives approval of its EQRO contract from CMS.[78,79]

This protocol provides guidance to states on the implementation of additional (non-QAPI) PIPs using EQROs to assess and improve processes and outcomes of care provided by MCPs in the state.

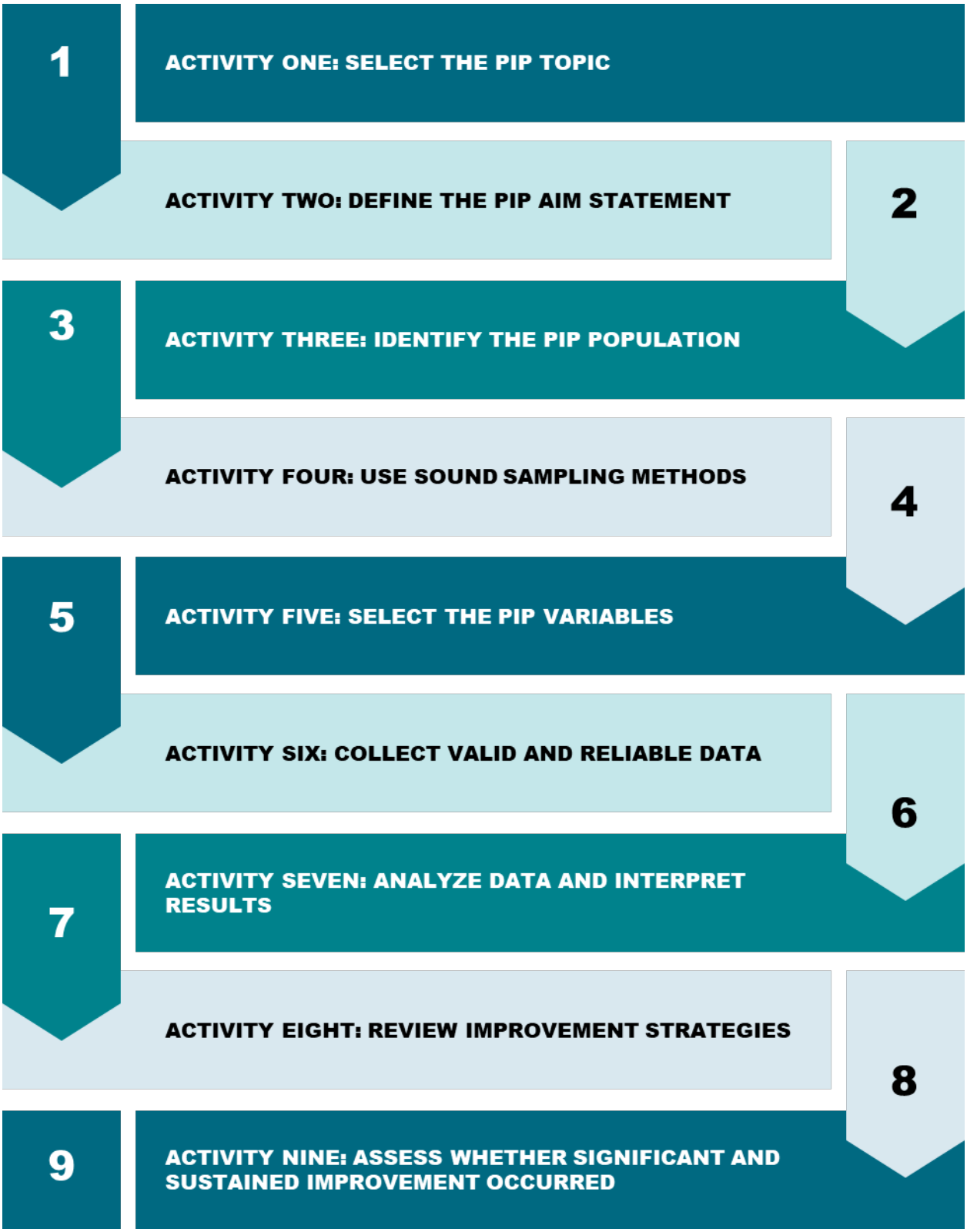
Getting Started on Protocol 8

Protocol 8 consists of nine activities for implementing additional PIPs (Figure 8.1).

[78] See 42 CFR 433.15 and 438.370(a) and the July 10, 2016 CMCS Informational Bulletin (CIB), Federal Financial Participation for Managed Care External Quality Review, available at https://www.medicaid.gov/federal-policy-guidance/downloads/cib061016.pdf.

[79] If the state or the state's agent that is not an MCP conducts the EQR-related activity on an MCO, it would be eligible for the 50 percent match rate. See 42 CFR 438.370(a)–(b).

Figure 8.1. Protocol 8 Activities



As shown in Table 8.1, these activities align with the nine steps in Activity 1, Protocol 1, Validation of Performance Improvement Projects. To streamline the content in this protocol, and avoid duplication with Protocol 1, please refer to the relevant sections in Protocol 1 and the associated worksheets.

Table 8.1. Crosswalk between Protocol 8, PIP Implementation and Protocol 1, PIP Validation

Protocol 8. PIP Implementation Activities	Protocol 1. PIP Validation Activity 1 Steps	Protocol 1. PIP Validation Tool Worksheets
Activity 1. Select the PIP Topic	Step 1. Review the Selected PIP Topic	Worksheet 1.1
Activity 2. Define the PIP Aim Statement	Step 2. Review the PIP Aim Statement	Worksheet 1.2
Activity 3. Identify the PIP Population	Step 3. Review the Identified PIP Population	Worksheet 1.3
Activity 4. Use Sound Sampling Methods	Step 4. Review the Sampling Method	Worksheet 1.4
Activity 5. Select the PIP Variables	Step 5. Review the Selected PIP Variables and Performance Measures	Worksheet 1.5
Activity 6. Collect Valid and Reliable Data	Step 6. Review the Data Collection Procedures	Worksheet 1.6
Activity 7. Analyze Data and Interpret Results	Step 7. Review Data Analysis and Interpretation of PIP Results	Worksheet 1.7
Activity 8. Review Improvement Strategies	Step 8. Assess the Improvement Strategies	Worksheet 1.8
Activity 9. Assess Whether Significant and Sustained Improvement Occurred	Step 9. Assess the Likelihood that Significant and Sustained Improvement Occurred	Worksheet 1.9

Three supplemental resources are available to help EQROs design and implement additional PIPs which can lead to significant and sustained improvement in health care delivery processes and outcomes:

- Protocol 1. Validation of Performance Improvement Projects
- Worksheets for Protocol 1. PIP Validation Tools and Reporting Framework
- Appendix B. Sampling Approaches for EQR Data Collection Activities

Activity 1: Select the PIP Topic

Additional PIP topics should target improvement in clinical and/or nonclinical services provided to Medicaid and CHIP enrollees in the state. Selected topics should reflect the characteristics of Medicaid and CHIP enrollees in terms of demographics, prevalence of disease, and the potential consequences of the disease. It is recommended that PIP topics align with: (1) the National

Quality Strategy,[80] (2) the CMS Quality Strategy,[81] and (3) the state's managed care quality strategy. The EQRO should also review the state's performance on the CMS Child and Adult Core Set measures to identify measures whose performance could be impacted by a managed care PIP.[82] Additional PIPs can be used to help drive improvement on these measures. For more information about selecting a PIP topic, see Protocol 1, Activity 1, Step 1.

Activity 2: Define the PIP Aim Statement

The PIP aim statement identifies the focus of the PIP and establishes the framework for data collection and analysis. The PIP aim statement should define the improvement strategy, population, and time period. It should be clear, concise, and answerable. When identifying the PIP aim statement, potential sources of information include:

- State performance on the Child and Adult Core Sets
- State data relevant to the topic being studied
- MCP data relevant to the topic being studied
- Enrollee focus groups or surveys
- Relevant clinical literature on recommended care and external benchmarks

For more information about developing the PIP aim statement, see Protocol 1, Activity 1, Step 2.

Activity 3: Identify the PIP Population

The additional PIP must clearly identify the target population in relation to the PIP aim statement (such as age, length of enrollment, diagnoses, procedures, and other characteristics). Depending on the nature of the PIP aim statement, population, and available data, the PIP may include the entire population or a sample of the population. PIPs that rely on existing administrative data, such as claims and encounter data, registry data, or vital records are typically based on the universe of the PIP's population. PIPs that require medical record review typically include a representative sample of the identified population. If a sample is used, go to Activity 4. If the entire population will be studied, skip Activity 4 and go to Activity 5. If HEDIS® measures and sampling methodology are used, go to Activity 5. For more information about identifying the PIP population, see Protocol 1, Activity 1, Step 3.

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[80] More information about the HHS National Quality Strategy is available at https://www.ahrq.gov/workingforquality/about/index.html.

[81] More information about the CMS Quality Strategy is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

[82] More information about the Child Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html. More information about the Adult Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html.

Activity 4: Use Sound Sampling Methods

Appropriate sampling methods are necessary to ensure the collection of information that produces valid and reliable results. Refer to Appendix B, Sampling Approaches for EQR Data Collection Activities, for an overview of sampling methodologies applicable to PIPs. When HEDIS® measures are used and sampling is required (e.g., for measures calculated using the hybrid method), HEDIS® sampling methodology should be used. For more information about sampling approaches for EQR activities, see Protocol 1, Activity 1, Step 4, and Appendix B.

Activity 5: Select the PIP Variables

The next step is to select the PIP variables. Variables can take a variety of forms as long as the selected variables measure performance on the PIP aim statement objectively and reliably and use clearly defined indicators of performance. The additional PIP should include the number and type of PIP variables that are adequate to answer the PIP aim statement and for which appropriate and reliable data are available to measure performance and track improvement over time. Data availability should also be considered when selecting PIP variables, as more frequent access to data, such as on a monthly, quarterly, or semi-annual basis, supports continuous quality improvement (QI) and Plan Do Study Act (PDSA) efforts and can allow and MCP or state to correct or revise course more quickly, if needed. CMS encourages states to select PIP variables and performance measures that can be examined on at least a semi-annual basis.

To the extent possible, CMS encourages EQROs to choose variables for PIPs that reflect health outcomes. Performance measures are then used to measure these outcomes. When selecting measures for an additional PIP, first consider existing performance measures because the specifications for these measures often have been refined over time, may reflect current clinical guidance, and may have benchmarks for assessing performance. CMS encourages the use of the following existing performance measure sets: Child and Adult Core Set measures, behavioral health clinic quality measures, and Core Quality Measures Collaborative.[83] Other examples of existing measures include NCQA's Healthcare Effectiveness Data Information Set (HEDIS®) or measures that have been developed by AHRQ (such as the prevention quality indicators, inpatient quality indicators, patient safety indicators, and pediatric quality indicators).[84]

[83] More information about the Child Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html. More information about the Adult Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html. More information about measures for behavioral health clinics is available at https://www.samhsa.gov/section-223/quality-measures. More information about the Core Quality Measures Collaborative is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.

[84] More information about HEDIS® is available at http://www.ncqa.org/hedis-quality-measurement. More information about AHRQ quality measures is available at http://www.qualityindicators.ahrq.gov/.

When there are gaps in existing measures, new measures may need to be developed based on current clinical practice guidelines or health services research. Consider the following questions:

- Does the measure address accepted clinical guidelines relevant to the focus study question?
- Does the measure address an important aspect of care or operations that is meaningful to MCP enrollees?
- Do the available data sources allow the measure to be calculated reliably and accurately? Are there any limitations on the ability to collect valid and reliable data?
- Are all criteria used in the measure defined clearly (e.g., time periods, characteristics of eligible enrollees, services to be assessed, and exclusion criteria)?

For more information about the selection of PIP variables, see Protocol 1, Activity 1, Step 5.

Activity 6: Collect Valid and Reliable Data

Data collection procedures during implementation of the PIP must ensure that the data used to measure performance are valid and reliable. Validity means that the data are measuring what is intended to be measured. Reliability means that the data are producing consistent results.

To ensure validity and reliability of the data collected as part of implementing the PIP, the data collection plan should specify:

- The data sources for the PIP
- The data to be collected
- How and when the data are to be collected
- Frequency of data collection
- Who will collect the data
- Instruments used to collect the data

The PIP may involve two main kinds of data collection: administrative data sources and medical record review. Procedures to collect data from administrative data systems will be different from procedures for visual inspection of medical records or other primary source documents. However, both types of data collection require assurances that data are valid and reliable. For more information about assuring the validity and reliability of PIP data collection procedures, see Protocol 1, Activity 1, Step 6.

Activity 7: Analyze Data and Interpret Results

Data analysis begins with assessing performance on the selected clinical or nonclinical measures using appropriate statistical techniques, as specified in the data analysis plan. Interpretation and analysis of the PIP data should be based on a continuous improvement philosophy and reflect an

understanding of lessons learned and opportunities for improvement. Interpretation of the PIP results should involve assessing the causes of less-than-optimal performance and collecting data to support the assessment. Accurate data analysis, including measurements at multiple points in time and tests for statistical significance, is essential because the state or MCP may implement changes based on the results. For more information on data analysis and interpretation of PIP results, see Protocol 1, Activity 1, Step 7.

Activity 8: Review Improvement Strategies

Building on the data analysis and interpretation of PIP results in Activity 7, the next step is to review the improvement strategies implemented as part of the PIP. Significant, sustained improvement is the result of developing and implementing effective improvement strategies (including strategies that are culturally and linguistically appropriate for the target population). Selected strategies should be evidence-based, that is, there should be existing evidence (published or unpublished) suggesting that the test of change would be likely to lead to the desired improvement in processes or outcomes (as measured by the PIP variables). The effectiveness of the improvement strategy is determined by measuring change in performance according to predefined measures.

CMS encourages states to work with their EQROs and MCPs to determine which PIP methodology best suits the needs of the state, its MCPs, and their beneficiaries. For example, a state may use the Institute for Healthcare Improvement's (IHI) Model for Improvement to guide improvement work and test changes on a small scale using Plan Do Study Act (PDSA) cycles (see Protocol 1 for more information on the Model for Improvement and PDSA cycles)[85] PDSA cycles provide a methodology to test changes on a small scale and to apply rapid-cycle learning principles to adjust intervention strategies over the course of the improvement. This approach involves a continuous cycle of measuring and analyzing performance and requires frequent reflection and course correction. Data should be evaluated on a regular basis and interventions should be adjusted based on what was learned. Interventions can then be scaled to larger settings or populations if found effective. PIPs, based on the Model for Improvement and PDSA process are sometimes known as rapid-cycle PIPs. For more information on the use of the IHI Model for Improvement and PDSA cycles, see Protocol 1, Activity 1, Step 8.

Activity 9: Assess Whether Significant and Sustained Improvement Occurred

A PIP is intended to result in significant and sustained improvement in health care delivery processes and outcomes, rather than short-term or random change. The final activity in the PIP is

[85] More information about the Model for Improvement and PDSA approach is available from the following sources: http://www.ihi.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx and https://innovations.ahrq.gov/qualitytools/plan-do-study-act-pdsa-cycle.

to assess whether the PIP resulted in statistically significant changes over time that could reasonably be attributed to the improvement strategy implemented as part of the PIP.

To assess whether significant and sustained improvement occurred, repeated measurements are required, using the same methodology used for the baseline measurement. In addition, tests of statistical significance are required to assess whether there is evidence of statistically significant improvement. For more information on assessing the likelihood that significant and sustained improvement occurred, see Protocol 1, Activity 1, Step 9.

END OF PROTOCOL 8

Protocol 9. Conducting Focus Studies of Health Care Quality

An Optional EQR-Related Activity

ACTIVITY 1: SELECT THE STUDY TOPIC(S)

ACTIVITY 2: DEFINE THE STUDY QUESTION(S)

ACTIVITY 3: SELECT THE STUDY VARIABLE(S)

ACTIVITY 4: DEVELOP A PLAN TO STUDY THE POPULATION

ACTIVITY 5: COLLECT DATA

ACTIVITY 6: ANALYZE AND INTERPRET STUDY RESULTS

ACTIVITY 7: REPORT RESULTS TO THE STATE

Background

States may direct their external quality review organizations (EQROs) to conduct focus studies for quality improvement (QI), administrative, legislative, or other purposes. Similar to performance improvement projects (PIPs), focus studies may examine clinical or nonclinical aspects of care provided by managed care plans (MCPs). However, there are key differences between focus studies and PIPs (see Box 9.1). Focus studies assess quality of care at a point in time, whereas PIPs assess improvement over time. For example, a focus study may be conducted for a single year to provide the state with information about the baseline status of health care quality for a particular aspect of care across managed care in the state or for subpopulations served by managed care within the state. By comparison, PIPs are designed to achieve significant improvement, sustained over time, in health outcomes and enrollee experience. PIPs include the implementation of interventions to achieve improvement, evaluation of the intervention's effectiveness (including performance measurement), and initiation of activities to increase or sustain improvement.

Box 9.1. How Does a Focus Study Differ from a PIP?

A Focus Study is a study of a particular aspect of clinical care or nonclinical services provided by an MCP at a point in time.

A PIP is a project that implements an intervention designed to achieve and sustain significant improvement over time.

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Although the goals and regulations for focus studies and PIPs differ, EQROs can use similar processes to design both types of projects. Both must be designed, conducted, and reported in a methodologically sound manner. Because of these similarities, the process for conducting focus studies described in this protocol mirrors many of the activities in Protocol 8 for conducting PIPs.

Getting Started on Protocol 9

To complete this protocol, the EQRO undertakes seven activities for each MCP (Figure 9.1).

Figure 9.1. Overview of Protocol 9 Activities

Activity 1: Select the Study Topic(s)

Focus studies may target a single MCP, a subset of MCPs, or all MCPs in the state. They should target relevant areas of clinical care and nonclinical services in which it is known or suspected that improvement is needed. For example, the focus study may examine patterns of over- or under-utilization of services to assess the potential threat to health or functional status of enrollees. Selected topics should:

- Reflect MCP enrollment in terms of demographic characteristics, prevalence of disease, and the potential consequences of the disease
- Affect a significant portion of enrollees, a specified subpopulation of enrollees, or a significant portion of enrollees impacted by a specific health care issue (such as oral health or maternal and infant health)
- Align with priority areas as identified in the HHS and/or CMS quality strategies.[86]

When selecting the focus study topic, the EQRO and state should consider a variety of factors related to enrollee characteristics, health risks, experience of care, and special population or service needs. Box 9.2 provides additional information on selecting a focus study topic.

Box 9.2 Factors to Consider when Selecting a Focus Study Topic

- Demographic and epidemiologic information about current MCP enrollees
- Enrollee health risks and disease prevalence
- State performance on CMS Child and Adult Core Set measures
- Input from enrollees about specific services, such as mental health or substance abuse
- A spectrum of enrollee populations, services, and experiences:
  - Care for children with special health care needs
  - Care for adults with physical disabilities
  - Care for people with intellectual and developmental disabilities
  - Care for people with dual eligibility who use long-term services and supports (LTSS)
  - Preventive care
  - Acute and chronic care
  - High-volume and high-risk services (even if they are low frequency)
  - Specialized care received from centers (burn, transplant, and cardiac surgery centers)
  - Access to and availability of care
  - Continuity or coordination of care from multiple providers and over multiple episodes
  - Appeals and grievances

[86] More information about the HHS Quality Strategy is available at https://www.ahrq.gov/workingforquality/about/index.html. More information about the CMS Quality Strategy is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.

Activity 2: Define the Study Question(s)

In this activity, the EQRO defines the study question(s). The study question identifies the focus of the study and establishes the framework for data collection and analysis. The study question should be clear, concise, and answerable. Box 9.3 provides considerations for the study question(s). Table 9.1 critiques illustrative study questions for a focus study.

Box 9.3 How do we know if a Focus Study Question is Clear, Concise, and Answerable?

A good focus study question specifies measurable indicators and analytics for a defined population and time period. Potential sources of information to help form the study question include:

- State data relevant to the topic being studied
- MCP data relevant to the topic being studied
- CMS Child and Adult Core Set measures
- Enrollee focus groups or surveys
- Relevant clinical literature on recommended care and external benchmark

Table 9.1. Examples of Focus Study Questions

	Illustrative Study Questions	Critique
Poor Study Question	What is the status of preventive dental care in Medicaid?	• Does not specify measurable indicators and analytics • Does not define the population and time period
Good Study Question	How does the rate of preventive dental visits among children enrolled in Medicaid for at least six months in calendar year 2021 vary by age, geographic location, and race/ethnicity?	• Specifies the measurable indicator (preventive dental visits) • Specifies the analytic issue of interest (variation in utilization rates by age, geographic location, and race/ethnicity) • Defines the population and time period (children enrolled in Medicaid for at least six months in calendar year 2016)

Activity 3: Select the Study Variable(s)

In this activity, the EQRO selects the study variable(s) (see Box 9.4). Study variables can take a variety of forms as long as the selected variables identify the MCP's performance on the study questions objectively and reliably and use clearly defined measurable indicators of performance. The study variables for the focus study should allow the EQRO to measure the MCP's performance on the elements of care identified in the study question(s). For example, for a focus study on preventive dental services in an MCP, the EQRO should select one or more study variables that directly assess enrollees' access to and use of these services. Examples of such study variables may include:

- The proportion of eligible enrollees who received any preventive dental service within a defined timeframe
- The proportion of eligible enrollees who received a dental sealant within a defined timeframe
- The ratio of dental service providers providing preventive services per 1,000 MCP enrollees within a defined geographic area
- The proportion of MCP enrollees who report being able to obtain preventive dental services within a specified timeframe in an enrollee survey

Box 9.4 What is a Study Variable?

A study variable is a measurable characteristic, quality, trait, or attribute of a particular individual, object, or situation being studied. When selecting study variables, consider different types of variables and choose the variables that are best suited to the available data, resources, and study questions.

The EQRO should choose the number and type of study variables that are adequate to answer the study question(s) and for which appropriate and reliable data are available to determine the state of the population at a point in time. Study variables may be continuous, categorical, or discrete (Table 9.2), and use a variety of measurement scales to assess performance (Table 9.3).

Table 9.2. Types of Variables for Focus Studies

Variable Type	Definition	Example
Continuous	Have a range of numerical values Note: Data collected for a continuous variable can be recoded as a discrete variable (e.g., an enrollee's blood pressure is above or below a specified level)	• Age, blood pressure, temperature, height/weight, body mass index, birthweight
Categorical	Have a range of non-ordered, qualitative values (or categories)	• An enrollee survey question that asks enrollees to identify the most important among a list of incentives offered to improve well-care visit rates
Discrete	Have a limited number of possible categories Note: binary variables have two categories	• An enrollee has/has not received a flu shot in the past 12 months

Table 9.3. Types of Measurement Scales for Focus Studies

Measurement Scales	Definition	Example
Interval	The distances between numbers denote significant and interpretable differences (e.g., dollars, degrees, inches, pounds) and the differences are interpretable as higher or lower.	• The interval between an annual income of $40,000 and $30,000 = $10,000

Measurement Scales	Definition	Example
Ordinal	Can be treated as quantitative in some circumstances, and qualitative in others	• An enrollee survey question that asks enrollees to rank their experience of care on a scale from 1 (low quality) to 5 (high quality)
Nominal	The set of categories for a qualitative variable	• Mode of transportation to work (car, bus, subway, bicycle, walk)

When selecting study variables, the EQRO should consider measures that currently exist within the health services research community or the managed care industry because the specifications for these measures often have been refined over time, may reflect current clinical guidance, and may have benchmarks for assessing MCP performance. CMS encourages use of the CMS Child and Adult Core Set measures, behavioral health clinic quality measures, and Core Quality Measures Collaborative for examples.[87] Additional examples of existing measures include NCQA's Healthcare Effectiveness Data Information Set (HEDIS®) or measures that have been developed by AHRQ (such as the prevention quality indicators, inpatient quality indicators, patient safety indicators, and pediatric quality indicators).[88]

When there are gaps in existing measures, the EQRO may develop new measures based on current clinical practice guidelines or health services research. The EQRO should consider the following questions:

- Does the measure address accepted clinical guidelines relevant to the focus study question?
- Does the measure address an important aspect of care or operations that is meaningful to MCP enrollees?
- Do the available data sources allow the EQRO to reliably and accurately calculate the measure? Are there any limitations on the ability to collect valid and reliable data?
- Are all criteria used in the measure defined clearly (e.g., time periods, characteristics of eligible enrollees, services to be assessed, and exclusion criteria)?

[87] More information about the Child Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html. More information about the Adult Core Set is available at https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-core-set/index.html. More information about measures for behavioral health clinics is available at https://www.samhsa.gov/section-223/quality-measures. More information about the Core Quality Measures Collaborative is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.

[88] More information about HEDIS® is available at http://www.ncqa.org/hedis-quality-measurement. More information about AHRQ quality measures is available at http://www.qualityindicators.ahrq.gov/.

Activity 4: Develop a Plan to Study the Population

The focus study should be designed to assess performance for all eligible enrollees in the population being studied (e.g., a single MCP, all MCPs in the state, or all Medicaid beneficiaries in the state). If the study focuses on a specific service (e.g., preventive dental care) or condition (e.g., diabetes), the EQRO should include all members of the population that meet measure-specific eligibility criteria (see Box 9.5). For example, in a focus study on human papillomavirus (HPV) vaccine rates, the EQRO should specify the population of MCP enrollees who meet the eligibility criteria based on age or other factors.

Box 9.5 Tips for Defining the Study Population

EQROs should carefully review the technical specifications for existing measures or develop detailed specifications for new measures to define the measure-eligible population included in the denominator for the study variables.

Once the study population is defined, the EQRO should decide whether to review performance for every enrollee in the study population or whether performance needs to be assessed for a representative sample of the population (see Box 9.6). The appropriate method for the focus study may depend on factors related to the availability and quality of data.

Box 9.6. Factors to Consider in Deciding Whether to Study the Total Population or a Sample

- If the information needed for a study variable is reliable and complete for the population in an available data source (such as claims/encounters or enrollment data), measuring the total population might be appropriate
  - For example, if the MCP's encounter data reliably provide information about the use of prenatal care (e.g., date, type of visit, type of provider), then the EQRO can use these records to assess performance for the total study population
- If the EQRO has concerns about the reliability and completeness of administrative data, it may be more appropriate to conduct the study for a sample of the population
  - For example, a study on childhood obesity that requires data on body mass index (BMI) assessments may not be able to obtain this information in existing administrative data and may need to use medical records for a sample of enrollees
  - Similarly, a study on prenatal and postpartum care may need to use medical records where an MCP pays for maternity care using a bundled payment approach; in such cases, administrative data may not provide the necessary level of detail on the number and date of prenatal and postpartum care visits

If the EQRO decides to assess performance for a sample of the study population, it should use standard statistical methods to select the sample. The sample should be drawn in a way that ensures that it will reflect the total study population. If the sample is not representative, then the focus study will not produce valid and reliable (generalizable) results. To ensure that the sample is representative, every enrollee in the study population should have an equal probability of being selected for the sample and the sample should be large enough to reflect the diversity in the study population. If the focus study results will be assessed for particular subpopulations of enrollees, the sampling strategy should be designed so that there are sufficient numbers of

enrollees in each subpopulation included in the sample. Please refer to Appendix B for additional guidance on sampling approaches and sample sizes.

Activity 5: Collect Data

Once the EQRO has established the focus study topic, question(s), variable(s), and population, the next step is to collect data. Because data collection can be costly and burdensome, the EQRO should first develop a data collection plan that specifies:

- The data sources for the focus study
- The data to be collected
- How and when the data will be collected
- Frequency of data collection
- Who will collect the data
- Instruments that will be used to collect the data

The plan should clearly specify the data sources and explain how the EQRO will ensure that the collected data are complete and reliable for the total study population. For example, if the EQRO will analyze claims or encounter records for an MCP, the EQRO should assess the data to ensure that it contains consistent and complete information for all enrollees included in the study population. Moreover, the EQRO should ensure that diagnosis and procedure codes are used consistently across providers and that services provided in all settings are included.

If the EQRO plans to develop original data collection tools for the focus study, these tools should be designed to obtain reliable results for all subpopulations included in the study. In addition, the data collection plan should confirm that the individuals conducting the data collection have the necessary expertise and training for the task. For example, if the focus study requires a survey, interviewers should be trained to conduct the survey in a systematic, unbiased manner. Similarly, if the focus study requires medical record reviews, special attention should be given to the qualifications of the medical record reviewers, the specificity of the guidelines for data collection, and plans for ensuring inter- and intra-rater reliability. The reviewers should have a standard protocol for reviewing records, have the knowledge to interpret the records, and have been trained to identify and code the information in the records using consistent decision rules. Box 9.7 identifies considerations for medical record reviews.

Box 9.7. Considerations for Medical Record Reviews

- Medical record reviewers require the conceptual and organizational skills to abstract data. These skills will vary depending on the nature of the data and the degree of professional judgment required. For example, experienced clinical staff (such as registered nurses) should be used to extract the appropriate data from medical records to support a judgment about whether clinical criteria are met. In contrast, trained medical assistants or medical records clerks may collect data if the abstraction involves verifying the presence of a diagnostic test report
- Guidelines for obtaining and recording the data are essential. A glossary of terms should be developed before data collection begins to ensure consistent interpretation among and between reviewers. In addition, reviewers should have clear and succinct written instructions, including an overview of the study, how to complete each section of the form, and general guidance on how to handle situations not covered by the instructions. This is particularly important when multiple reviewers are collecting data
- Plans for ensuring inter- and intra-rater reliability are key. The number of reviewers used for a given project affects the reliability of the data. A smaller number of staff promotes inter-rater reliability; however, it may also increase the amount of time it takes to complete the task. The focus study should also consider and address intra-rater reliability (i.e., reproducibility of judgments by the same abstractor at a different time)

Activity 6: Analyze and Interpret Study Results

Before beginning the focus study, the EQRO should establish a plan for analyzing and interpreting the data. Data analysis begins with examining performance on the selected clinical or nonclinical indicators. Accurate data analysis is essential because the state and MCPs may implement changes in treatment and operations based on the results. The review should be conducted using statistical analysis techniques defined in the data analysis plan.

Interpretation and analysis of the study data should involve developing hypotheses about the causes of less-than-optimal performance and collecting data to validate the hypotheses. Interpretation and analysis should also be based on a continuous improvement philosophy to identify areas for improving administrative or delivery system processes.

The EQRO should conduct a quality assurance (QA) review of the analysis before it is finalized. When reviewing the data analysis and study results, the QA reviewer should consider the following questions:

- Was the analysis conducted in accordance with the data analysis plan? Were conventional methods used to conduct the analysis?
- Are numerical results and findings presented in an accurate, clear, and easily understood manner?
- Does the analysis identify:
    - The focus study question and variables used to address the question?
    - Realistic and unambiguous targets/benchmarks for the measures?
    - Performance by key subgroups (e.g., by age, geographic location, health status, MCP)?
    - Statistical significance of differences among subgroups?

- Factors that threaten the validity and reliability of the findings (e.g., missing data)?

- Does the analysis of the study data include an interpretation of the extent to which the focus study is successful and what follow-up activities are planned as a result?

Activity 7: Report Results to the State

After completing the focus study (including the QA review), the EQRO will report the results to the state in its EQR technical report (see Box 9.8). Because the state may use the report to meet its reporting requirements to federal or state agencies, the state legislature, local advocacy groups, or other interested parties, the state may need the report to include specific information presented in a specific format. At minimum, the report should include the following information about the focus study:

- Overall summary of findings
- Study question and objectives
- Methods of data collection and analysis
- Detailed findings, including tables and graphics
- Conclusions drawn from the data

To ensure that the report includes appropriate information in the desired format, the EQRO should submit an outline to the state before writing up the results. The EQRO should also confirm the audience for the report and the plans for dissemination (e.g., to CMS, MCPs, providers, advocates, state legislators). With this information, the report can be appropriately targeted to the intended audience.

Box 9.8. Tips on Reporting on Focus Studies in EQR Technical Reports

- Define the study question and objectives, methods, and data sources clearly and completely. Specify the study population and time frame
- Use tables and graphics to "tell a story" with the data; make sure to answer the study question with the data.
- If comparisons are made between subgroups, conduct tests of statistical significance to determine whether differences are statistically meaningful
- Describe the implications of the findings for understanding current performance and for developing quality improvement initiatives. Identify strengths and weaknesses related to quality, timeliness, and access.
- Clearly state the study limitations and caveats

END OF PROTOCOL 9

Protocol 10. Assist With Quality Rating of Medicaid and CHIP Managed Care Organizations, Prepaid Inpatient Health Plans, and Prepaid Ambulatory Health Plans

An Optional EQR-Related Activity

Reserved.

PROTOCOL TEN

Appendix A. Information Systems Capabilities Assessment

ACTIVITY 1: MCP COMPLETES THE ISCA TOOL

ACTIVITY 2: PERFORM PRELIMINARY ISCA REVIEW

ACTIVITY 3: CONDUCT MCP ONSITE OR VIRTUAL SITE VISIT

ACTIVITY 4: COMPILE AND ANALYZE ISCA FINDINGS

ACTIVITY 5: DRAFT ISCA SUMMARY FOR EQR TECHNICAL REPORT

APPENDIX A

Background

This appendix defines the recommended capabilities of a managed care plan's (MCP's)[89] information system (IS) to meet regulatory requirements for managed care quality assessment and reporting, and provides an approach the external quality review organization (EQRO) can use to assess the strength of each MCP's information system capabilities. Portions of the Information Systems Capabilities Assessment (ISCA) are voluntary; however, some components are required for the mandatory EQR-related activities protocols. The regulations at 42 CFR 438.242 and 457.1233(d) also require the state to ensure that each MCP maintains a health information system that collects, analyzes, integrates, and reports data for purposes including utilization, claims, grievances and appeals, disenrollment for reasons other than loss of Medicaid or CHIP eligibility, rate setting, risk adjustment, quality measurement, value-based purchasing, program integrity, and policy development.

Figure A.1 shows the interrelationship of data activities for providers, MCPs, and EQROs. Per 42 CFR 438.242, the MCP's information system must be able to achieve the following:

1. Provide the state with all data elements the state deems necessary for the mechanized claims processing and information retrieval systems it uses for the management, monitoring, and administration of its Medicaid or CHIP program. Collect data on enrollee and provider characteristics as specified by the state provider and eligibility files, and on all services received by an

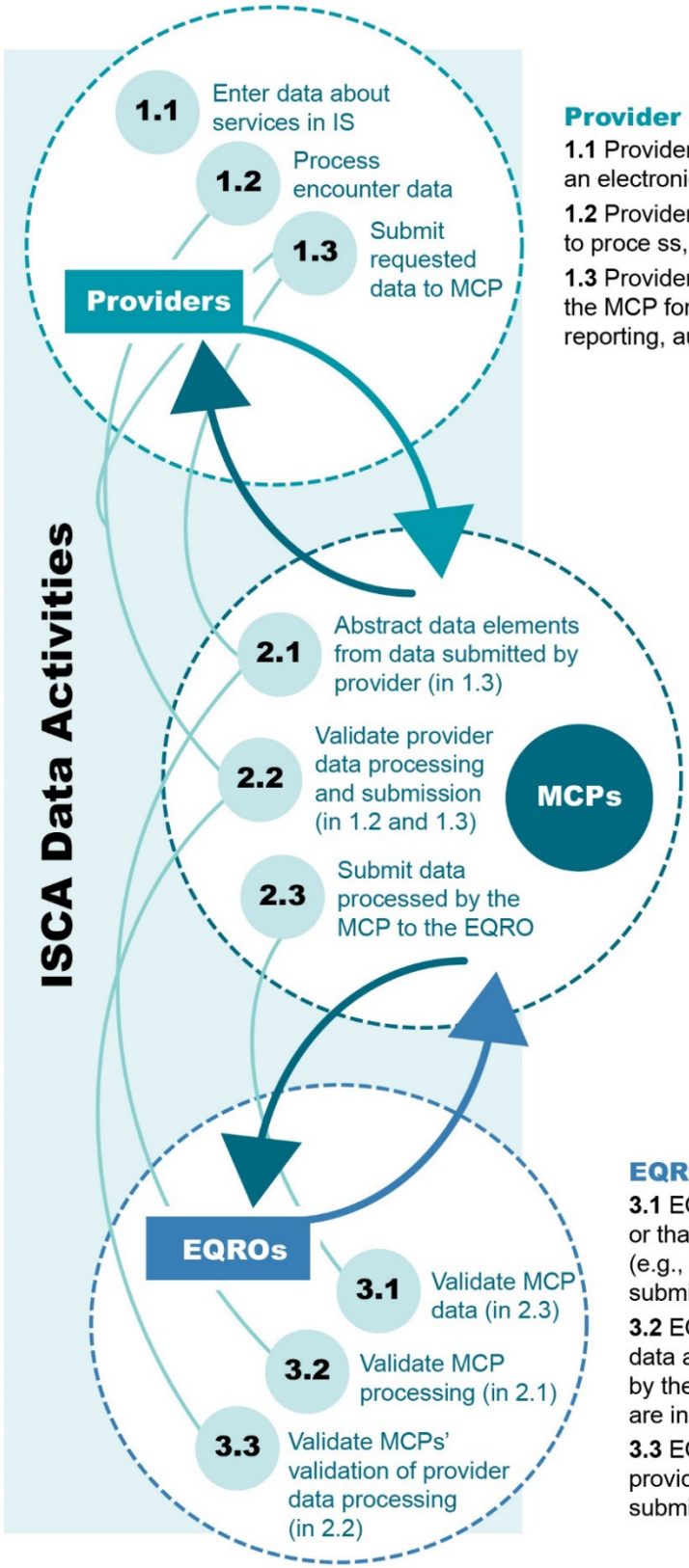
[89] For the purposes of the EQR protocols, the term MCP includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs), but does not include primary care case management (PCCM) entities.

enrollee regardless of payment methodology, including services sub-capitated by a MCP to a provider, through an encounter data system or other method that meets state requirements

2. Ensure that data received from providers are accurate and complete by:
    - Verifying the accuracy and timeliness of reported data
    - Screening the data for completeness, logic, and consistency
    - Collecting data from providers in standardized formats (e.g., T-MSIS) to the extent feasible and appropriate
3. Make all collected data available to the state and to CMS upon request

This appendix provides an overview of the activities for assessing an MCP's data collection, processing, and reporting systems. The appendix concludes with information about the future of information system assessments.

Figure A.1. Provider, MCP, and EQRO Data Activities



Provider Data Activities

1.1 Provider records their encounters in an electronic or paper format

1.2 Provider uses the information system to proce ss, clean, and compile data

1.3 Provider submits encounter data to the MCP for payment, measure reporting, audit, etc.

MCP Data Activities

2.1 MCP receives provider data (claims, encounters, and data from certified EHR technologies), uses it for payment (claims), or other purposes (received in a transaction file), and enters it into a data repository

2.2 MCP validates the provider's data entry, processing, and submission via edit checks on claims, random medical record reviews, and/or other methods

2.3 MCP processes the data in its data repository and submits data to the EQRO or the state

EQRO Data Activities

3.1 EQRO validates the data in its repository or that the MCP or other organization (e.g., claims processing vendor, state repository) submitted to the EQRO

3.2 EQRO validates the accuracy of provider data and accuracy with which it was processed by the MCP (Note: instructions for this validation are included in Protocols 2, 5, 7, and 9)

3.3 EQRO validates that the MCP is ensuring providers are accurately processing and submitting data to the MCP

Getting Started on the ISCA

Assessing an MCP's information systems encompasses five consecutive activities (Figure A.2). In the event that onsite activities are not feasible due to the COVID-19 pandemic, site visits may be conducted virtually.

Figure A.2. Overview of ISCA Activities

One supplemental resource is available to help EQROs conduct validation of the ISCA:

- Worksheets for Appendix A. Information System Capabilities Assessment (ISCA) Tools, which can be used to enable the MCP to collect standard information about its information system, and to guide onsite or virtual information systems interviews of MCP staff

TIP

Navigate to the corresponding worksheet by clicking the WORKSHEET box under each section

Activity 1: MCP Completes the ISCA Tool

The MCP should complete the ISCA tool (Worksheet A.1) to provide standard information about its IS and gather all requested documentation identified on a checklist at the end of the assessment tool. The MCP should return the completed ISCA tool and documentation to the EQRO within a timeframe defined by the state.

Some states assess the capabilities of the MCP's information system as part of pre-contracting, contract compliance, or contract renewal activities. The MCP must make any previously conducted assessments accessible to the EQRO. The EQRO should review any such assessments as part of its ISCA review process.

WORKSHEET A.1

Resource for Activities 1 & 2

Worksheet A.1. Information System Capabilities Assessment (ISCA) Tool

- An information collection tool provided to an MCP by the state or its EQRO to obtain the information needed to validate the capabilities of the MCP's information systems, processes, and data, to support annual EQR-related activities and associated EQR analysis and recommendations

Activity 2: Perform Preliminary ISCA Review

The EQRO assesses the adequacy of MCP policies and procedures based on the information submitted by the MCP on the ISCA tool (Worksheet A.1) and its accompanying documentation. MCP answers should be evaluated against the information system standards established by the state to calculate and report specific plan-level performance measures, and collect and submit encounter data to the state. The EQRO should identify sections of the ISCA that the MCP has not fully completed. The EQRO may use the Managed Care Plan (MCP) Information System Review Worksheet & Interview Guide (Worksheet A.2) to organize information for the site visit interviews with MCP staff (Activity 3).

Activity 3: Conduct MCP Onsite or Virtual Site Visit

The EQRO conducts an onsite or virtual site visit to the MCP to validate the completed ISCA tool (Worksheet A.1) and to gather additional information as needed. The EQRO conducts interviews with MCP staff responsible for completing the ISCA, as well as additional staff responsible for the MCP's information system functions. The interviews focus on the topics outlined in the ISCA Interview Guide (Worksheet A.2), based on the pre-site analysis of the ISCA in Activity 2. The interview with the MCP should be closely coordinated with the MCP site visit performed in Protocol 3. Assessment of Compliance with Medicaid and CHIP Managed Care Regulations. Refer to Protocol 3, Activity 3 for steps in conducting a successful MCP site visit.

WORKSHEET A.2

Resource for Activity 3

Worksheet A.2. Information System Review Worksheet & Interview Guide

- A tool to conduct interviews with MCP staff that completed the ISCA tool (Worksheet A.1), as well as other MAP staff as needed
- These questions are intended to guide the reviewer's discussion with MCP staff to help validate the completed ISCA
- The questions are first organized by MCP staff roles and then by regulatory provision

Activity 4: Compile and Analyze ISCA Findings

At the conclusion of the ISCA site visit, the EQRO compiles and analyzes the information gathered through the preliminary ISCA review (Activity 2) and from the site visit (Activity 3). After completing its analysis, the EQRO writes a statement of findings about the MCP's information system. This statement should include implications of the findings for the following:

- Completeness and accuracy of encounter data collected and submitted to the state
- Validation and/or calculation of performance measures
- Completeness and accuracy of tracking of grievances and appeals
- Utility of the information system to conduct MCP quality assessment and improvement initiatives
- Ability of the information system to conduct MCP quality assessment and improvement initiatives
- Ability of the information system to oversee and manage the delivery of health care to the MCP's enrollees
- Ability of the information system to generate complete, accurate, and timely T-MSIS data
- Utility of the information system for review of provider network adequacy
- Utility of the MCP's information system for linking to other information sources for quality-related reporting (e.g., immunization registries, health information exchanges, state vital statistics, public health data)

Activity 5: Draft ISCA Summary for EQR Technical Report

A summary of the ISCA should be included in the EQR technical report developed by the EQRO. This summary should include:

- When the most recent ISCA was completed
- The statement of the findings from the review
- Overall findings from the review
- Based on findings from the ISCA, recommendations to the state relevant to EQR-related activities and/or revisions to the state's managed care quality strategy

The Future of Information Systems Assessment

With increasingly sophisticated and comprehensive information systems, it is important to adapt the way information systems' capabilities are assessed. As information systems evolve, so will the tools and rules with which states and EQROs assess them. As an example, information systems may now be built on on-premise physical infrastructure, a cloud platform, or a hybrid of both, which requires the ability to assess system security on these platforms to ensure the privacy and security of protected health information (PHI) data. Supports for meeting existing statutory requirements regarding privacy and security, including guidance and tools, might be considered suitable topics for one of two optional EQR-related activities, additional performance improvement projects (Protocol 8. Implementation of Additional Performance Improvement Projects) or focus studies (Protocol 9. Conducting Focus Studies of Health Care quality).

Given the ongoing and accelerating accumulation of health information technology (HIT) standards, HIT certification requirements, and HIT qualifications proposed and imposed by federal payers, organizations should anticipate changes in assessments of new information system requirements. Two recent developments are particularly pertinent to the future of information systems assessment:

1. In 2011, CMS began working with state agencies and other stakeholders to finalize a new data infrastructure, the Transformed Medicaid Statistical Information System (T-MSIS). T-MSIS is designed to modernize the way that states submit data about beneficiaries, providers, fee-for-service claims, and encounters to CMS. T-MSIS (1) expands required data elements on person-level eligibility and services; (2) captures data on providers, managed care plans, and third-party insurance; (3) provides for improved quality of state data; and (4) requires states to submit data monthly instead of quarterly, making the data available sooner. CMS expects that state agencies will thoroughly audit the managed care data to ensure that it complies with all T-MSIS requirements before submission to CMS
2. New efforts to implement value-based purchasing, alternative payment models, and integrated care models will require assessment of the MCPs' ability to track (1) bundled, incentive, bonus, and capitated payments, (2) whether all the needed services were delivered,

and (3) how clinical quality data for performance measurement is captured and communicated back and forth to care managers. Including all paid amounts on encounter data provides important information to the state and CMS, enabling more data-driven analytic methods to value-based purchasing efforts and rate development

Of continuing importance to successful information systems is the adoption and meaningful use of certified electronic health records (EHRs). The passage in 2016 of the 21st Century Cures Act[90]—which is designed to help improve care delivery by ensuring the interoperability of health information exchange (HIE) systems for seamless patient care through increased coordination and continuity of health care among health care providers—highlights the significance of certified EHRs and HIE systems as potential drivers of improvements in individual and population health. The design and utilization of secure EHRs will become an increasingly important element in the EQR process as is reflected in the questions included in the ISCA tool. States and MCPs should work collaboratively in the planning and use of certified EHRs and health information exchange systems.

States and MCPs must also coordinate their HIT planning efforts to ensure interoperability between systems that effectively provide for future data needs to meet eligibility, enrollment, Health Insurance Exchange, quality reporting, and delivery system reform statutory and regulatory requirements. EQROs should continually assess MCP planning activities to ensure alignment with and responsiveness to these initiatives. For example, this could include use of data from bi-directional data exchange with immunization registries to support state reporting of the CMS Child Core Set immunization measures.

To learn from and share state experiences with emerging HIT and EHR initiatives that can impact performance measure and performance improvement project outcomes reporting, CMS strongly encourages states that contract with EQROs to include results of state HIT and EHR initiatives impacted by MCP reporting in annual EQR reports. This may include successful implementation of health information exchange with various state agencies to improve data source collection efforts for performance measures (such as electronic clinical quality measures or other administrative data sources used in the calculation of quality measures) or performance improvement projects. Similarly, including lessons learned from challenging or unsuccessful HIT initiatives are just as informative to federal and other state partners, and may also be included in annual EQR technical reports.

END OF APPENDIX A

[90] See https://www.gpo.gov/fdsys/pkg/PLAW-114publ255/content-detail.html for more information about the 21st Century Cures Act.

Worksheets for Appendix A

Worksheet A.1. Information System Capabilities Assessment (ISCA) Tool

Instructions. The ISCA tool is an information collection tool provided to an MCP[91] by the state or its EQRO to obtain the information needed to validate the capabilities of the MCP's information systems, processes, and data, with the intent of supporting annual EQR-related activities and associated EQR analysis and recommendations as documented in the EQR technical report. The state or its EQRO will define a timeframe in which the MCP is expected to complete and return the tool or comparable information. For purposes of this worksheet, it is assumed the MCP will record data in this tool. Documents from the MCP requested throughout the tool are listed in the Summary of Requested Documentation Checklist, below.

The state and the MCP should be certain that data being reported are not only accurate today, but also have a reasonable chance of being accurate for future reporting periods. Future accuracy can be predicted by assessing the MCP's system development cycle and supporting environment. Plans that lack development checkpoints and controls are much more likely to introduce errors as systems change. The questions in this tool can be used to subjectively assess the likelihood of future reporting anomalies. However, it should be noted that very few entities with information systems meet all the desirable criteria. The EQRO is directed to consider the status of checkpoints and controls in its overall assessment of findings.

If the MCP's information has been formally assessed within the last two years, please attach a copy of the assessment report. Complete only those sections of the ISCA tool that were not covered by or have changed since the formal assessment was conducted. If applicable, attach a copy of the MCP's most recent information systems analysis completed as a part of an accreditation review or third party performance measure validation process.

Note: The information requested in the ISCA pertains to the collection and processing of data for an MCP's Medicaid and/or CHIP line of business. In many situations, if not most, this may be no different than how an MCP collects and processes commercial or Medicare data. However, for questions that address areas where Medicaid or CHIP data are managed differently than commercial or other data, please provide the answers to the questions as they relate to Medicaid or CHIP enrollees and Medicaid or CHIP data.

Any time there is a system difference between Medicaid and CHIP, it should be reported in the MCP's responses. However, unless noted, it is assumed that the MCP treats data from these two programs in the same manner.

MCP Contact Information

Please insert or verify the MCP contact information below, including the MCP name, MCP contact name and title, mailing address, telephone and fax numbers, E-mail address, and date of interview, if applicable.

MCP Name:	
MCP Contact Name:	
Title:	
Mailing address:	
Phone number:	
E-mail address:	

[91] For the purposes of the Appendix A worksheets, the term MCP includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs), but does not include PCCM entities, because 42 CFR Section 342, which is the basis for the requirement that states ensure maintenance of health information systems, is only applicable to MCOs, PIHPs and PAHPs.

MCP Name:	
Interview Date:	
Type of delivery system (check all that apply)	□ MCO □ PIHP □ PAHP □ Other (specify): _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP

Summary of Requested Documentation Checklist

Instructions. As you complete the ISCA tool and gather the files, please label all attached documentation as described in the table column "Requested Document," and when applicable by the activity number from the ISCA. You are not limited to providing only the documentation listed below; you are encouraged to provide any additional documentation that helps clarify an answer or eliminates the need for a lengthy response.

Check box if document is attached	Requested Document	Details
	Previous Medicaid Performance Measure Audit Reports	If applicable, attach the information system analysis report completed as a part of the MCP's most recent accreditation review or its most recent third party performance measure validation process
	Organizational Chart	Attach an organizational chart for your MCP. The chart should make clear the relationship among key Individuals/departments responsible for information management, including performance measure reporting.
	Data Integration Flow Chart	Attach a flowchart that gives an overview of the structure of your management information system. See the example provided in Section II-D. "Integration and Control of Data for Performance Measure Reporting." Be sure to show how all claims, encounter, membership, provider, EHR, and vendor data are integrated for performance measure reporting.
	Performance Measure Repository File Structure (if applicable)	Attach a complete file structure, file format, and field definitions for the performance measure repository.
	Program/Query Language for Performance Measure Repository Reporting (if applicable)	Attach full documentation on the software programs or codes used to convert performance measure repository data to performance measures.
	Continuous Enrollment Source Code	Attach a copy of the source code that you use to calculate continuous enrollment for Medicaid or CHIP enrollees. If no source code is use, then provide the computer program used
	Medicaid Member Months Source Code	Attach a copy of the source code/computer programs that you use to calculate member months, member years for Medicaid or CHIP enrollees.
	Medicaid or CHIP Claims Edits	Attach a list of specific edits performed on claims as they are adjudicated with notation of performance timing (pre- or post-payment) and whether they are manual or automated functions.

Check box if document is attached	Requested Document	Details
	Statistics on Medicaid or CHIP claims/encounters and other administrative data	Attach documentation that explains statistics reported in the ISCA.

Section 1. Background Information

1. Please select your Managed Care Model. Mark only one.

   □ MCO
   □ PIHP
   □ PAHP

2. What year was the MCP incorporated? _____

3. Enter your average unduplicated member enrollment for the last three years. For each column enter the reference year.

Insurer	Year 1:	Year 2:	Year 3:
Privately insured			
Medicare			
Medicaid			
CHIP			
Other (specify)			

4. Has your organization ever undergone a formal information system capability assessment?

   □ Yes
   □ No (GO TO SECTION 2)

   4a. If yes, who performed the assessment? _____

   4b. When was the assessment completed? _____

   4c. Please provide a copy of the results of each assessment performed within the past 2 years.

Section 2. Information Systems: Data Processing Procedures & Personnel

These questions attempt to determine the stability and expertise of the information system department. Responses can provide additional insight into the development cycle responses. Outsourcing means using non-employees to get the work done, sometimes off-site, in which case project specification, management, coordination, and acceptance become key success factors. Enter an educated guess if the turnover rate is unknown.

1. What type of system or repository does your organization use to store Medicaid and CHIP claims and encounter data?

2. Is this data system or repository located onsite or located in the cloud?

   □ Onsite (GO TO QUESTION 3)
   □ In the cloud

   2a. If in the cloud, which cloud provider hosts the data?

3. How would you characterize this system or repository? Mark all that apply.

   □ Relational database management system (DBMS)
   □ Network
   □ Hierarchical DBMS
   □ Flat file
   □ Indexed
   □ Proprietary
   □ Other: Specify _____
   □ Don't know

4. Into what repository or DBMS(s), if any, do you extract relevant Medicaid or CHIP encounter/claim/enrollment detail for analytic reporting purposes?

5. How would you characterize the repository/DBMS(s)? Mark all that apply.

   □ Relational DBMS
   □ Network
   □ Hierarchical DBMS
   □ Flat file
   □ Indexed
   □ Proprietary
   □ Other: Specify _____
   □ Don't know

6. What programming language(s) do you use to create Medicaid and CHIP data extracts or analytic reports?

   _____

   6a. How many staff are trained and capable of modifying these programs?

   _____

7. Do you calculate defect rates for programs?

   □ Yes
   □ No (GO TO QUESTION 8)

7a. If yes, what methods do you use to calculate the defect rate?

7b. What was the most recent time period?

7c. What were the results?

8. Approximately what percentage of your organization's programming work is outsourced? _____%

9. What is the average years of experience among those staff who perform programing and data analysis in your organization?

10. Approximately how many resources (time, money, etc.) are spent on training per programmer and analysis staff per year?

Number of hours: _____
Dollars spent: $_____
Other resources (specify): _____

10a. What type of training for programmers is provided?

11. What is the turnover rate for your programming and analysis staff for each of the last 3 years (new staff per year/total staff)?

Year 1 (20xx): _____ % Year 2 (20xx): _____ % Year 3 (20xx): _____ %

12. Does your organization follow a standard software development methodology (SDLMC)?

□ Yes
□ No (GO TO QUESTION 13)

12a. Outline the steps of the maintenance cycle for your state's mandated Medicaid and CHIP reporting requirement(s). Include any tasks related to documentation, debugging, roll out, training, etc. The level of detail should result in 10–25 steps in the outline.

13. Does your organization use version control software for change management and deployment to the production environment?

□ Yes
□ No (GO TO QUESTION 14)

13a. If yes, what product is used?

Note (Q13a): The information system department should follow a standardized process when updating and revising code. This process should include safeguards that ensure that the correct version of a program is in use

13b. Do all programmer and analysis staff and all of your systems use this product for development and deployment?

□ Yes
□ No

14. How does your organization know if changes to the claims/encounter/enrollment tracking system affect required reporting to the state Medicaid or CHIP program (e.g., what prompts your organization to change these systems)?

Note (Q14): A specific individual within the organization should be responsible for determining the impact of any changes made to the plan's claims/encounter/enrollment tracking systems. The plan should have in place a system for triggering information system staff to update the programs.

15. Who is responsible for your organization meeting the state Medicaid and CHIP reporting requirements? Mark all that apply.

□ CEO
□ CFO
□ COO
□ CCO
□ Other (Specify) _____

Section 3. Staffing

1. Describe the Medicaid or CHIP data processing organization in terms of staffing and the expected productivity goals. What is the overall daily, monthly, and annual productivity of the overall department and by processor?

Note (Q1): Unusually high productivity goals can affect the accuracy and quality of a processor's work.

2. Describe processor training from new hire to refresher courses for seasoned processors.

Note (Q2): New hires should be provided with on-the-job training and supervision. Supervisors should closely audit the work of new hires before concluding the training process. Seasoned processors should have occasional refresher courses and training concerning any system modifications.

Section 4. Security

1. Does your organization have a disaster recovery (DR) plan and DR system?

□ Yes
□ No (GO TO QUESTION 6)

2. Where is the DR system located?

3. Does it provide failover capability?

4. How long does it take to switch over to the DR system when the primary system fails?

5. How often is the DR system tested?

6. How frequently are system backups performed?

7. Where are backup data stored?

8. How and how often are the backups tested to make sure that the backup procedure is functioning properly?

9. How is Medicaid or CHIP data corruption prevented due to system failure or program error?

Note (Q9): A back-up procedure will protect the data from destruction due to system failure and program error. Plans can also institute additional safeguards to protect data from being written over during these processes.

10. Describe the controls used to assure that all Medicaid and CHIP claims data entered into the system are fully accounted for (e.g., batch control sheets).

Note (Q10): The plan should have a process in place that ensures that all claims/encounters that have been logged as received are entered into the system and processed.

11. Describe the provisions in place for physical security of the computer system and manual files:

    Premises:
    Documents:
    Computer facilities:
    Desktops, laptops and mobile devices:

Note (Q11): The system should be protected from both unauthorized usage and accidental damage. Paper based claims/encounters should be in locked storage facilities when not in use. The computer system and terminals should be protected from unauthorized access using a password system and security screens. Passwords should be changed frequently and should be re-set whenever an employee terminates

12. Describe the steps taken to verify that the MCP's information system processes for protecting PHI, including its encryption methods, are compliant with Federal Information Processing Standards Publication (FIPS) 140-2 (for more information on the FIPS 140-2 process and validation list, please review the FIPS 140-2 related documents at https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/fips1402.pdf?language=es).

    12a. Provide the results of the most recent FIPS 140-2 tests completed on the MCP's information system.

13. Describe the procedures in place to determine which system users may access levels of the system that include PII. Please identify the job titles and responsibilities of each system user with access to systems that include PII.

14. Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

15. Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.

16. Describe the process and guidelines in place with regard to the retention and destruction of PII.

17. Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

18. If you employ cloud-based technology, describe the provisions in place to secure the virtual system.

19. If you utilize remote network access to connect users with the MCP's secure networks via the internet, describe the provisions in place to secure the network against unauthorized access.

20. Which staff position(s) is responsible for the security and user administration task that grants access to the system?

21. Which staff positions have access to what levels of the system?

22. Can your programming and analysis staff access the production system or only the development system?

    □ Production system only
    □ Development system only

23. How often must passwords be changed?

24. How quickly are logons deactivated after employee terminations and resignations?

25. Describe your patch management protocols and processes.

26. What other individuals have access to the computer system? Customers? Providers? Describe their access and the security that is maintained restricting or controlling such access.

Note (Q26): Both members and providers should have their access limited to read-only so that they cannot alter any files. They should be given access to only those files containing their own patients or members. Customers should be prevented from accessing highly confidential patient information by being given "blinded" patient names and "scrambled" ID numbers, or restricted access to particular files.

Section 5. Data Acquisition Capabilities

The purpose of this section is to obtain a high-level understanding of how you collect and maintain administrative data (claims and encounter data), enrollment information, data on ancillary services such as prescription drugs.

A. Administrative Data (Claims and Encounter Data)

These questions request information on input data sources (e.g., electronic claims and paper) and on the transaction system(s) you use.

1. How are data submitted (e.g. electronically, on paper or both)?

   - □ Submitted electronically
   - □ Submitted on paper
   - □ Submitted both electronically and on paper

   1a. What percent of data are submitted electronically?

   1b. What formats are used?

   1c. Is there a front-end web portal available for data submissions?

   - □ Yes
   - □ No

2. Do you use standard claims or encounter forms for the following? Mark yes or no for each data source. If yes, please specify (e.g., CMS1500, UB 94).

Data source	No	Yes	If "Yes," please specify
Hospital			
Physician			
Drug			
Nursing home			
Home health			
Mental health			
Dental			

Note (Q2): Plans that do not use either CMS 1500 or UB 92 forms may be using forms they developed themselves. If a plan is using its own forms, these forms should be reviewed to ensure they are capturing the following key data elements: patient identification information (Medicaid ID, name, date of birth, gender), provider identifying information (national provider identifier (NPI), Tax ID, name), date of service, place of service and diagnoses and procedure codes. An evaluation of their forms to ascertain adequacy and completeness of data collection may be necessary.

3. We would like to understand how claims or encounters are submitted to your plan. We are also interested in an estimate on an *annual* basis of what percentage (if any) of services provided to your enrollees by all providers serving your Medicaid and CHIP enrollees are NOT submitted as claims or encounters, and therefore, are not represented in your administrative data. Please fill in the following table with the appropriate percentages:

Claims or Encounter Types							
Medium	**Hospital**	**PCP**	**Specialist Physician**	**Dental**	**Mental health/ substance abuse**	**Drug**	**Other**
Claims/encounters submitted electronically							
Claims/encounters submitted on paper							

Claims or Encounter Types							
Medium	**Hospital**	**PCP**	**Specialist Physician**	**Dental**	**Mental health/ substance abuse**	**Drug**	**Other**
Services not submitted as claims or encounters							
TOTAL	100%	100%	100%	100%	100%	100%	100%

Note (Q3): Since paper forms need to be entered into a plan's system, processing paper forms is prone to error. If a plan is receiving more that 50 percent of its data on paper forms, verify the data checks the plan uses to test processor accuracy. Electronic data submission should also undergo data edits and validity checks. Plans with a high percentage of unavailable data for a particular category will have difficulty reporting measures that use that category. For example, a plan receiving no drug data from its vendor would not be able to report the HEDIS® measures for Outpatient Drug Utilization.

3a. For each type of claims or encounter type for which some percentage are not represented in your administrative data, please explain why such activity is not reported.

4. In the following table, please enter an "R" in the appropriate cell if the following data elements (data fields) are required by you for providers, for each of the types of Medicaid claims/encounters identified below. Note that each of these elements is required by T-MSIS, and that the MCP's data elements should align with T-MSIS requirements:

Claims or Encounter Types							
Medium	**Hospital**	**PCP**	**Specialist Physician**	**Dental**	**Mental health/ substance abuse**	**Drug**	**Other**
Patient gender[a]							
Patient date of birth and age							
ICD9/10 Diagnosis Codes							
Procedure Code Types:							
CPT-4/HCPCS							
National Drug Code (NDC)							
Universal Product Code (UPC							
Manufacturer Part Number (MPN)							
First date of service							
Last date of service							
Quantity of Service							
Revenue code							

Claims or Encounter Types							
Medium	**Hospital**	**PCP**	**Specialist Physician**	**Dental**	**Mental health/ substance abuse**	**Drug**	**Other**
Provider NPI							
Provider specialty							
TOTAL	100%	100%	100%	100%	100%	100%	100%

[a] UN, M, or F (UN = the gender of a person could not be uniquely defined as male or female; M = Male; F = Female). Please see AHRQ's Administrative Gender Value Set document at https://ushik.ahrq.gov/ViewItemDetails?&system=mu&itemKey=86667000 for more information.

Note (Q4): Standard measures of plan performance such as Medicaid HEDIS® are dependent upon the availability of the fields listed above. If procedure codes or diagnosis codes are not available, the data will not include the necessary level of detail to report performance measures.

5. In the following table, please enter how many diagnoses and procedures are captured on each claim and on each encounter:

	Claim		**Encounter**	
	Diagnoses	**Procedures**	**Diagnoses**	**Procedures**
Institutional data				
Provider/Provider group data				

Note (Q5): All diagnosis codes types should be standard, nationally recognized codes, rather than plan-specific codes. Diagnosis code fields should include all diagnosis codes needed to identify the reason for the encounter, and all relevant comorbidities and complications should be included. Each service rendered or product dispensed should be identified with the appropriate identifier.

6. Can you distinguish between principal and secondary diagnoses?

□ Yes
□ No

Note (Q6): Some plans will consider the first diagnosis on the claim to be principal. Other plans determine the principal diagnosis by selecting the most expensive condition represented.

6a. If "Yes" to 6, above, how do you distinguish between principal and secondary diagnoses?

7. Please explain what happens if a Medicaid or CHIP claim or encounter is submitted and one or more required fields are missing, incomplete, or invalid. For example, if diagnosis is not coded, is the claims examiner required by the system to use an on-line software product like AutoCoder to determine the correct ICD-10 code?

Institutional Data:
Professional Data:

8. How is the MCP able to distinguish backend-system-assigned data versus data submitted by the service provider?

9. What steps do you take to verify the accuracy of submitted information (e.g., procedure code, diagnosis edits, gender-diagnosis edits, gender-procedure code edits)?

   Institutional Data:
   Professional Data:

Note (Q9): Plans will often verify that the information in procedure code and diagnosis code fields are valid codes. Plans may also verify that diagnosis and procedure codes are appropriate for age and gender. For example, a claim with a procedure of hysterectomy should be for a female patient.

10. Under what circumstances can claims processors change Medicaid or CHIP claims/encounter information?

Note (Q10): If processors are given the ability to modify claims/encounter information, the accuracy of that information could be affected either negatively or positively. Processors may simply correct data that was submitted incorrectly, which would increase the quality of the data. However, processors may also change diagnosis and procedure codes which could result in a loss of coding specificity. Does the plan check processed data against paper claims?

11. Identify any instance where the content of a field is intentionally different from the description or intended use of the field. For example, if the dependent's SSN is unknown, do you enter the member's SSN instead?

Note (Q11): Changing the content of a field can create data processing issues. For example, if the enrollee's SSN is used as an ID for a number of dependents, the claim may be given the age and sex of the member rather than the actual patient. The use of the enrollee's SSN would make it difficult to track the dependent's experience over time.

12. How are Medicaid or CHIP claims/encounters received from each of the following sources? Please mark one column per source:

Source	Received directly from provider	Received through an intermediary
Hospital		
Physician		
Pharmacy		
Nursing home		
Home health		
Mental health		
Dental		
Other		

12a. If the data are received through an intermediary, what changes, if any, are made to the data? Please answer for each source received through an intermediary in the table above.

Note (Q12): Intermediaries that are processing the data, such as a pharmacy benefit firm, could modify the data, creating a data set that is inconsistent with the plan's data. The intermediary may define field content differently or may not be using the same fields as the plan, making it difficult to integrate the intermediary's data into the plan's systems. All data submitted through an intermediary should be monitored for quality by the plan.

13. In the following table, please estimate the percentage of Medicaid or CHIP claims/encounters that are coded using the following coding schemes:

Coding scheme	Inpatient diagnosis	Inpatient procedure	Ambulatory/outpatient diagnosis	Ambulatory/outpatient procedure	Drug
ICD-10 CM					
CPT®-4					
HCPCS					
DSM-IV					
National Drug Code					
Internally developed					
Other: Specify					
Not required					
TOTAL (can be greater than 100% if a claims type is subject to more than one coding system)					

Note (Q13): If a plan is using internally-developed coding schemes, the state should verify whether this coding can be mapped to standard coding such as ICD-10 or CPT-4. If the coding can be translated for reporting purposes (Medicaid HEDIS® requires diagnosis and procedure codes), the plan should provide information on the level of specificity with which the coding maps to standard coding (e.g., three-digit specificity or five-digit specificity). If the mapping has a low level of specificity, information on co-morbidities and complications may not be retained during translation.

14. Please list all information systems through which service and utilization data for the Medicaid or CHIP population is processed.

15. Please describe any major systems changes or updates that have taken place in the last three years in your Medicaid or CHIP claims or encounter system (be sure to provide specific dates on which changes were implemented). Check all that apply

□ New system installed to replace old system

□ New system purchased and installed to replace most of old system; old system still used

- Major enhancements to old system

□ If enhancements were made to the old system, please summarize what enhancements were made and whether (and if so, how) the enhancements have impacted historical data:

□ New product line adjudicated on old system

□ Conversion of a product line from one system to another

Note (Q15): When a plan undertakes any major system changes such as an upgrade or conversion to a new system, the system changes could affect data quality. Data quality problems include corruption of data, loss of data, and loss of the level of detail within the data. The implementation of a new system can also affect access to historical data. Changes in data quality and access will affect the plan's ability to report performance measures and utilization. The plan should have a fallback option, such as parallel operations.

16. How many years of Medicaid or CHIP data are retained on-line?

16a. How is historical Medicaid or CHIP data accessed when needed?

Note (Q16a): Due to system constraints, a plan may remove historical data and place it in off-line storage. The MCP's ability to report on experience spanning several years of data could be affected by the accessibility of the data stored off-line.

17. What percent of your Medicaid or CHIP data is processed on-line vs. batch? If batch, how often are batch jobs run?

18. Describe your policy regarding Medicaid or CHIP claim/encounter audits.

18a. Are Medicaid or CHIP encounters audited regularly or randomly?

□ Regularly
□ Randomly

18b. What are the standards regarding timeliness of processing?

Note (Q18b): Plans should be performing random periodic audits of their encounter data to determine the quality of data processing. Plans that do not perform audits at least annually are not closely monitoring the quality of data processing. Plan standards regarding timeliness of processing will influence the lag time for encounter data processing.

19. Please describe system edits that are targeted to field content and consistency. Are diagnostic and procedure codes edited for validity?

Note (Q19): MCPs should have an established, standard set of edits that verify field content and consistency. For example, a field content data edit would verify that a valid date is entered into the date of service field. Key fields which should be edited include patient identifying information (Medicaid ID, name, date of birth, sex), provider identifying information (name, tax ID, type), date and place of service, and diagnosis and procedure codes. The quality of diagnosis and procedure coding will affect the validity of reports and performance measures submitted by the MCP/PIHP.

20. Please complete the following table for Medicaid and CHIP claims and encounter data and other Medicaid and CHIP administrative data. Attach any documentation that should be reviewed to explain the data that is being submitted.

Item	Claims	Encounters	Other administrative data
Percent of total service volume			
Percent complete			
How are the above statistics quantified?			
Incentives for data submission			

Note (Q20): MCPs with claims data comprising more than 50 percent of their total service volume are likely to have a more complete representation of total MCP experience than MCPs that rely heavily on encounter data. While providers have an incentive to submit claims in order to receive payment for services, they do not always have incentives to submit encounter information. If an MCP does not offer providers an incentive, or does not require the submission of encounter data, the MCP may not receive data for every encounter. Other administrative data collected by an MCP could include data from pharmacy or laboratory vendors.

21. Describe the Medicaid or CHIP claims/encounter suspend ("pend") process including timeliness of reconciling pended services. What percentage of claims are suspended or pended?

Note (Q21): Pended claims/encounters are those claims/encounters that have been suspended during processing because they failed data quality edits or violated provider payment parameters. Information on these claims and encounters will not be available for reporting until they have been reconciled and processed into the system.

22. Describe how Medicaid or CHIP claims are suspended/pended for medical review, for non-approval due to missing authorization code(s) or for other reasons. What triggers a processor to follow up on "pended" claims? How frequent are these triggers?

Note (Q22): Review and processing should not be handled by the same employee. A system should be in place which encourages the processor to follow-up on the status of claims in review that have not yet been approved to ensure they are resolved.

23. Are any of your Medicaid or CHIP services/providers capitated?

    23a. If yes, have you conducted studies on the completeness of the information collected on capitated services?

    23b. If yes, what were the results?

Note (Q23b): Because provider payment for capitated services is not determined by the encounter data submitted, providers do not have an incentive to submit complete and accurate information on every service provided. Data on capitated services often does not include the same level of detail as fee-for-service claims information. Per service pricing information may not be available when providers are paid on a capitated basis but at least the amount of the capitation payment should be available. Plans should be aware that capitated data is less complete and should audit the data at least annually to monitor its quality.

24. In the following table, enter the claim/encounter system(s) for each product line offered to Medicaid or CHIP enrollees.

Note (Q24): Typically, there is just one product line offered to Medicaid or CHIP enrollees, but there may be some circumstances in which an MCP offers additional product lines to the state (e.g., partial risk products, premium assistance programs).

Medicaid			
Systems Used to Process _____	**Product Line:** _____	**Product Line:** _____	**Product Line:** _____
Fee-for-service (indemnity) claims			
Capitated service encounters			
Clinic patient registrations			
Pharmacy claims			
Other (describe)			

CHIP (if applicable)			
Systems Used to Process _____	**Product Line:** _____	**Product Line:** _____	**Product Line:** _____
Fee-for-service (indemnity) claims			
Capitated service encounters			
Clinic patient registrations			
Pharmacy claims			
Other (describe)			

25. Beginning with receipt of a Medicaid or CHIP claim in-house, describe the claim handling, logging, and processes that precede adjudication. Describe the following: When are claims assigned a document control number and logged or scanned into the system? When are claims stored using document imaging? If there is a delay in document imaging, how do processors access a claim that is logged into the system, but is not yet filmed?

    25a. Please describe each system or process that is involved in adjudicating:

- A professional encounter(s) for a capitated service (e.g., childhood immunizations that arrive separately from the office visit)

- A hospital claim for a delivery or for a newborn that exceeds its mother's stay

Note (Q25a): Professional encounters arriving separately from an office visit may not be processed as quickly as the actual office visits. If these encounters are treated as "non-standard" events, the plan may not be able to easily link these encounters with the related office visit. For example, newborns exceeding a mother's stay may have their hospital stay split into two parts. The part of the stay which coincides with the mother's hospitalization may be processed on the mother's claim and the remainder of the stay could be processed separately. Processing the newborn's stay as two separate claims could affect the plan's ability to report accurately on newborn hospital utilization.

25b. Discuss which decisions in processing a Medicaid or CHIP claim/encounter are automated, which are prompted by automated messages appearing on the screen, and which are manual. Document the opportunities a processor has for overriding the system manually. Is there a report documenting overrides or "exceptions" generated on each processor and reviewed by the claim supervisor? If so, please describe this report.

25c. Are any outside parties or contractors used to complete adjudication, including but not limited to:

- Bill auditors (hospital claims, claims over a certain dollar amount)

  □ Yes
  □ No

- Peer or medical reviewers

  □ Yes
  □ No

- Sources for additional charge data (usual & customary)

  □ Yes
  □ No

- Bill "re-pricing" for carved out benefits (mental health, substance abuse)

  □ Yes
  □ No

- Other

  □ Yes (If yes, please provide additional information)
  □ No

25d. How are these data incorporated into your organization's data?

Note (Q25d): If outside parties are used, the plan should be incorporating data generated by those parties into the system. The data should first be run through the plan's data quality checks to verify its accuracy and completeness.

25e. Describe the system's editing capabilities that assure that Medicaid and CHIP claims are correctly adjudicated

- Attach a list of the specific edits that are performed on claims as they are adjudicated, and note (1) whether the edits are performed pre- or post-payment, and (2) which are manual functions and which are automated functions.

Note (Q25e): When reviewing plan adjudication edits, the state should concentrate on edits which affect the data fields that are used to generate plan performance measures and reports. Are outliers for length of stay and charges edited? Utilizing an automated editing process provides more consistent results that do not require processor judgment. Edits that are performed pre-payment can prevent invalid data from being incorporated into the system.

25f. Discuss the routine and non-routine (ad hoc or special) audits that are performed on claims/encounters to assure the quality and accuracy and timeliness of processing. In your response, note which audits are performed per processor, which rely on targeted samples, and which use random sampling techniques. What is the total percentage of claims on-hand that are audited through these QA processes? How frequently do these audits occur?

Note (Q25f): This item is not relevant in instances where the EQRO is performing encounter data validation. When reviewing edits that are used to determine processor accuracy, consider that these edits will not provide information on the quality of the initial provider data submission. The audit plan should include random sampling techniques to provide an overall picture of quality. Plans will often concentrate on auditing complicated or aberrant claims/encounters rather than using a random sample. The plan should have instituted a process for sharing audit results with the processor to facilitate quality improvement.

25g. Please describe how Medicaid and CHIP eligibility files are updated, how frequently and who has "change" authority. How and when does Medicaid and CHIP eligibility verification take place?

25h. How are encounters for capitated services handled by payment functions? What message appears to notify processors that they are handling a capitated service?

25i. Describe how your systems and procedures handle validation and payment of Medicaid claims when procedure codes are not provided.

Note (Q25i): Plans requiring valid procedure coding for all claims/encounters will have more detailed data available for reporting and analysis. However, these plans may allow processors to supply missing codes using a code book or override the system using an unspecified code. A number of plans use programs such as the GMIS AutoCoder product to fill in missing codes. When a plan supplies missing codes, the coding can be less accurate than codes supplied directly by the provider of service.

26. Describe all performance monitoring standards for Medicaid and CHIP claims/encounters processing. Provide the results of a recent performance monitoring activity.

26a. How is performance against targets figured into the official performance appraisal process? Into processor and supervisor compensation?

B. Enrollment System

1. Please describe any major changes/updates that have taken place in the last three years in your Medicaid or CHIP enrollment data system. Include the specific dates on which changes were implemented. For example:

- New enrollment system purchased and installed to replace old system
- New enrollment system purchased and installed to replace most of old system; is the old system still used?
- Major enhancements to old system; what kinds of enhancements, and what impact on your historical data?
- New product line members stored on old system

Note (Q1): Changes to a plan's enrollment system requiring data conversion and data integration can create data quality problems. Implementing a new enrollment system could lead to a loss of access to data on the old system, or the assignment of new member numbers for all enrollees. Data conversion and integration can also limit a plan's ability to track an enrollee's enrollment history. When a new product line is added to an existing system, a plan may need to make the new data fit the older process, therefore modifying the system to "handle" new information. Implementing such modifications can be difficult for a plan that has been using the same system for a number of years. The level of enrollment detail retained can be affected by such modifications.

2. In your opinion, have any of these changes influenced, even temporarily, the quality and/or completeness of the Medicaid or CHIP data that are collected? If so, how and when?

Note (Q2): Consider whether changes in data quality will affect the validity of the data submitted to the state.

3. How does your plan uniquely identify enrollees?

Note (Q3): Major changes to an MCP's enrollment system could involve the conversion of membership data to a new system. When MCPs convert members, they may change the enrollee's ID number, making it difficult to track the enrollee's enrollment pattern across time. Changes to the enrollment system could also lead to a loss of data for specific patients.

4. How do you handle enrollee disenrollment and re-enrollment in the Medicaid or CHIP product line? Does the member retain the same ID?

Note (Q4): Enrollees should have a single ID number to facilitate tracking their experience. However, some plans change an enrollee's ID number when the enrollee re-enrolls. Experience for enrollees who have switched ID numbers will be more difficult to track. Dependents using an enrollee's ID are also difficult to identify for reporting purposes. For example, children without a unique ID could affect the ability of the plan to report on low birth-weight babies, childhood immunizations, and asthma inpatient admissions. This is an important point. EQROs should give higher "grades" to plans that use strong methods of identifying enrollees.

5. Can your systems track enrollees who switch from one product line (e.g., Medicaid, commercial plan, Medicare) to another?

□ Yes
□ No

5a. Can you track an enrollee's initial enrollment date with your MCP?

□ Yes (GO TO QUESTION 5C)
□ No

5b. If not, is a new enrollment date assigned when a member enrolls in a new product line?

□ Yes
□ No

5c. Can you track and link previous claim/encounter data across product lines?

□ Yes
□ No

6. Under what circumstances, if any, can a Medicaid or CHIP member exist under more than one identification number within your MCP's information management systems? Under what circumstances, if any, can a member's identification number change?

7. How does your MCP enroll and track newborns born to an existing Medicaid or CHIP enrollee?

7a. If your MCP has a Medicare product line, describe how your enrollment systems link individuals simultaneously enrolled in both your Medicare product line and the Medicaid plan product line.

8. Is claim/encounter data linked for Medicare/Medicaid dual eligibles so that all encounter data can be identified for the purposes of performance measure reporting?

□ Yes
□ No

8a. Is claim/encounter data linked for individuals enrolled in both a Medicare and Medicaid plan so that all encounter data can be identified for the purposes of performance measure reporting?

□ Yes
□ No

9. How often is Medicaid and CHIP enrollment information updated?

Note (Q9): Enrollment information should be updated real-time, daily, or weekly.

10. How is Medicaid and CHIP continuous enrollment being defined? In particular, does your system have any limitations that preclude you from fully implementing continuous enrollment requirements exactly as specified in the state performance measure requirements?

11. Please attach a copy of the source code that you use to calculate Medicaid/ CHIP continuous enrollment.

12. How do you handle breaks in Medicaid or CHIP enrollment, e.g., situations where a Medicaid enrollee is disenrolled one day and re-enrolled the next simply for administrative reasons? Does this affect your continuous enrollment calculations?

13. Do you have restrictions on when Medicaid or CHIP enrollees can enroll or disenroll? Please describe.

14. How do you identify and count the following:

Medicaid member months?

Medicaid member years?

15. Please list all data from which claims/encounters for the Medicaid or CHIP product line are verified.

Note (Q15): Eligibility of the patient should be verified before claims and encounters are processed. Dates of enrollment and disenrollment are key reporting fields for Medicaid HEDIS® measures. Eligibility status is dynamic for Medicaid beneficiaries and should be updated frequently. Eligibility status should also be verified before data is submitted to the state.

16. Does the plan offer vision or pharmacy benefits to its Medicaid or CHIP members that are different from the vision or pharmacy benefits offered to its commercial enrollees (within a given contract or market area)?

□ Yes
□ No (GO TO SECTION C, ANCILLARY SYSTEMS)

16a. If vision benefits vary by benefit package, outline the different options available. How are enrollees tracked?

16b. If pharmacy benefits vary by benefit package, outline the different options available. How are enrollees tracked?

C. Ancillary Systems

Use this section to record information on stand-alone systems or benefits provided through subcontracts, such as pharmacy or mental health/substance abuse.

1. Does your MCP incorporate data from one or more third-parties to calculate any of the following Medicaid and CHIP quality measures? If so, which measures require third-party data?

Note (Q1): The measures listed in the following table are examples of measures that can be calculated with administrative data and align with CMS quality measurement initiatives as of 2021. The state and EQRO should tailor this table to list the measures that the state requires its MCP contractors to produce and any other measures in which the state is interested.

Measure	Third-Party Data Source
Well-Child Visits in the First 30 Months of Life (W30-CH)	
Child and Adolescent Well-Care Visits (WCV-CH)	
Childhood Immunization Status (IMA-CH)	
Immunizations for Adolescents (IMA-CH)	
Developmental Screening in the First Three Years of Life (DEV-CH)	
Chlamydia Screening in Women Ages 16–20 (CHL-CH) and Ages 21 to 24 (CHL-AD)	
Breast Cancer Screening (BCS-AD)	
Cervical Cancer Screening (CCS-AD)	

Measure	Third-Party Data Source
Prenatal and Postpartum Care: Timeliness of Prenatal Care (PPC-CH) and Postpartum Care (PPC-AD)	
Screening for Depression and Follow-Up Plan: Ages 12 to 17 (CDF-CH) and Age 18 and Older (CDF-AD)	
Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication (ADD-CH)	
Follow-Up After Hospitalization for Mental Illness: Ages 6–20 (FUH-CH) and Age 18 and Older (FUH-AD)	
Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET-AD)	
Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD)	

2. Describe any concerns you may have about the quality or completeness of any third-party data.

Note (Q2): If a plan is using third-party data, the plan should have a formal process in place to validate that data before incorporating it into their information system. The plan needs to check the third-party data for reliability, completeness and timeliness of submission.

3. Please list subcontracted Medicaid or CHIP benefits that are adjudicated through a separate system that belongs to a third-party.

Note (Q3): Many plans contract out services for pharmacy benefits management, mental health/substance abuse, laboratory and radiology services. If the data are processed on the third-party's system, it may not be forwarded to the plan in a complete form or on a timely basis. Such entities may also use a different method of processing resulting in data that will not merge with or complement plan data.

4. Describe the kinds of information sources available to the MCP from the vendor (e.g., monthly hard copy reports, full claims data).

5. Do you evaluate the quality of this information?

□ Yes
□ No (GO TO QUESTION 6a)

5a. If yes, how?

Note (Q5a): All of the third-party information should be verified for accuracy before a plan loads it into their information system. The plan and the third-party data source may not define variables consistently or use the same reporting format.

6. Did you incorporate these vendor data into the creation of Medicaid or CHIP-related studies?

□ Yes (GO TO SECTION D)

□ No

6a. If no, why?

D. Additional Data Sources that Support Quality Reporting

This section requests any data sources beyond third party collection of claim/encounter data that support quality reporting.

1. Does the MCP use any other data sources beyond claim/encounter data (such as, beneficiary provided data, HIE, registry data source, vital statistics, etc.)?

□ Yes
□ No

If yes, please list additional data sources: _____

If yes, please describe how the MCP verifies the accuracy of the data and data exchange process for each data source listed above.

E. Integration and Control of Data for Performance Measure Reporting

This section requests information on how your MCP integrates Medicaid and CHIP claims, encounter, membership, provider, third-party, and other data to calculate performance rates. All questions relate to your current systems and processes, unless indicated otherwise.

1. Please attach a flowchart outlining the structure of your management information systems, indicating data integration (i.e., claims files, encounter files, etc.) at the most granular level you have it.

2. In consolidating data for Medicaid and CHIP performance measurement, how are the data sets for each measure collected:

   - By querying the processing system online?
   - By using extract files created for analytical purposes? If so, how frequently are the files updated? How do they account for claim and encounter submission and processing lags? How is the file creation process checked for accuracy?
   - By using a separate relational database or data warehouse (i.e., a performance measure repository)? If so, is this the same system from which all other reporting is produced?

3. Describe the procedure for consolidating Medicaid or CHIP claims/encounter, member, and provider data for performance measure reporting (whether it is into a relational database or file extracts on a measure-by-measure basis).

   3a. How many different sources of data are merged together to create reports?

   3b. What control processes are in place to ensure that data merges are accurate and complete?

   3c. What control processes are in place to ensure that no extraneous data are captured (e.g., lack of specificity in patient identifiers may lead to inclusion of non-eligible members or to double counting)?

4. Describe both the files accessed to create Medicaid or CHIP performance measures and the fields from those files used for linking or analysis. Use either a schematic or text to respond.

5. Are any algorithms used to check the reasonableness of data integrated to report Medicaid or CHIP performance measures?

6. Are Medicaid or CHIP reports created from a third-party software product?

   □ Yes
   □ No (GO TO QUESTION 7)

   6a. If yes, how frequently are the files updated? How are reports checked for accuracy?

7. Are the data files used to report Medicaid or CHIP performance measures archived and labeled with the performance period in question?

   □ Yes
   □ No

8. Information on several types of external encounter sources is requested. In the following table, please indicate the following for each type of delegated service:

   - Column 2. Indicate the number of third-parties contracted (or subcontracted) to provide the Medicaid or CHIP service. Count the entities that offer all or some of the portion of the service indicated.
   - Column 3. Indicate whether your MCP receives member-level data for any Medicaid or CHIP performance measure reporting from the vendor(s). Only answer "Yes" if all data received from contracted third-parties(s) are at the member level. If any encounter-related data is received in aggregate form, you should answer "No". If type of service is not a covered benefit, indicate "N/A".
   - Column 4. Indicate whether all data needed for Medicaid or CHIP performance measure reporting are integrated, at the member-level, with MCP administrative data.
   - Columns 5 and 6. Rank the completeness and quality of the Medicaid or CHIP data provided by the third party(s). Consider data received from all sources when using the following data quality grades:

     A. Data are complete or of high quality

     B. Data are generally complete or of good quality

     C. Data are incomplete or of poor quality

   - Column 7. Describe any concerns you have in ensuring completeness and quality of Medicaid or CHIP data received from contracted third-parties. If the measure is not being calculated because there are no eligible members, please indicate "N/A".

Medicaid or CHIP Claim/Encounter Data from Third Parties						
Type of delegated service	**Number of contracted third-parties**	**Always receive member-level data from all third party(s) (Y or N)**	**Integrate third-party data with MCP administrative data? (Y or N)**	**Data completeness (A, B, or C)**	**Data quality (A, B, or C)**	**Describe rating concerns with data collection**
Behavioral health						
Family planning						
Home health care						

Medicaid or CHIP Claim/Encounter Data from Third Parties						
Type of delegated service	**Number of contracted third-parties**	**Always receive member-level data from all third party(s) (Y or N)**	**Integrate third-party data with MCP administrative data? (Y or N)**	**Data completeness (A, B, or C)**	**Data quality (A, B, or C)**	**Describe rating concerns with data collection**
Hospital						
Laboratory						
Pharmacy						
Primary care						
Radiology						
Specialty care						
Vision care						
Dental for children						

9. Does your MCP use a performance measure repository?

□ Yes
□ No (GO TO QUESTION 10)

9a. If your MCP uses a performance measure repository for Medicaid or CHIP performance measures, review the repository structure. Does it contain all the key information necessary for Medicaid or CHIP performance measure reporting?

10. Please describe your Medicaid or CHIP report production logs and run controls.

10a. Please describe your Medicaid or CHIP performance measure report generation process.

11. How are Medicaid or CHIP report generation programs documented?

12. How does your MCP test the process used to create Medicaid and CHIP performance measure reports?

13. Are Medicaid and CHIP performance measure reporting programs reviewed by supervisory staff?

□ Yes
□ No

14. The purpose of these questions is to evaluate the Medicaid and CHIP provider compensation structure and reporting of certain types of compensation, as this may influence the quality and completeness of data. Please identify the percentage of member months in your plan contributed by Medicaid members whose primary care providers and specialists are compensated through each of the following payment mechanisms:

Payment mechanism	Primary care physician	Specialist physician
Salaried		
Fee-for-Service, no withhold or bonus		

Payment mechanism	Primary care physician	Specialist physician
Fee-for-Service, with withhold Please specify % withhold:_____		
Fee-for-Service with bonus Bonus range: _____		
Capitated - no withhold or bonus		
Capitated with withhold Please specify % withhold:_____		
Capitated with bonus Bonus range: _____		
Global/bundled payments		
Other: (Specify)_____		
TOTAL	100%	100%

Note (Q14): Timeliness and completeness of provider data submissions often varies by contracting arrangement. Salaried providers work directly for the MCP and will submit data on a timely basis if data submission is a parameter in their contract with the MCP. Fee-for-service providers have the largest incentive to submit accurate and complete data since their payment depends upon it. Capitated providers will need incentives to submit accurate and complete data. Their compensation should be linked to data submission, which can be done through the use of bonuses and withholds. For example, lag times may differ by compensation arrangement as follows: Capitation/Salaried-no lag, Fee-for-Service - 60 day lag, Hospital - 45 day lag.

15. How are bonuses and penalties captured within your system? Is this information part of your standardized reporting?

    15a. Is the underlying data that determines whether and the extent of bonuses and penalties captured in your system? Is this information part of your standard reporting?

    15b. For bundled/global payments, how does your system capture information about the individual services provided for this bundled/global payment? Is this information part of your standardized reporting?

    15c. Does your system capture clinical data for quality measurement purposes for providers who receive bundled/global payments? Is this information part of your standardized reporting?

16. Please describe how Medicaid or provider directories are updated, how frequently, and who has “change” authority.

    16a. Does your MCP maintain provider profiles on its website?

    □ Yes
    □ No (GO TO QUESTION 17)

    16b. If yes to “16a,” what provider information is maintained in on the website (e.g., languages spoken, special accessibility for individuals with special health care needs). Other? Please describe:

17. Does your MCP maintain provider profiles on its information system?

□ Yes
□ No (GO TO QUESTION 18)

Note (Q17): Provider directories should be updated to reflect changes in provider status to prevent members from selecting providers no longer under contract with the plan. The plan should have adequate security procedures in place to restrict the number of individuals who can access confidential provider information and institute changes in status.

17a. If yes to "17," what provider information is maintained in the provider profile database (e.g., languages spoken, special accessibility for individuals with special health care needs). Other? Please describe.

18. How are Medicaid or CHIP fee schedules and provider compensation rules maintained? Who has updating authority?

Note (Q18): Since providers consider fee schedule and compensation information to be confidential, access to this information should be restricted by the MCP. The MCP should have standardized process for updating and maintaining this information.

19. Are Medicaid or CHIP fee schedules and contractual payment terms automated? Is payment against the schedules automated for all types of participating providers?

Note (Q19): Manual payment processes are more prone to error and reduce processing speed.

END OF WORKSHEET A.1

Worksheet A.2. Information System Review Worksheet & Interview Guide

Instructions. EQROs can use this managed care plan (MCP) Information System Review Worksheet & Interview Guide (Worksheet A.2) to conduct interviews with MCP staff who completed the ISCA tool (Worksheet A.1), as well as other MCP staff as needed. Worksheet A.2 is organized in an open-ended format by section to correspond to the ICSA tool completed by the MCP.[92]

Before the site visit with the MCP, EQRO staff should:

- Review the ISCA Worksheet A.1 and attached documentation submitted by the MCP, including documentation referenced in the Summary of Requested Documentation Checklist submitted with the ISCA tool.
- Identify issues to address in follow-up interviews with MCP personnel and record the questions in this worksheet. Revise prompts in Sections 1 through 5 as needed.
- If the MCP's information system has been formally assessed within the past 2 years, please review the copy of the assessment report included with Worksheet A. Follow-up on only those sections of the assessment report that are not covered or that may have changed since the formal assessment was conducted.

During the site visit, EQRO staff should:

- Use the space in this Worksheet to record responses or document specific issues. It is not necessary to cover every question in the ISCA Worksheet A.1 submitted by the MCP if responses are clear.
- Revise this Worksheet, as needed, to provide additional space under each question to record issues and findings.

After the site visit, EQRO staff should:

- Analyze findings from the ISCA Worksheet A.1 and this Worksheet and prepare a statement of findings about the MCP's information system.

Contact Information

Please insert or verify the MCP contact information below, including the MCP name, MCP contact name and title, mailing address, telephone and fax numbers, E-mail address, and date of interview, if applicable.

MCP Name:	
Contact Name:	
Title:	
Mailing address:	
Phone number:	
E-mail address:	
Interview Date:	

[92] For the purposes of the Appendix A worksheets, the term MCP includes managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs), but does not include primary care case management (PCCM) entities, because 42 CFR 438.242, which is the basis for the requirement that states ensure maintenance of health information systems, is only applicable to MCOs, PIHPs and PAHPs.

Type of delivery system (check all that apply)	□ MCO □ PIHP □ PAHP □ LTSS □ Other: specify _____
Programs (please check)	□ Medicaid (Title XIX only) □ CHIP (Title XXI only) □ Medicaid and CHIP

Section 1. Background Information

List questions for discussion with the MCP Potential prompts: • Managed Care Model • Year MCP was incorporated • Member enrollment • Formal information system capability assessment • Recent information system enhancements
MCP responses to follow-up questions
Additional information provided by the MCP

Section 2. Information Systems: Data Processing Procedures & Personnel

List questions for discussion with the MCP Potential prompts: • System or repository for Medicaid claims and encounter data • Programming language(s) to create Medicaid data extracts or analytic reports • Programmer training, time, experience, turnover • Standard software development methodology • Version control software
MCP responses to follow-up questions
Additional information provided by the MCP

Section 3. Staffing

List questions for discussion with the MCP Potential prompts: • Staffing productivity • Processor training
MCP responses to follow-up questions
Additional information provided by the MCP

Section 4. Security

List questions for discussion with the MCP Potential prompts: • Disaster recovery plan • Disaster recovery system • Testing, backup systems, and storage • Computer system security • Cloud-based security • System access
MCP responses to follow-up questions
Additional information provided by the MCP

Section 5A. Data Acquisition Capabilities: Administrative Data

List questions for discussion with the MCP about administrative data (claims and encounters) Potential prompts: • Data submission methods • Claims or encounter submissions • Claims or encounter types • Diagnoses and procedures • Principal and secondary diagnoses • Missing, incomplete, or invalid claim/encounter submission fields • Claim/encounter accuracy verification • Systems changes/updates • Medicaid and CHIP data retention • Medicaid and CHIP claim/encounter audit policy • Pended claims/encounters process and reconciliation • Claim handling and processes that precede adjudication • Performance monitoring standards for Medicaid claims/encounters and results
MCP responses to follow-up questions
Additional information provided by the MCP

Section 5B. Data Acquisition Capabilities: Enrollment System

List questions for discussion with the MCP about the enrollment system Potential prompts: • Changes/updates to the Medicaid enrollment data system • Changes/updates effect on data quality/completeness • Continuity of enrollee ID numbers after data system changes • Continuity of enrollee ID numbers if disenrolled and reenrolled • Linkage of claim/encounter data for Medicare/Medicaid dual eligibles • If using a traditional PCCM, PCCM data follows T-MSIS coding guidance • Timeliness of Medicaid and CHIP enrollment updates • Medicaid continuous enrollment
MCP responses to follow-up questions
Additional information provided by the MCP

Section 5C. Data Acquisition Capabilities: Ancillary Systems

List questions for discussion with the MCP about ancillary systems Potential prompts: • Use of vendor data to calculate Medicaid and CHIP quality measures • Subcontracted Medicaid or CHIP benefits adjudicated through a vendor's system • Quality and accuracy of vendor data • Use of vendor data in Medicaid or CHIP-related studies • Use of unilateral or bi-directional data linkages to health information exchanges, registries, state vital statistics, public health data   ○ How the MCP verifies the data and data exchange process for these data sources
MCP responses to follow-up questions
Additional information provided by the MCP

Section 5D. Data Acquisition Capabilities: Integration and Control of Data for Performance Measure Reporting

List questions for discussion with the MCP integration and control of data for performance measure reporting Potential prompts: • MCP integration of Medicaid and CHIP claims, encounter, membership, provider, vendor, and other data to calculate performance rates • Consolidation of data sets for each Medicaid and CHIP measure collected • Process for consolidating claims/encounter, member, and provider data for Medicaid and CHIP • Performance measure reporting • Performance measure repository • Report generation • Bonuses and penalties • Bundled/global payments • Provider profiles/directories • Process for maintaining Medicaid fee schedules and provider compensation rules
MCP responses to follow-up questions
Additional information provided by the MCP

END OF WORKSHEET A.2

Appendix B. Sampling Approaches for EQR Data Collection Activities

Background

Sampling is used frequently in EQR-related activity processes for validation and analysis purposes, such as:

- Validating performance improvement projects (PIPs) (Protocol 1)
- Validating the performance measures included in managed care plans' (MCPs') quality assessment and performance improvement (QAPI) programs (Protocol 2)
- Validating the encounter data reported by the MCP (Protocol 5)
- Administering or validating quality of care surveys (Protocol 6)
- Calculating additional performance measures (Protocol 7)
- Implementing additional PIPs (Protocol 8)
- Conducting focus studies of health care quality (Protocol 9)

This appendix provides a brief overview of the types of sampling approaches and guidance for determining minimum sample sizes for EQR data collection activities. A statistician or other staff with expertise in sample design and implementation should advise the EQRO on the appropriate sampling strategy to be used for each activity.

Types of Sampling Approaches

Probability Sampling

Probability (or random) sampling methods leave selection of population units to chance and not to convenience or preference on the part of the individuals conducting the study or otherwise participating in the study. Probability sampling removes systematic bias due to observed and unobserved differences in the sampling units. There are several types of probability sampling methods:

- **Simple random sampling** is a method where all members of the study population are listed in the sampling frame (see Box B.1) and have an equal chance of being selected for the sample from the sampling frame. One way to select a simple random sample is to first assign all units in the sampling frame a unique identifier. Next, random numbers are generated for each unit using random number generators (available in statistical software or

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products). The random numbers then dictate the order in which units from the sampling frame appear. Units are selected for the sample taking the first n units in that random order, where n is the desired sample size. Simple random sampling ensures that all members of the target population have an equal chance of selection.

Box B.1. What is a Sampling Frame?

A sampling frame is the list from which the sample is drawn. It includes the universe of members of the target study population, such as individuals, households, providers, or other population units that are eligible to be included in the study. The completeness and accuracy of the sampling frame are key to the representativeness of the sample.

- **Systematic random sampling** is a method where units are systematically selected starting with a randomly selected first unit. Systematic sampling can be used when a sampling frame is organized or ordered in a way that does not bias the sample. Bias can occur if, for example, there is a cyclical or seasonal order to the data that happens to coincide with the sampling interval, in which case the sample will not fully represent the sampling frame. To select a systematic sample, first determine what the sampling interval (i) is by dividing the total units in the sampling frame (N) by the number of units in the sample (n). For example, if there are 250 units in the sampling frame and the desired sample size is 25, then the sampling interval (i) is 250/25 = 10. Use a random number generator to select a number (k) between 1 and i. Then select the kth, (k + i)th, (k + 2i)th, etc. units from the frame until the end of the sampling frame is reached and you have selected n units
- **Stratified random sampling** controls the proportion of the sample from subgroups of the target population called strata. This technique divides the population into specific strata or subgroups where the units are, ideally, homogeneous (the same or similar) within a stratum and heterogeneous (different) between strata with respect to certain characteristics (e.g., age, ethnicity, or diagnosis). Stratified sampling requires weighting the sample when a disproportionately larger number of units may be selected from one strata compared to others ("oversampling"). Stratification is done both to improve the representativeness of the total population's characteristics and to provide information about the characteristics of interest within subgroups. Stratification can be used to oversample certain subgroups or simply to ensure that the sample ends up with the same proportion as the population with respect to these subgroups. Once strata are identified and constructed, sampling must be conducted within each strata, independently, using probability sampling
- **One-stage cluster sampling** is used when a comprehensive sampling frame of all units is not readily available or would be too much of a burden to construct, or when data collection cannot occur across the entire population due to financial or operational constraints. Units in the population are gathered or classified into groups called clusters (these groups are similar to strata used for stratified random sampling). Unlike the stratified sampling method, the groups ideally should be heterogeneous with respect to the measured characteristic (but rarely are). And, unlike stratified sampling, once clusters are identified, a random sample of clusters is selected for data collection, with data then collected from *all* units in the selected clusters

- **Two-stage cluster sampling** is an adaptation of one-stage cluster sampling. As with one-stage cluster sampling, a sample of clusters is selected. However, unlike one-stage cluster sampling, within the clusters there is a second stage of sampling—units within the clusters are randomly selected so that some but not all units are selected for data collection. Two-stage cluster sampling is ideal for situations where you do not have or are unable to construct a frame of all the units in the population and you also cannot collect data from all clusters nor all units in the selected clusters due to financial, operational, or other constraints

Non-Probability Sampling

Non-probability sampling methods are used when subjects are scarce or hard to sample (no sampling frame) and/or the study relies on volunteers. The sample is based on the choice of those administering the survey rather than chance; therefore, some bias can be expected. The following are types of non-probability sampling:

- **Convenience sampling** includes sampled units that are readily available or convenient to sample. An example of a convenience sample for a focus study on patient experience with Medicaid providers could include all patients sitting in the waiting room in a primary care office on any given day. As another example, a focus study on health behaviors could involve approaching people at a shopping mall
- **Quota sampling** includes sampled units with known characteristics in the same proportion as in the population. For example, if a target population is 55 percent female and 45 percent male, the quota sample requires a similar female/male distribution. Quota sampling is considered a non-probabilistic version of a stratified sample, in which a population is segmented into mutually exclusive subgroups and judgment is used to select a sample based on a specified proportion

Though non-random sampling methods may be statistically analyzed, caution should be exercised when making inferences to the study population because the sample was not drawn randomly and therefore, may not be representative of the population. Considering the risk of biased results and the challenges to statistical interpretation, non-probability sampling is discouraged. However, at times, it can be an appropriate and efficient way of collecting needed information.

Calculating Minimum Sample Sizes for EQR Data Collection Activities

Many EQR-related activities may involve sampling for data collection, such as validating the completeness and accuracy of encounter data, assessing the reliability and validity of performance measures calculated using the hybrid method, and implementing a survey. Statistical power is a function of the sample size, the statistical significance criterion, and the magnitude of the effect in the population.

Table B.1 provides guidance for determining minimum sample sizes for EQR data collection activities. The minimum sample sizes vary based on the magnitude of the proportion (or percentage) of the effect of interest. EQROs may base the proportion on the current year's administrative rate or the prior year's reported rate (column 1). When the rate is unknown, researchers typically base the sample size on a proportion of 0.50. Researchers also typically use a statistical significance criterion of $p < 0.05$, As shown in Table B.1, the minimum sample size for a rate of 0.05 or 0.95 (5 percent and 95 percent) is 100, while the minimum sample size for a rate of 0.50 (50 percent) is 411 (column 2). The 95 percent confidence interval (and corresponding lower and upper bounds) indicates the range in which the true value is estimated to lie.

Table B.1. Guidance for Minimum Sample Sizes for EQR Data Collection Activities

Proportion	Minimum sample size for EQR data collection activities	95 percent confidence interval (lower and upper bound)
0.05	100	0.043 (0.007-0.093)
0.10	159	0.047 (0.053-0.147)
0.15	219	0.047 (0.103-0.197)
0.20	270	0.048 (0.152-0.248)
0.25	313	0.048 (0.202-0.298)
0.30	348	0.048 (0.252-0.348)
0.35	380	0.048 (0.302-0.398)
0.40	398	0.048 (0.352-0.448)
0.45	409	0.048 (0.402-0.498)
0.50	411	0.048 (0.452-0.548)
0.55	409	0.048 (0.502-0.598)
0.60	398	0.048 (0.552-0.648)
0.65	380	0.048 (0.602-0.698)

Proportion	Minimum sample size for EQR data collection activities	95 percent confidence interval (lower and upper bound)
0.70	348	0.048 (0.652-0.748)
0.75	313	0.048 (0.702-0.798)
0.80	270	0.048 (0.752-0.848)
0.85	219	0.047 (0.803-0.897)
0.90	159	0.047 (0.853-0.947)
0.95	100	0.043 (0.907-0.993)

Documenting Sampling Methods for EQR Data Collection Activities

In general, the following information should be documented about sampling approaches used for EQR data collection activities:

- Definition of the population included in the data collection activity (such as denominator for performance measure, target population for PIP or focus study, time frame for measurement)
- Sampling approach (such as simple random sampling, systematic random sampling, stratified random sampling, one-stage cluster sampling, two-stage cluster sampling, convenience sampling, quota sampling)
- Sampling frame (such as enrollment file, claims extract, patient roster)
- Sample exclusions (if any)
- Sample size (including method used to determine minimum sample size)
- Potential biases and selection issues that may affect representativeness of the sample and generalizability of the results

END OF APPENDIX B

Appendix C. Acronyms Used In the Protocols

AAFP	American Academy of Family Physicians
AHRQ	Agency for Healthcare Research and Quality
CAHPS®	Consumer Assessment of Healthcare Providers and Systems
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act of 2009
CMS	Centers for Medicare & Medicaid Services
CPT®	Current Procedural Terminology
DBMS	Database Management System
DOB	Date of Birth
DR	Disaster Recovery
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders
EHR	Electronic Health Record
EQR	External Quality Review
EQRO	External Quality Review Organization
EVV	Electronic Visit Verification
FFP	Federal Financial Participation
FFS	Fee-For-Service
HCBS	Home and Community Based Services
HCPCS	Healthcare Common Procedure Coding System
HEDIS®	Healthcare Effectiveness Data and Information Set
HHS	U.S. Department of Health & Human Services
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HPV	Human Papillomavirus Vaccine
ICD-10	International Statistical Classification of Diseases and Related Health Problems
IS	Information System
ISCA	Information Systems Capability Assessment
LOINC	Logical Observation Identifier Names and Codes
LOS	Length of Stay
LTSS	Long-Term Services and Supports
MACBIS	CMS Medicaid and CHIP Business Information System
MCO	Managed Care Organization
MCP	Managed Care Plan

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MGMA	Medical Group Management Association
MHSIP	Mental Health Statistics Improvement Program
MLTSS	Managed Long-Term Services and Supports
MRR	Medical Record Review
MSIS	Medicaid Statistical Information System
NCPDP	National Council for Prescription Drug Programs
NCQA	National Committee for Quality Assurance
NQS	National Quality Strategy
PAHP	Prepaid Ambulatory Health Plan
PCCM-E	Primary Care Case Management Entity
PCMH-A	Patient Centered Medical Home Assessment
PCP	Primary Care Provider
PDSA	Plan Do Study Act
PHI	Protected Health Information
PIHP	Prepaid Inpatient Health Plan
PII	Personally Identifiable Information
PIP	Performance Improvement Project
QA	Quality Assurance
QAPI	Quality Assessment and Performance Improvement
QI	Quality Improvement
QS	Quality Strategy
T-MSIS	Transformed Medicaid Statistical Information System

END OF APPENDIX C

Appendix D. External Quality Review Glossary of Terms

Acceptable Error Rate	The maximum percentage of missing, surplus, or erroneous records that the state accepts.
Algorithm	A specific set of instructions for carrying out a procedure or solving a problem.
Bias	A systematic distortion in data collection, analysis, or reporting of research findings.
Binary Variable	A discrete variable with only two categories.
Categorical Variable	A non-numeric variable with a range of non-ordered, qualitative values (or categories). The values may be coded as numbers but should not be interpreted numerically.
Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)	Reauthorized the Children's Health Insurance Program (CHIP) under Title XXI of the Social Security Act. CHIPRA included provisions to strengthen the quality of care provided to children and improve health outcomes of children in Medicaid and CHIP. CHIPRA requires the U.S. Department of Health & Human Services (HHS) to identify and publish a core measure set of children's health care quality measures for voluntary use by state Medicaid and CHIP programs (CMS Core Set of Children's Health Care Quality Measures for Medicaid and the Children's Health Insurance Program (CHIP) (the Child Core Set) and the Core Set of Health Care Quality Measures for Adults Enrolled in Medicaid (the Adult Core Set). The Child Core Set includes a range of children's quality measures encompassing both physical and mental health. The initial Child Core Set was released in 2010, updated in 2013, and is updated annually thereafter.
Claims Data	See "Encounter Data."
Compliance Review	A process to determine the extent to which Medicaid and CHIP managed care plans (MCPs) are complying with the Medicaid standards set forth at 42 CFR 438, subpart D and 42 CFR 438.330, which are adopted by CHIP at 42 CFR 457.

Confidence Level	The likelihood, expressed as a percentage, that percentage that a sample finding is true for the population from which the sample was taken. For example, a 95 percent confidence interval indicates a 5 percent chance that the sample result is due to chance and is not true for the population.
Consumer Assessment of Healthcare Providers and Systems (CAHPS®)	A series of consumer and patient surveys rating health care experiences in the U.S. All surveys officially designated as CAHPS® surveys have been approved by the CAHPS® Consortium, which is overseen by the Agency for Healthcare Research and Quality (AHRQ). CAHPS® surveys are an integral part of CMS' efforts to improve health care in the U.S. CAHPS® surveys follow scientific principles in survey design and development, are designed to reliably assess the experiences of a large sample of patients, and use standardized questions and data collection protocols to ensure that information can be compared across health care settings.
Continuous Variable	A numeric variable with a range of numerical values. Data collected for a continuous variable may be recoded as a discrete variable.
Correlation Coefficient	A statistical measure of the interdependence of two random variables, the value of which indicates how much a change in one variable is related to a change in the other variable. Correlation coefficients range in value from -1 to +1. A perfect positive correlation is +1 and a perfect negative correlation is -1. Zero indicates the absence of a relationship between the variables.
CPT®	A coding system, defined in the American Medical Association publication "Current Procedural Terminology", for medical procedures that are used for billing and quality measures.
Database Management System (DBMS)	System software for creating, managing, and maintaining databases.
Definition of Network Adequacy Indicator	A clear description of the network adequacy indicator, including criteria for calculating the numerator and denominator. The definition should address specific methodological issues that impact indicator calculations. For example, for time and distance indicators, the definition should specify whether distance is measured "as the crow flies" or using driving distances. The definition should also identify the provider types to which the indicator applies.

Denominator	The bottom part of the fraction that represents the total number of parts created from the whole. For the purposes of the EQR protocols, the denominator provides the general specifications of any clinical component that is the basis for inclusions and exclusions in the population to be considered in a measure.
Discrete Variable	A numeric variable with a limited number of possible categories. A binary variable is a type of discrete variable with only two categories.
Edit Checks	A program instruction that tests the quality and validity of data entered.
Encounter Data	The managed care equivalent of fee-for-service (FFS) claims. Encounter data is the information related to the receipt of any item or service by a beneficiary enrolled in a managed care plan (MCP). They reflect that a provider rendered a specified service under a managed care delivery system, regardless of if or how the MCP ultimately reimbursed the provider. Encounter data include substantially the same information included on claim forms (e.g., UB-04 or CMS 1500), although not necessarily in the same format. Providers submit claims or encounters to MCPs for service(s) rendered that would traditionally be submitted as claims in a FFS system.
Enrollee	An eligible individual who is covered by a managed healthcare plan. A beneficiary is an eligible individual who receives health care insurance through the Medicare or Medicaid programs.
EQR-Related Activities	The activities addressed in these protocols. EQR-related activities may be conducted by the state, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described at 42 CFR 438.310(c)(2)), or an EQRO. See 42 CFR 438.358.
Erroneous Encounters	Encounters that occurred and are represented by an encounter record that contains incorrect data elements.
External Quality Review (EQR)	The analysis and evaluation by an external quality review organization (EQRO), of aggregated information on quality, timeliness, and access to the health services that an MCO, PIHP, PAHP, or PCCM entity (described at 42 CFR 438.310(c)(2)), or their contractors furnish to Medicaid beneficiaries.
External Quality Review Organization (EQRO)	An organization that meets the competence and independence requirements set forth at 42 CFR 438.354, and performs external quality review or other EQR-related activities as set forth in 42 CFR 438.358, or both.
Fee-for-Service	A payment mechanism in which payment is made for each service used.
Focus Study	A study of a particular aspect of clinical care or nonclinical services provided by a managed care plan (MCP) at a point in time. See 42 CFR 438.358(c)(5).

Generalizability	The extension of findings and conclusions from a study sample to the population from which the sample was drawn.
Healthcare Common Procedural Terminology (HCPCS)	A standardized coding system for describing the specific items and services provided in the delivery of health care. HCPCS contains levels of codes, including the American Medical Association's CPT® and alphanumeric codes for non-physician services, items, and supplies not contained in CPT®.
Healthcare Effectiveness Data and Information Set (HEDIS®)	A collection of standardized performance measures and their definitions designed to ensure that purchasers and consumers can reliably compare the performance of managed health care plans. The performance measures are related to public health issues such as cancer, heart disease, and asthma and also include well-child visits. HEDIS® is sponsored, supported, and maintained by the National Committee for Quality Assurance (NCQA).
Health Information Technology (HIT)	Used by health care providers to manage patient care and health through using and sharing health information in a secure system. EHR, meaningful use, and mobile health laws and regulations all fall under the umbrellas of HIT.
Hybrid Data	Administrative data supplemented by medical record review.
Improvement Strategy	An intervention designed to change behavior at the member, provider, and/or managed care plan (MCP)/system level.
Indicator	An observable and measurable characteristic that can be used to show changes or progress over time toward achieving a specific outcome.
Information System Capabilities Assessment (ISCA)	Assessment of the desired capabilities of the MCP's information system which poses standard questions used to assess the strength of the system; this provides information to the EQRO about the extent to which the information system is capable of producing valid encounter data, performance measures, and other data necessary to support quality assessment and improvement, as well as managing the care delivered to its beneficiaries. Please refer to Appendix A. Information System Capabilities Assessment for more information.
Kappa statistic	A test statistic that measures interrater reliability for categorical data (e.g., sex, gender, race, etc.).
Locating	Locating is a technique used to improve response rates by locating and contacting sample members. This includes verified collection of data, such as first and last name, home address, email address, phone number(s), date of birth, language preference, etc.

Managed Care Plans (MCPs)	For the purposes of the EQR protocols, encompasses managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and the subset of primary care case management (PCCM) entities described in 42 CFR 438.310(c)(2).
Managed Care Quality Strategy	See "State Quality Strategy."
Margin of Error	A statistic expressing the amount of random sampling error in a survey's results. The larger the margin of error, the less faith one should have that the sample result is the true population value.
Measure	A standard used for valuing or determining the extent or quantity of something.
Missing Encounters	Encounters that occurred but are not represented by an encounter record.
Network Adequacy Indicators	Metrics used to measure adherence to network adequacy standards and to determine plan compliance with state network adequacy standards. For the example given above, the network adequacy indicator may be the proportion of enrollees who have access to a PCP within 30 miles or 30 minutes of their home.
Network Adequacy Standards	Quantitative parameters that states establish to set expectations for contracted managed care plans' provider networks. For example, a state may set a network adequacy standard that all enrollees have access to a primary care provider (PCP) within 30 miles or 30 minutes of their home.
Non-Probability Sampling	Methods that are used when subjects are scarce or hard to sample (no sampling frame) and/or the study relies on volunteers. The sample is based on the choice of those administering the survey rather than chance; therefore, some bias can be expected. Non-probability sampling includes convenience sampling and quota sampling. Please refer to Appendix B. Sampling Approaches for EQR Data Collection Activities for more information.
Numerator	The top part of the fraction that represents how many parts of that whole are being considered. For example, with large population of patients, the numerator would be the number of patients in a study meeting the specifications of a clinical component in a measure.
Pay for Performance	An umbrella term for initiatives aimed at improving the quality, efficiency, and overall value of health care. These arrangements provide financial incentives to hospitals, physicians, and other health care providers for improvements in quality of care and health outcomes for patients.

Pearson Correlation Coefficient (also, Pearson's)	The most common measure of correlation in statistics. It shows the linear relationship between two variables X and Y, with results between -1 and +1, where 1 is total positive linear correlation, 0 is no linear correlation, and -1 is negative linear correlation. The closer the value to zero, the greater the variation the data points are around the line of best fit.
Performance Improvement Project (PIP)	A project that implements an intervention designed to achieve and sustain significant improvement in health outcomes over time.
Performance Measure	Used to monitor performance at a point in time, track performance over time, compare performance, and inform decisions. For the purposes of the EQR protocols, it refers to monitoring the performance of individual managed care plans (MCPs) at a point in time, to track MCP performance over time, to compare performance among MCPs, and to inform the selection and evaluation of quality improvement activities.
Plan Do Study Act (PDSA)	A continuous cycle of measuring and analyzing performance. For the purposes of the EQR protocols, PDSA cycles refer to testing changes on a small scale and applying rapid-cycle learning principles to adjust intervention strategies over the course of time (such as in PIPs).
Prepaid Ambulatory Health Plan (PAHP)	An entity that provides services to enrollees under contract with the state and on the basis of capitation payments or other payment arrangement's that do not use state plan payment rates; does not provide or arrange for and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and does not have a comprehensive risk contract.
Prepaid Inpatient Health Plan (PIHP)	A prepaid health plan that provides services to enrollees under contract with the state and on the basis of capitation payments or other payment arrangements that do not use State plan payment rates; provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and does not have a comprehensive risk contract.
Primary Care Case Management (PCCM)	A system under which a primary care case manager contracts with the state to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid beneficiaries.
Primary Care Case Management (PCCM) Entity	The term PCCM entity in these EQR protocols only applies to those PCCM entities whose contracts with a state provide for shared savings, incentive payments, or other financial reward for the PCCM entity for improved quality outcomes, as described at 42 CFR 438.310(c)(2).

Probability (or random) Sampling	Refers to sampling methods that leave selection of population units to chance and not to convenience or preference on the part of the individuals conducting the study or otherwise participating in the study. Probability sampling removes systematic bias in the selected sample due to observed and unobserved differences in the sampling units. Types of probability sampling include simple random sampling, systematic random sampling, stratified random sampling, one-stage cluster sampling, and two-stage cluster sampling. Please refer to Appendix B. Sampling Approaches for EQR Data Collection Activities for more information.
Programmatic Significance	The practical effect or importance of an intervention implemented through a program or specified method.
Protected Health Information	A class of patient data that can be linked to a specific individual.
Quality	The degree to which an MCO, PIHP, PAHP, or PCCM entity (described at 42 CFR 438.310(c)(2)) increases the likelihood of desired health outcomes of its enrollees through structural and operational characteristics, the provision of services that are consistent with current professional, evidence-based knowledge, and interventions for performance improvement.
Quality Assurance Plan	A plan that includes processes to monitor, evaluate and review all aspects of the survey administration procedures. The purpose of a quality assurance plan is to document reviews and audits to ensure appropriate processes are correctly followed.
Registry Data	Clinical data that is recorded about the health status of patients and health care they receive over time. This data is maintained in a clinical data registry.
Reliability	Refers to (1) the internal consistency of a study instrument, and (2) that data are producing consistent results.
Sample	A subset selected from a population.
Sampling Frame	The list from which the sample is drawn. It includes the universe of members of the target study population, such as individuals, households, encounters, providers, or other population units that are eligible to be included in the study. The completeness, recency, and accuracy of the sampling frame are key to the representativeness of the sample.
Significant Improvement	A measurable, statistically significant change in performance related to an intervention.

State Quality Strategy	A strategy to assess and improve the quality of Medicaid managed care services within a state, per 42 CFR 438.340 and adopted by CHIP at 42 CFR 457.1240(e).
Statistical Significance	A measure of whether research findings are meaningful. More specifically, whether results match closely to what one would expect to find in an entire population. The test for statistical significance requires (1) deciding an alpha level, meaning, the error rate (typically 5 percent or less), (2) collecting data, (3) calculating the test statistic, and (4) comparing the calculated test statistic with a statistic from a statistical table.
Study Population	The population identified for the study. It may include the entire population or a sample of the population depending on the nature of the study question and available data.
Study Question	Identifies the focus of the study and sets the framework for data collection and analysis. The study question should be clear, concise, and answerable.
Study Variable	A measurable characteristic, quality, trait, or attribute of a particular individual, object, or situation being studied.
Sustained Improvement	Significant changes in processes or performance as demonstrated through repeated measurements over comparable time periods using the same methodology as in the baseline measurement.
Target Population	The group of individuals that are the intended recipient of a particular service or intervention.
Transformed Medicaid Statistical Information System (T-MSIS)	A critical data and systems component of the CMS Medicaid and CHIP Business Information System (MACBIS). CMS has been working with states to transform the MSIS system, which was used to (1) collect utilization and claims data as well as other key Medicaid and CHIP program information, (2) keep pace with the data needed to improve beneficiary quality of care, (3) assess beneficiary care and enrollment, (4) improve program integrity, and (5) support states, the private market, and stakeholders with key information. The T-MSIS data set contains (1) enhanced information about beneficiary eligibility, (2) beneficiary and provider enrollment, (3) service utilization, (4) claims and managed care data, and (5) expenditure data for Medicaid and CHIP.
T-test	Most commonly used with small sample sizes, this test asks whether a difference between two samples/groups' averages is unlikely to have occurred because of random chance in sample selection. A difference is more likely to be meaningful or if (1) the difference between the averages is large, (2) the sample size is large, and (3) the standard deviation is low.
Unit of Analysis	The entity ("what" or "whom") that is being studied.

Validation	The review of information, data, and procedures to determine the extent to which it is accurate, reliable, free from bias, and meets standards for data collection.
Validity	The degree to which a tool measures what it is intended to measure.
Verification	The internal review of documentation, data, measures, and assessments to determine if measurements are accurate.
Vital Records	Records of life events kept under government authority. These include life events such as birth certificates, marriage licenses, and death certificates.

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