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VALIDATING PERFORMANCE MEASURES

A protocol for use in Conducting Medicaid External Quality Review Activities

Department of Health and Human Services
Centers for Medicare & Medicaid Services

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VALIDATING PERFORMANCE MEASURES

I. PURPOSE OF THE PROTOCOL

This protocol specifies activities to be undertaken by an external quality review organization (EQRO)[1] in order to validly:

1. Evaluate the accuracy of Medicaid performance measures reported by, or on behalf of, a Managed Care Organization (MCO) or a Prepaid Inpatient Health Plan (PIHP), and

2. Determine the extent to which Medicaid-specific performance measures calculated by an MCO/PIHP (or by entity acting on behalf of an MCO or PIHP) followed specifications established by the State Medicaid agency (the State) for the calculation of the performance measure(s).

II. ORIGIN OF THE PROTOCOL

This protocol was derived from protocols and tools commonly used in the public and private sectors for auditing performance measures. These include:

- The National Committee for Quality Assurance's (NCQA) 1999 tools used by the Health Plan Employer Data and Information Set (HEDIS)® publication: *Volume 5, HEDIS Compliance Audit™ Standards and Guidelines*,
- Tools use by the Island Peer Review Organization (IPRO) in their audits of HEDIS measures for Medicare, and
- Documents from the MEDSTAT Group, Inc., published in conjunction with work performed in 1997 and 1998 for the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration (HCFA).

A review of the tools found that, while there are differences, these documents had much in common.

[1] It is recognized that a State Medicaid agency may choose an organization other than an EQRO as defined in Federal regulation to validate Medicaid performance measures submitted by or on behalf of an MCO/prepaid inpatient health plan (PIHP). However, for convenience, in this protocol we use the term, "external quality review organization" (EQRO) to refer to any organization that validates performance measures.

Both NCQA's and IPRO's documents address the validation of HEDIS measures only. They assess:

- The structure and integrity of the MCO's/PIHP's underlying information system (IS),
- MCO/PIHP ability to collect valid data from various internal and external sources,
- Vendor (or subcontractor) data and processes, and the relationship of these data sources to those of the MCO/PIHP,
- MCO/PIHP ability to integrate different types of information from disparate data sources into a data repository or set of consolidated files for use in constructing MCO/PIHP performance measures, and
- Documentation of the MCO's/PIHP's processes to: collect appropriate and accurate data, manipulate those data through programmed computer queries, internally validate the results of the operations performed on the data sets, follow specified procedures for calculating the specified performance measures, and report the measures appropriately.

The MEDSTAT publications focus primarily on validation of encounter-level data, and the use of those data in Medicaid MCO performance measures, regardless of whether the performance measures are based on the NCQA Medicaid HEDIS measures or have been developed by other groups or organizations. However, the MEDSTAT publications do not provide detailed instructions or guidelines that an EQRO might use to validate the MCO/PIHP performance measures once the encounter data are validated.

The protocol presented here is consistent with the approaches used in the IPRO and NCQA documents, but is designed with a MEDSTAT-like approach in that it describes how to validate all performance measures - HEDIS measures as well as non-HEDIS measures. It varies from the IPRO and NCQA protocols in that certain components of performance measure validation may be performed as a part of this protocol or accomplished through some other mechanism(s) used by the State. For example, as part of this protocol, an assessment of the MCO's/PIHP's IS is required. This IS assessment may be conducted as a part of this protocol by the EQRO validating the performance measures, or the EQRO may review an assessment of the MCOэs /PIHPэs IS conducted by another party.

III. OVERVIEW OF THE PROTOCOL

The protocol assumes that the State has specified:

- Performance measures to be calculated by MCOs/PIHPs,
- Specifications to be followed in calculating these measures, and
- The manner and mechanisms for reporting these measures to the State.

Protocol activities address:

1. Review of the data management processes of the MCO/PIHP,

2. Evaluation of algorithmic compliance (the translation of captured data into actual statistics) with specifications defined by the State, and

3. Verification of either the entire set or a sample of the State-specified performance measures to confirm that the reported results are based on accurate source information.

The protocol consists of three phases of activities: Pre-Onsite, Onsite, and Post-Onsite activities. For each of these phases, the protocol specifies outcomes or objectives and lists the activities to be performed. Methods of evaluation are suggested and tools and worksheets are provided throughout the protocol and as attachments to the protocol.

Pre-Onsite activities involve:

1. Communicating with the State to ensure that the EQRO understands:

    - The measures to be validated (i.e., the entire set versus a subset of those calculated by the MCO/PIHP)

    - The methodology(ies) the State requires the MCO/PIHP to follow when calculating and reporting the performance measures

2. Preparing MCOs/PIHPs for onsite activities

3. Either conducting an assessment, or reviewing the results of a prior assessment, of the MCO's/PIHP's underlying IS

Onsite activities focus on: 1) following up on IS findings identified in the Pre-Onsite activities as being potentially problematic or in need of further review or clarification; and 2) validating the production and reporting of performance measures through observation of documentation or procedures. These activities include:

1. Reviewing and assessing the procedures the MCO/PIHP has in place for collecting and integrating medical, financial, member and provider information, covering both clinical and service-related data, from internal and external sources,

2. Evaluating processes used by the MCO/PIHP to produce performance measures(e.g., sampling, calculating denominators and numerators), and

3. Evaluating the MCO's/PIHP's processes for reporting required performance measures to the State.

To accomplish these activities, the EQRO reviews policy and procedure manuals and documents, observes required activities, and conducts interviews with key MCO/PIHP staff such as the Director of Health/Medical Information Systems, IS programmers or operators, Director of Member/Patient Services, Director of Utilization Management, and the Director of Quality Improvement.

Post-Onsite activities focus on the analysis of the data and information obtained through Pre-Onsite and Onsite activities, and submission of the validation report and supporting documentation to the State following the format and time frames established by the State. These activities include:

1. Evaluating gathered information and preparing a report of preliminary findings,

2. Submitting reports of preliminary findings identifying areas of concern to the MCO/PIHP,

3. If the State provides the MCO/PIHP with the opportunity to recalculate performance measures based on EQRO findings, re-reviewing selected performance measurement processes,

4. Evaluating gathered information and preparation of findings for the State, and

5. Submitting reports to the State.

The protocol identifies alternative approaches to determining the extent to which the MCO/PIHP has complied with requirements for calculating and reporting performance measures. In one option, the EQRO would submit a summary of its findings along with the completed protocol assessment tools to the State as supporting documentation, but without a validation designation for individual performance measures. Based on the information submitted by the EQRO, the State would make a determination of the extent to which the MCO/PIHP has adequately calculated and reported the specified performance measures. Alternatively, the EQRO could apply clearly defined decision rules established by the State and specify a validation finding for each performance measure.

IV. PROTOCOL ACTIVITIES

PRE-ONSITE ACTIVITIES

Objectives for Pre-Onsite Activities:

The EQRO will:

- Understand the technical specifications for each of the performance measures required by the State
- Understand the State's requirements for performance measure reporting by the MCO/PIHP to the State (e.g., report template, electronic submission format, etc.)
- Conduct and review an assessment (or review the results of a previously conducted assessment) of the MCO's/PIHP's IS.

PRE-ONSITE ACTIVITY 1: Review the State's requirements for MCO/PIHP performance measurement and reporting.

The EQRO will need to obtain from the State a list of all performance measures that the State requires the MCO/PIHP to produce and ascertain, in consultation with the State, whether the validation activities are to include all such measures or a subset of those measures. The EQRO will also need to obtain the State's instructions (specifications) on how the MCO/PIHP is to calculate each performance measure.

The specific performance measures that a State requires its Medicaid MCOs/PIHPs to report will depend on a number of factors unique to each State. If a State chooses to use a set or subset of established standardized plan-level performance measures, there are a number of options from which to choose. These include the NCQA's HEDIS measures, measures identified by the Foundation for Accountability (FACCT), measures found in the Agency for Healthcare Research and Quality's (AHRQ's) CONQUEST database, or measures suggested by MEDSTAT in its publication, *A Guide for States to Assist in the Collection and Analysis of Medicaid Managed Care Data*[2]. In addition, States with the resources and expertise to develop and test the detailed specifications necessary for valid and reliable performance measures may establish their own performance measures. Regardless of the type or number of performance measures chosen by the State, the EQRO must understand the State's specifications (e.g., sampling guidelines and instructions for calculating numerators and denominators) for each performance measure, as well as the State's instructions to the MCO/PIHP for reporting the required performance measures to the State.

[2]Prepared under CMS Contract #500-92-0035. December 1998.

Four basic data collection methodologies typically are used to produce MCO/PIHP performance measures: 1) use of administrative data, 2) review of medical records, 3) use of administrative data together with medical record review (commonly called the "hybrid" methodology), and 4) use of surveys.

Use of administrative data requires the MCO/PIHP to access data contained in its management information system(s) to calculate both the denominator and numerator of a given performance measure. Such data includes encounter or claims data (transaction data) as well as other automated enrollee and provider information. The rate that is reported is based on information found solely in these administrative data sources.

Calculating performance measures from medical record review requires the visual inspection of the medical records of a sample of MCO/PIHP enrollees (denominator) to determine if each enrollee received the service(s) in question (typically, this is the numerator of the performance measure). Because medical record reviews are time-consuming and costly, most developers and users of performance measures are attempting to use, to the extent feasible, performance measures that can be calculated from administrative data. If medical record review is unavoidable, the less costly and less burdensome "hybrid" methodology can be used.

The hybrid methodology combines the use of administrative data with a review of medical records. The denominator of the measure is first identified using administrative data for a sample of eligible members. The numerator is then determined using data from both administrative and medical record reviews. Typically, the MCO/PIHP will first query its administrative data for evidence of the numerator event for all individuals included in the denominator sample. For any member of the sample who is missing an administrative notation that the numerator service was received, the medical record is reviewed.

Finally, surveys also are used to produce MCO/PIHP performance measures. Surveys may include information collected directly from enrollees, relatives, primary caregivers of enrollees, or providers of healthcare services. Administration and validation of surveys are complex subjects and are discussed in separate EQR protocols.

States may require or allow MCOs/PIHPs to report performance measures to the State in different ways. A State may choose to have MCO/PIHP performance measures reported to it in an electronic format (such as a comma-delimited ASCII file) or it may establish a set of electronic reporting "shells" that MCOs/PIHPs fill out and send to the State, with attestations of the accuracy of the information. States could also allow hardcopy submission of calculated performance measures.

States will also determine the timing of the submission of the calculated performance measures. Typically, States require performance measures to be calculated and submitted annually. The annual submissions may be timed to coincide with the end of the State fiscal year, the calendar year, or another reporting cycle, such as that used by NCQA for HEDIS submissions. The

EQRO needs to understand the expected dates and format for MCO/PIHP reporting.

To facilitate its onsite validation of measures, the EQRO should create a AList of Performance Measures to be Calculated by the MCO/PIHPs (such as that shown in TABLE 1) in order to understand the measures required by the State, the possible methods the MCO/PIHP may use to collect them, and the reporting frequencies and format mandated by the State.

TABLE 1

List of Performance Measures to be Calculated by the MCO/PIHP (EXAMPLE)

SAMPLE MEASURES	METHOD FOR CALCULATING PERFORMANCE MEASURE				
	Administrative Data	**Medical Record Review**	**Hybrid**	**Survey**	**Reporting Frequency and Format**
The table should have a row for each measure to be calculated and reported by the MCO/PIHP, as illustrated below:					
Childhood immunization rate					
Adolescent immunization rate					
Percentage of enrollees with at least one PCP visit					
Lead screening rate					
Breast cancer screening rate					
Initiation of prenatal care					
Comprehensive diabetes care					
Availability of language interpretation services					
Follow-up after hospitalization for mental illnesses					

TABLE 1

List of Performance Measures to be Calculated by the MCO/PIHP (EXAMPLE)

Women's chlamydia screening rate					
Rate of adverse asthma events					

For each measure in the EQRO-created "List of Performance Measures to be Calculated by the MCO/PIHP," the EQRO also should create a separate performance measure validation worksheet that contains the specifications and components of each performance measure that is to be validated, including: 1) specifications for the eligible population for the measure, 2) data collection methodology, 3) sampling methodology (if used), 4) denominator calculations, 5) numerator calculations, and 6) calculated and reported rates. A generic "Performance Measure Validation Worksheet" is found below (see TABLE 2), containing placeholders for the components to be validated and the elements to be audited. The EQRO should customize this or a similar worksheet to include the specifications (defined by the State) for each performance measure to be reported by the MCO/PIHP. For example, if the measure is Breast Cancer Screening (following the HEDIS specifications), the EQRO would replace the general "age and sex" categories in the denominator portion of the tool with the particular age and sex specifications associated with that measure (i.e., females between the ages of 52-69). Using a performance measure validation worksheet will improve the efficiency of the validation work performed on site. An example of a completed *Performance Measure Validation Worksheet* is included as ATTACHMENT I.

TABLE 2

GENERIC PERFORMANCE MEASURE VALIDATION WORKSHEET

For each performance measure to be validated (as listed in TABLE 1 of this Pre-Onsite Activity), adapt the generic table shell below to create a validation worksheet for the measure. [An example of a completed Performance Measure Validation Worksheet is included as ATTACHMENT I].

PERFORMANCE MEASURE { Insert name of performance measure}

Validation Component	**Audit Element**	**Meets Validation Requirements**		
		Yes	**No**	**N/A**
Documentation	Appropriate and complete measurement plans and programming specifications exist that include data sources, programming logic, and computer source code.			
Denominator	Data sources used to calculate the denominator (e.g., claims files, medical records, provider files, pharmacy records) were complete and accurate.			
	Calculation of the performance measure adhered to the specifications for all components of the denominator of the performance measure (e.g., member ID, age, sex, continuous enrollment calculation, clinical codes such as ICD-9, CPT-4, DSM-IV, member months calculation, member years calculation, and adherence to specified time parameters).			
Numerator	Data sources used to calculate the numerator (e.g., member ID, claims files, medical records, provider files, pharmacy records, including those for members who received the services outside the MCO/PIHP=s network) are complete and accurate.			
	Calculation of the performance measure adhered to the specifications for all components of the numerator of the performance measure (e.g., clinical codes such as ICD-9, CPT-4, DSM-IV, pharmacy data, relevant time parameters such as admission/discharge dates or treatment start and stop dates, adherence to specified time parameters, number or type of provider).			
	If medical record abstraction was used, documentation/tools were adequate.			
	If hybrid method was used, the integration of administrative and medical record data was adequate.			
	If hybrid method or solely medical record review was used, the results of the medical record review validation substantiate the reported numerator.			
Sampling	Sample was unbiased.			
	Sample treated all measures independently.			
	Sample size and replacement methodologies met specifications.			
Reporting	State specifications for reporting performance measures were followed.			

ASSIGNING A VALIDATION FINDING TO THE MEASURE*

The validation finding for each measure is determined by the magnitude of the errors detected for the audit elements, not by the number of audit elements determined to be "NOT MET." Consequently, it is possible that an error in a single audit element may result in a designation of "NV" because the impact of the error biased the reported performance measure by more than *"x"* percentage points. Conversely, it is also possible that several audit element errors may have little impact on the reported rate and, thus, the measure could be given a designation of "SC." The following is a list of validation findings and their corresponding definitions:

FC **=** ***Fully Compliant***
Measure was fully compliant with State specifications.

SC **=** ***Substantially Compliant***
Measure was substantially compliant with State specifications and had only minor deviations that did not significantly bias the reported rate.

NV **=** ***Not Valid***
Measure deviated from State specifications such that the reported rate was significantly biased. This designation is also assigned to measures for which no rate was reported, although reporting of the rate was required.

NA **=** ***Not Applicable***
Measure was not reported because MCO/PIHP did not have any Medicaid enrollees that qualified for the denominator.

AUDIT DESIGNATION	

*** Assigning a validation finding to a measure is discussed in Post-Onsite Activity 1. This material is included here because it should be part of a performance measure validation worksheet.**

PRE-ONSITE ACTIVITY 2: Prepare the MCO/PIHP for EQRO Onsite Activities.

Prior to conducting onsite activities, the EQRO will contact the MCO/PIHP in order to:

- Explain the procedures and time line for performance measure validation activities,
- Request identification of personnel within the MCO/PIHP who will be responsible for responding to EQRO requests for documentation or information, as well as scheduling activities and interviews, and
- Communicate the EQRO's policies and procedures with respect to safeguarding confidential information.

An introductory letter to the MCO/PIHP should discuss the above issues and explain the EQRO's potential need to interview MCO/PIHP personnel, so that interviewees are prepared in terms of time and information. Potential interviewees include any MCO/PIHP or vendor staff whose areas of expertise or responsibility relate to performance measurement and whose insights might improve the EQRO's understanding of MCO/PIHP processes to calculate or report performance measures. These include, for example: the Director of Health/Medical Information Systems, IS programmers or operators, Director of Member/Patient Services, Director of Utilization Management, and the Director of Quality Improvement.

Also, the EQRO will provide to, or request from, the MCO/PIHP four other types of information in preparation for its onsite activities:

1. A list and description of all State-required performance measures calculated by or on behalf of the MCO/PIHP,
2. A list of all enrollees (or enrollee identifiers) included in the numerators of performance measures calculated wholly or in part by medical record review,
3. A list of documents that the EQRO may potentially review during onsite activities, and
4. Background information on the MCO's/PIHP's IS.

1. List of performance measures calculated by the MCO/PIHP. This list of performance measures calculated by the MCO/PIHP (see TABLE 3) is similar to the list completed by the EQRO during Pre-Onsite Activity 1 (see TABLE 1). However, while the TABLE 1 list was prepared by the EQRO to familiarize itself with the State's requirements for performance measures, TABLE 3 is sent to the MCO/PIHP by the EQRO for the MCO/PIHP to complete. The MCO/PIHP is to insert into the table, next to each performance measure listed in the table, information on the methods the MCO/PIHP used to calculate the performance measures required by the State. This is especially important for those measures for which the MCO/PIHP has a choice of methods to use for their calculation (e.g., administrative, medical record review, or hybrid data collection methodologies). The EQRO should send to the MCO/PIHP the same list of measures contained in TABLE 1, but with a modified title and instructions (as illustrated in TABLE 3) to reflect that the MCO/PIHP is to complete the table and return it to the EQRO.

TABLE 3

List of Performance Measures Calculated by the MCO/PIHP - Example

Instructions to MCOs/PIHPs: *For each measure the State requires you to report (in column 1), indicate the method(s) your MCO/PIHP used to produce it by checking columns 2 - 5, as appropriate. In column 6 note the reporting frequencies (e.g., quarterly, annually) and format (e.g., paper report, electronic medium) your MCO/PIHP has used (or expects to use) to report to the State. Return this table to (name of EQRO) by (date), so that this information may be reviewed prior to our site visit to validate your MCO's/PIHP's performance measures.*

(1) Measure {Examples}	(2) Administrative	(3) Medical Record Review	(4) Hybrid	(5) Survey	(6) Reporting Frequency and Format
The table should contain a row for each measure to be calculated and reported by the MCO/PIHP.					
Childhood immunization rate					
Adolescent immunization rate					
Percent of enrollees with at least one PCP visit					
Lead screening rate					
Breast cancer screening rate					
Initiation of prenatal care					
Comprehensive diabetes care					
Language interpretation services - availability					
Follow-up after hospitalization for mental illnesses					
Women's chlamydia screening rate					
Rate of adverse asthma events					

2. A list of all enrollees (or enrollee identifiers) included in the numerators of all measures calculated in part or wholly from medical record review. For each of at least three performance measures which the MCO/PIHP calculated either entirely by medical record review or by the hybrid methodology, the EQRO will review, onsite, 30 medical records found to meet numerator requirements. The purpose of this review is to verify the accuracy of the medical record review conducted by each MCO/PIHP.

To provide sufficient time for each MCO/PIHP to gather the required medical record documentation, the MCO/PIHP will need to identify to the EQRO, prior to the EQRO's onsite visits: 1) all performance measures calculated through medical record review or the hybrid methodology (obtained by completing TABLE 3), and 2) for measures which used medical record review or the hybrid methodology and selected by the EQRO, a list of enrollees included in the numerator for each measure as a result of positive findings through medical record review. From this list, the EQRO will select 30 members for each performance measure. The MCO/PIHP will then be asked to make available the medical records or copies of medical records for these enrollees at the time of the onsite visit. In cases where there are fewer than 30 numerator positives, the EQRO will review all records for that measure.

3. List of potential validation documents and processes. The *List of Potential Validation Documents and Processes* (ATTACHMENT II) identifies documents and information concerning the MCO's/PIHP's data sources and processes that the EQRO may review during the course of the validation activities. This list is intended to assist the MCO/PIHP in preparing for the validation audit.

4. Information Systems Capabilities Assessment Tool (ISCA). The EQRO will send an ISCA to the MCO/PIHP, to be completed and returned to the EQRO prior to the onsite visit. The ISCA consists of questions and requested documentation to provide the EQRO with background information on the MCO's/PIHP's policies, processes, and data needed for the onsite validation activities. The ISCA is discussed in detail, in Pre-Onsite Activity 3. A recently conducted ISCA by another party can be used.

PRE-ONSITE ACTIVITY 3: Assess the integrity of the MCO'S/PIHP's information system.

Complete and accurate data are keys to valid and reliable performance measurement. If these two data characteristics are not maintained, then calculated measures become biased, and their validity jeopardized. Therefore, prior to validating individual performance measures, the EQRO must first assess the integrity of the MCO's/PIHP's IS and the completeness and accuracy of the data produced by that system.

Methods of Evaluation

Prior to conducting the onsite visit, the EQRO should send to the MCO/PIHP an ISCA such as that located in Appendix Z. The ISCA asks questions of and requests documentation from the MCO/PIHP in order to provide information on the MCO's/PIHP's IS policies and procedures to help focus onsite validation activities. The ISCA found in Appendix Z corresponds to the key objectives identified in this protocol. The first section of the ISCA provides general background information on the MCO/PIHP. Subsequent sections address the structural components of the IS, focusing on the collection of administrative, encounter, and clinical data, and the consolidation or coordination of those data files for use in performance measurement and quality improvement activities.

The ISCA also requests information from the MCO/PIHP concerning the conduct and timing of any other recent, independent, documented assessment of its IS. An assessment may already have been conducted by the State itself or by another entity. IS assessment could have been performed as a component of validating encounter data or determining compliance with Medicaid standards pertaining to MCO/PIHP ISs. If the MCO/PIHP has not had an IS capability assessment completed, or has not had one completed within a time frame that meets State specifications[3], the EQRO will conduct an IS assessment as part of this protocol, using an information systems assessment tool, such as that in Appendix Z. Alternatively, if the MCO/PIHP recently had an independent assessment of its IS, the EQRO could review the results of this prior assessment.

[3] Each State will determine the frequency with which it wants an MCO's/PIHP's IS capability assessment to take place (thereby determining the length of time such an assessment is valid). On the one hand, the process is time- and resource-intensive, so limiting the burden on the MCO/PIHP should be a factor in the determination. On the other hand, IS technology changes rapidly, so the State should ensure that changes to an MCO's/PIHP's IS are assessed frequently enough to ensure that the structure and function continue to be adequate for the State-required tasks.

The EQRO should assess the MCO's/PIHP's IS using questions and approaches such as those contained in Appendix Z, or review the results of a recent IS assessment consistent with the content in Appendix Z. This will ensure that auditors are familiar with the strengths and weaknesses of the MCO's/PIHP's IS. As the EQRO reviews the IS assessment report, it should pay close attention to the strengths and weaknesses of the MCO's/PIHP's IS with respect to the types of data frequently used in MCO/PIHP performance measures, such as data on: membership/enrollment, providers, claims/encounters, laboratory and pharmacy services, and medical record data. Some of the characteristics commonly associated with these data elements that may affect performance measures are:

- **Membership/Enrollment Data.** Elements of the membership or enrollment database will vary by MCO/PIHP. However, for the purposes of MCO/PIHP performance measurement, the membership or enrollment database should capture at least the following information:
    - Age/date of birth,
    - Enrollment and/or termination dates ***(Note: The MCO's/PIHP's data system should be able to track multiple enrollment and termination dates)***,
    - Primary care provider (e.g., name, provider identification number), and
    - Member identification number such as the member's social security number, MCO- or PIHP-designated number, State-issued Medicaid number, CMS-issued Medicare number ***(Note: Be aware of cases in which more than one member may exist under the same identification number within the system,; the same member exists under more than one identification number within the system,; or in a member's identification number may change through re-enrollment, name change, or switch in product-line coverage)***.

  The EQRO also should be aware of whether the MCO/PIHP has processes in place to periodically ensure that enrollment/membership data are current and accurate, particularly at the time it runs its source code/computer programs to identify denominators for MCO/PIHP performance measures.

  Further, the EQRO should be aware of changes in the MCO's/PIHP's membership data systems that might affect the production of the MCO/PIHP performance measures. Major changes, upgrades, or consolidations within the system, or acquisitions/mergers with other MCOs/PIHPs may impact the accuracy or completeness of any of the data elements, which, in turn, may impact the validity of the reported measures.

- **Provider Data.** Elements of the provider data set should typically include:
    - Designation as a primary care physician and/or providers' specialty,
    - Provider identification number, such as a Tax ID number, or MCO- or PIHP-designated number ***(Note: Though it may be less common to see duplication of provider numbers within a provider database than duplication of member identifications within a membership/enrollment database, the EQRO should be aware of any circumstances in which more than one provider can exist with the same identification number within the system, or circumstances in which the same provider may have more than one identification number within the system)***,
    - Providers with more than one office location,
    - Providers with closed panels (i.e., provider availability),
    - Provider start and termination dates, and
    - Provider certification data such as licensure, provider residency/fellowship, date, and specialty of Board Certification status.

  The EQRO should be aware of whether the MCO/PIHP has processes in place to periodically ensure that provider data are current and accurate for all types of providers (individual providers, provider groups, provider networks, contracted vendors). This becomes particularly important at the time the MCO/PIHP runs its source code/computer programs to identify elements of MCO/PIHP performance measures.

  Further, the EQRO should be aware of changes in the MCO's/PIHP's provider data systems that might affect the production of the performance measures. Major changes, upgrades, or consolidations within the system, or acquisitions/mergers with other MCOs/PIHPs may impact the accuracy or completeness of any of the data elements, which, in turn, may impact the validity of the reported measures.

- **Claims Data and Encounter Data.** Claim/encounter data should cover all types of services offered by the MCO/PIHP, such as: behavioral health, family planning, home health care, hospital, laboratory, pharmacy, primary care, radiology, specialty care, and vision care. These data typically include the following elements:

- Patient ID	- Name
- Sex	- Age
- Date of birth	- First date of service
- Last date of service	- Place of service
- Primary diagnosis	- Secondary diagnosis
- Primary procedure	- Secondary procedure
- Revenue codes	- Provider ID
- Provider specialty	- Discharge status

For each type of claim/encounter data captured, the EQRO should be aware of: 1) the total number of diagnosis and procedure codes that can be captured by the system; 2) whether or not principal or secondary diagnosis or procedure codes can be accurately distinguished in the system; and 3) the maximum number of digits or characters the system captures for each type of claim/encounter. For many MCO/PIHP performance measures, the accuracy and validity of the measure may be adversely affected if the MCO's/PIHP's IS is unable to collect and/or differentiate among a sufficient number of codes.

The various coding systems and forms used by the MCO/PIHP and its vendors to capture clinical information through its claims and encounter databases are relevant to validating MCO/PIHP performance systems. Coding systems are formal, standardized approaches (such as ICD-9, CPT-4, DSM-IV, revenue codes, or internally developed codes) to categorize types of encounters and procedures by data elements such as inpatient and ambulatory diagnoses and procedures for medical, surgical, or mental health/substance abuse encounters/claims. ***Note that internally developed codes may be particularly problematic***. The EQRO should understand how the MCO's/PIHP's IS translates or maps these codes back to standard codes for MCO/PIHP performance measure reporting, and how it ensures the accuracy of these translation processes.

- **Medical Record Data.** In cases where medical records are accessed to obtain information for calculating MCO/PIHP performance measures, the EQRO should be aware of how the MCO/PIHP retrieves information from medical records. For example, the training and tools that medical record review staff receives may affect the accuracy and completeness of the data retrieval and inter-rater reliability. A second area of concern is how medical record data is entered into any database that will be used to produce the performance measures.

- **Pharmacy and Laboratory Data.** A key issue commonly encountered with pharmacy and laboratory data for Medicaid managed care MCOs/PIHPs is that these services are frequently contracted out to a variety of providers. Ideally, pharmacy data will use standardized codes for prescription drugs such as those promulgated by the National Council for Prescription Drug Programs (NCPDP), and laboratory services will use a similar, nationally recognized system of coding. However, the diverse nature of the size, type, and ownership of pharmacy and laboratory providers should lead the EQRO to anticipate wide variations in the use of standardized coding and a multitude of unique "home grown" codes. These non-standard coding schemes require that the MCO/PIHP have a system to develop crosswalks among these different codes in order to store the necessary information in its performance measure database. As with the assessment of the claims/encounter data systems, the EQRO should understand not only the MCO's/PIHP's system of mapping non-standard pharmacy and lab codes to standardized codes, but the mechanism the MCO/PIHP uses to ensure the accuracy of these translation processes.

  If pharmacy or laboratory data are not collected through an administrative or claims database, pharmacy or lab data may be present in medical records. However, relying on medical records to supply pharmacy or laboratory data is problematic because of obstacles such as non-standard coding and terminology and poor coordination of records and record linkages between primary care and specialist providers. The EQRO should be aware of these issues and question providers on the reliability of medical record data and pharmacy data as appropriate.

In addition, for many MCO/PIHP performance measures, the IS will need to be able to link these different sources of data. For example, to identify enrollees with diabetes, a MCO/PIHP may 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 if one exists. To determine whether these diabetic enrollees have received a retinal examination from an ophthalmologist or optometrist within the previous year, the MCO/PIHP would have to link procedure code data from either encounter forms, medical records, or claims with information about the specialty of the providers that performed the examinations for these members.

The EQRO will analyze the results of the assessment of the MCO's/PIHP's IS and determine the implications of the findings for the ability of the MCO/PIHP to calculate the performance measures specified by the State. The EQRO will evaluate MCO/PIHP answers against IS capabilities necessary to accurately and completely calculate and report the specific MCO/PIHP performance measures mandated by the State, and will identify any problem areas or items in need of clarification. Where an answer seems incomplete or indicates an inadequate process, the EQRO notes this issue for follow-up and further review during the onsite activities. ***This will help the onsite validation activities focus on the areas most likely to be an issue in the validation process. In addition, knowledge gained from the ISCA provides a knowledge base for effective interviews with key MCO/PIHP staff.***

ONSITE ACTIVITIES

Objectives for Onsite Activities:

The EQRO will evaluate the extent to which the MCO/PIHP has:

- Adequate data integration and control procedures for accurate production of the State-specified performance measures,

- Complete and accurate documentation of data and processes used to calculate and report the State-specified performance measures, and

- Correctly implemented appropriate processes for calculating and reporting the State-specified performance measures.

ONSITE ACTIVITY 1: Assess data integration and control.

In the last activity (Pre-Onsite Activity 3), the EQRO examined background information on the capability of the MCO's/PIHP's IS to collect and integrate valid data from sources internal and external to the MCO/PIHP. This onsite activity further assesses: 1) the MCO's/PIHP's ability to link data from multiple sources in order to calculate the State-mandated performance measures; and 2) whether the MCO/PIHP has used these abilities in a manner that ensures the accuracy of the calculated performance measures. This assessment will be accomplished through:

1. Review of documentation, procedures, and data pertaining to the MCO's/PIHP's IS, and
2. Interviews of MCO/PIHP personnel with knowledge of the MCO's/PIHP's IS and its application to performance measurement.

ATTACHMENT III, *IS Data Integration and Control - Documentation Review Worksheet* lists documents, data, and procedures to be examined to assess MCO/PIHP data integration and control. EQROs should use a worksheet such as ATTACHMENT III to document their findings. In examining the MCO's/PIHP's documentation, procedures, and data, the EQRO should:

1. Examine for accuracy and completeness the details of the MCO's/PIHP's processes to transfer data from membership, provider, encounter/claims, and other data files into a data repository (or use of other mechanism(s) to consolidate data) to calculate performance measures and to keep the data until the calculations of the performance measures have been completed and validated,

2. Examine samples of data from the data repository and transaction files to assess completeness and accuracy,
3. Investigate the MCO's/PIHP's processes to consolidate diversified files and extract required information from a performance measure repository or other data consolidation file,
4. Compare actual results of file consolidations or extracts to those which should have resulted according to documented algorithms or specifications,
5. Review procedures for coordinating the activities of multiple subcontractors to ensure accurate, timely, and complete integration of the data into the performance measure database,
6. 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,
7. If the MCO/PIHP uses a data repository (or data warehouse), evaluate its structure and format and examine program flow charts and source codes to determine the extent to which the repository/warehouse enables and has enabled analyses and reports,
8. Assess the extent to which proper linkage mechanisms have been employed to join data from all necessary sources (e.g., identifying a member with a given disease/condition),
9. Examine and assess the adequacy of the documentation governing the performance measures production process, including MCO/PIHP production activity logs, and MCO/PIHP staff review of report runs,
10. Review documentation that confirms that prescribed data cutoff dates were followed,
11. If appropriate, request that the MCO/PIHP demonstrate it has retained copies of files or databases used for performance measure reporting, in the event that results need to be reproduced,
12. Review documentation standards that assure that the performance measure reporting software program is properly documented with respect to every aspect of the reporting repository, including building, maintaining, managing, testing, and report production, and
13. Review the MCO's/PIHP's process and documentation to ensure that it complies with the MCO/PIHP standards associated with the performance measure reporting program specifications, code review, and testing.

In addition, as needed, the EQRO should supplement the direct examination of IS policies, procedures, and data with interviews of MCO/PIHP personnel. MCO/PIHP personnel who can potentially provide helpful information include the Director of Health/Medical Information Systems, system programmers or operators, and selected sub-contractors. An Interview Guide and suggested questions to ask during these interviews are located at ATTACHMENT IV, *Guide for Interviews of MCO/PIHP Personnel Concerning Data Integration and Control.*

The EQRO should document all findings with respect to the adequacy of the MCO's/PIHP's data integration and control procedures on a worksheet such as that found in ATTACHMENT V, *Data Integration and Control Findings - Documentation Worksheet.*

ONSITE ACTIVITY 2: Assess documentation of data and processes used to calculate and report performance measures.

The MCO/PIHP should have documentation of all steps undertaken in the production of the State-specified performance measures, including documentation of: 1) the collection of data from various sources (e.g., membership, enrollment, provider, claims, or encounter files; medical records; laboratory and/or pharmacy records); 2) steps taken to integrate the required data into a performance measure data set or repository; and 3) 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.

During this activity, *for each measure to be validated*, the EQRO will:

1. Review performance measurement plans and policies to assess the extent to which they include:

    - Data file and field definitions,
    - Maps to standard coding if standard codes were not used in original data collection, and
    - Statistical testing of results, and any corrections or adjustments made after processing.

2. Examine documentation (which may be either a schematic diagram or in narrative form) of programming specifications to ensure that documentation exists for at least the following information:

    - A project or measurement plan, including work flow,
    - All data sources, including external data (whether from a vendor, public registry, or other outside source) and any prior years' data (if applicable),
    - Documentation of the original universe of data that includes record-level patient identifiers that can be used to validate entire programming logic for creating denominators, numerators, and samples,
    - 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 codes used to create all denominators, numerators, and samples (if applicable to the measure). This includes the processes for identifying the population or sample for the denominator and/or numerator for each measure. If sampling is used, this includes a description of sampling techniques and documentation that samples used for baseline and repeat performance measurements were chosen using the same sampling frame and methodology, and
- Documentation of calculation for changes in performance from previous periods (if applicable) including statistical tests of significance.

The EQRO will need to refer to the specifications for each measure that were developed by the EQRO during Pre-Onsite activities (illustrated in ATTACHMENT I). A list of the documentation to review is located at ATTACHMENT VI, *Data and Processes Used to Calculate and Report Performance Measures - Documentation Review Worksheet*. In addition, as needed, the EQRO will interview the Director of Health/Medical Information Systems, system programmers or operators, and the Director of Quality Improvement or other MCO/PIHP personnel to supplement this information, facilitate demonstrations of performance measurement processes, and provide the answers to questions such as the following:

1. 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?

2. How are programming specifications for MCO/PIHP performance measures documented? Who is responsible for this?

3. Are the documentation processes up to date?

The results of the EQRO's review of the MCO's/PIHP's documentation of data and processes used to prepare and submit performance measures should be recorded on a form such as that found as ATTACHMENT VII: *Data and Processes Used to Calculate and Report Performance Measures - Documentation Worksheet.*

ONSITE ACTIVITY 3: Assess processes used to produce denominators.

The fundamental question to be answered by validating the calculation of the denominator(s) of performance measures is to what extent the MCO/PIHP used the appropriate data (including linked data from separate data sets) to identify the entire at-risk population. The "appropriate data" will vary from measure to measure, depending on criteria such as age, sex, diagnosis, or procedure, and may be adjusted to exclude certain patients for reasons identified in the specifications established by the State for calculating the measure. In addition, in some cases the MCO/PIHP may have to estimate portions of the population, such as newborns, who cannot always be readily and fully counted. In such cases, the EQRO should confirm that the methodology used for such estimations is valid. In conducting this activity, the EQRO will need to refer to the State's specifications for each measure as noted by the EQRO during Pre-Onsite activities and as illustrated in ATTACHMENT I.

During this activity, *for each performance measure calculated by the MCO/PIHP and chosen to be included in the validation activity*, the EQRO will assess the extent to which:

1. All members who were eligible to receive the specified services under study were included in the initial population from which the final denominator was produced. This "at risk" population will include both members who received the services, as well as those who did not. This same validation activity applies to provider groups, or other relevant populations identified in the specifications of each performance measure,
2. Programming logic or source codes which identify, track, and link member enrollment within and across product lines (e.g., Medicare and Medicaid), by age and gender, as well as through possible periods of enrollment and disenrollment, have been appropriately applied according to the specifications of each performance measure. This is determined by evaluating the extent to which:
    - Calculations of continuous enrollment criteria were correctly carried out and applied to each measure (if applicable)
    - The MCO/PIHP used appropriate mathematical operations to determine patient age or range
    - The MCO/PIHP can identify the variable(s) that code the member's sex in every file or algorithm, and that the MCO/PIHP can explain what classification is carried out if neither of the required codes is present
3. The MCO/PIHP has correctly calculated member months and member years, if applicable to the performance measure,
4. The MCO/PIHP has properly evaluated the completeness and accuracy of any codes used to identify medical events, such as diagnoses, procedures, or prescriptions, and that these codes have been appropriately identified and applied as specified in each performance measure,

5. Time parameters required by the performance measure specifications are followed (e.g., cut-off dates for data collection, counting 30 calendar days after discharge from a hospital),
6. Performance measure specifications or definitions were followed in excluding members from a denominator. 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; and
7. Systems or methods used by the MCO/PIHP to estimate populations when they cannot be accurately or completely counted (e.g., newborns) are valid.

Policies, procedures, data, and information to be reviewed in conducting these activities are listed in ATTACHMENT VIII. Information obtained from a review of these policies, procedures, data, and information should be supplemented and confirmed, as needed, though interviews with MCO/PIHP personnel, including: the Director of Health/Medical Information Systems, system programmers or operators, and selected sub-contractors. Suggested questions to be asked are located in ATTACHMENT IX.

The findings of the EQRO's documentation review, interviews and any needed demonstrations of processes should be documented on a *Denominator Validation Findings - Reviewer Worksheet,* such as that located at ATTACHMENT X.

ONSITE ACTIVITY 4: Assess processes used to produce numerators.

The focus of numerator validation is on determining whether the MCO/PIHP has correctly identified and evaluated qualifying medical events (e.g., diagnoses, procedures, and prescriptions) in order to include appropriate events in the numerator of the performance measure. These "medical events" may be identified through membership/enrollment data, claim/encounter data, and/or provider data. They may also be identified through data extracted from medical records, or through a combination of both administrative data and medical record abstraction (i.e., the "hybrid" methodology).

As with denominators, accurate and complete data collection is vital to this element of performance measure calculation. For measures that include sampling in the methodology, the entire at-risk population must have an equal chance to be included in the numerator. For some measures, particularly those frequently focused on women and children in the Medicaid population, the member may have received the specified service outside of the MCO/PIHP provider base (e.g., children receiving immunizations through public health services or schools), so an effort must be made to include these events in the numerator.

If either medical record review or the hybrid methodology is used to calculate the performance measure, the EQRO will need to review a sample of medical records, which are identified as having been included in the sample drawn by the MCO/PIHP. Following specific rules and guidelines, the EQRO will determine the extent to which data obtained from medical records and noted as being part of the numerator results can be confirmed during medical record review validation activities.

During this activity, *for each performance measure calculated by the MCO/PIHP and chosen to be included in the validation activity*, the EQRO will assess the extent to which:

1. The MCO/PIHP has used the appropriate data, including linked data from separate data sets, to identify the entire at-risk population that meets the specified criteria for inclusion in the numerator.
2. The MCO/PIHP has adopted and followed procedures to capture data for those performance measures which could be easily under-reported due to the availability of services outside the MCO/PIHP.
3. The MCO's/PIHP's use of codes to identify medical events (such as diagnoses, procedures, prescriptions, etc.) are complete, accurate, and specific in correctly describing what has transpired and when. In particular, the EQRO will assess the extent to which these codes were correctly evaluated when classifying members for inclusion or exclusion in the numerator.
4. The MCO/PIHP has avoided or eliminated double-counted members or numerator events.
5. Any non-standard codes used by the MCO/PIHP are mapped to standard codes in a manner that is consistent, complete, and reproducible. The EQRO will assess this through a review of the programming logic or a demonstration of the program.
6. The MCO/PIHP has adhered to any time parameters required by the specifications of the performance measure (i.e., that the measured event occurred during the time period specified or defined in the performance measure).
7. Medical record reviews and abstractions have been carried out in a manner that facilitates the collection of complete, accurate, and valid data by ensuring that:
    - Record review staff have been properly trained and supervised for the task
    - Record abstraction tools require the appropriate notation that the measured event occurred
    - Record abstraction tools require notation of the results or findings of the measured event (if applicable)
8. Data included in the record extract files are consistent with data found in the medical records for a sample of medical records for applicable performance measures.9. The process of integrating administrative data and medical record data for the purpose of determining the numerator is consistent and valid.

Policies, procedures, data, and information to be reviewed in conducting these activities are listed in ATTACHMENT XI. These activities will need to be carried out with respect to each performance measure calculated by the MCO/PIHP and included in the EQRO validation activities. Because of this, the EQRO will need to refer to the specifications for each measure that were noted by the EQRO during Pre-Onsite activities as illustrated in ATTACHMENT I. In addition, for at least three of the performance measures calculated via medical record review or hybrid methodology, the EQRO will need to validate the results of the medical record review for 30 enrollees who were found to meet numerator requirements for each of the three or more measures. Procedures and sample tools for validating medical record review findings are included as ATTACHMENT XII.

Information obtained from a review of policies, procedures, data, and information should be supplemented or confirmed, as needed, though interviews with MCO/PIHP personnel, including: the Director of Health/Medical Information Systems, system programmers or operators, and selected sub-contractors. Suggested questions are the same as those asked with respect to denominators and are located at ATTACHMENT IX.

The findings of the EQRO's documentation review, interviews, any needed demonstrations of processes, and validation of medical record review should be documented on a *Numerator Validation Findings - Reviewer Worksheet* such as that located at ATTACHMENT XIII.

ONSITE ACTIVITY 5: Assess the sampling process (for measures NOT calculated through administrative data).

The basic task in validating the sampling methodology is determining whether the sample validly reflects: 1) the performance of all practitioners and providers who serve Medicaid enrollees and whose activities are the subject of the performance measure; and 2) the care given to the entire population (including special populations with complex care needs) to which the performance measure is relevant.

As in the previous activity of validating the population included in a denominator, the sampling methodology employed should not exclude any population subgroups to which the topic area and performance measure apply. For example, when studying well child care, an MCO's/PIHP's sample should not exclude children with special health care needs whose primary care provider is a specialist other than a pediatrician or family practitioner.

During this activity, the EQRO will assess the extent to which:

1. The sampling methodology used by the MCO/PIHP produced an unbiased sample, which is representative of the entire at-risk population.
2. Each relevant enrollee or provider had an equal chance of being selected; no enrollees were systematically excluded from the sampling.
3. The MCO/PIHP followed the specifications set forth by the State for 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 MCO/PIHP kept adequate documentation of that activity.
4. 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.
5. The MCO/PIHP examined its sampled for bias and if any bias was detected, the MCO/PIHP is able to provide documentation that describes efforts taken to correct it.
6. The sampling methodology treated all measures independently and there is no correlation between drawn samples. (This is not intended to be a validation of the prescribed sampling methodology included in the performance measure specifications, because the assumption is that it is a valid methodology. The EQRO validation efforts will focus on the MCO's/PIHP's implementation of that sampling methodology to assess the extent to which it has correctly followed the sampling specifications.)
7. Relevant members or providers who were not included in the sample for the baseline measurement have the same chance of being selected for the follow-up measurement as those who were included in the baseline.
8. The MCO/PIHP has policies, procedures, and documentation that files from which the samples were drawn are maintained so that if the sample must be re-drawn, or replacements made, the original population is intact.
9. The sample selected conforms to the methodology set forth in the performance measure specifications.
10. Sample sizes meet the requirements of the performance measure specifications.
11. The MCO/PIHP appropriately handled the documentation and reporting of the measure if the requested sample size exceeds the population size.
12. The MCO/PIHP properly oversampled in order to accommodate potential exclusions.
13. The MCO/PIHP followed proper substitution methodology in medical record review (for measures using the hybrid methodology or medical record review):
    - Substitution applied only to those members who met the exclusion criteria detailed in the performance measure specifications
    - Substitutions were made for properly excluded records and the percentage of substituted records was documented

Policies, procedures, data, and information to be reviewed in conducting these activities are listed in ATTACHMENT XIV. These activities need to be carried out with respect to each performance measure that was calculated using a sample. Because of this, the EQRO will need to refer to the "List of Performance Measures Calculated by the MCO/PIHP" (see TABLE 3) and the specifications for each measure that were noted by the EQRO during Pre-Onsite activities as illustrated in ATTACHMENT I.

Information on sampling obtained from a review of policies, procedures, data, and information should be supplemented and confirmed, as needed, though interviews with MCO/PIHP personnel, such as: the Director of Health/Medical Information Systems, system programmers or operators, and selected sub-contractors. Suggested questions to ask are those previously identified and included as ATTACHMENT IX. Validation findings regarding sampling should be documented on a worksheet such as that found as ATTACHMENT XV.

ONSITE ACTIVITY 6: Assess submission of required performance measure reports to the State.

Once the MCO/PIHP calculates the required performance measures, it must report them to the State in the manner prescribed by the State. This includes reporting the measures in a proper format, whether through the use of a hardcopy "shell" report, in an electronic medium and format, or some combination of both. During the Pre-Onsite phase of the review, the EQRO familiarizes itself with the State's format and reporting requirements for the MCO's/PIHP's performance measures. During this activity, the EQRO will assess whether measures were reported to the State in the manner and form prescribed by the State. These activities will need to be carried out with respect to each performance measure to be calculated by the MCO/PIHP. Because of this, the EQRO will need to refer to the reporting specifications for all of the measures that were noted by the EQRO during Pre-Onsite activities as documented in TABLE 1.

To assess the submission of required performance measure reports to the State, the EQRO will review:

- Procedures for submitting reports that meet State requirements (e.g., specified electronic format, supporting documentation, timing), and
- Documentation that procedures for properly submitting required reports to State were implemented appropriately.

The extent to which the MCO/PIHP reported the calculated performance measures to the State in the manner and form prescribed by the State should be documented in the EQRO's report to the State.

POST-ONSITE ACTIVITIES

Objectives for Post-Onsite Activities:

The EQRO will evaluate all gathered information and submit a report on its validation findings to the State following either Option 1 or Option 2 below.

OPTION 1: The EQRO submits its report of validation findings to the State after review by the MCO/PIHP for any factual errors or omissions, or

OPTION 2: The EQRO submits a final report to the State after providing the MCO/PIHP with the opportunity to make corrections to performance measures in response to preliminary EQRO findings. This would occur as follows:

- The EQRO submits to the MCO/PIHP a preliminary report detailing areas of concern and suggested methods for correction.
- After allowing the MCO/PIHP to correct (as practical) any problems in calculating or reporting performance measures that were identified in the preliminary report, the EQRO re-validates selected performance measures and the measurement processes.
- The EQRO again evaluates gathered information and prepares a final report for the State.
- The EQRO submits its report of validation findings to the State.

POST-ONSITE ACTIVITY 1: Determine preliminary validation findings for each measure.

Once the EQRO concludes its onsite activities, it aggregates the validation activity findings for each performance measure. This involves review and analysis of findings and worksheets produced for each performance measure selected for validation and for the MCO's/PIHP's IS as a result of Pre-Onsite and Onsite activities. In particular, these include:

- Completed performance measure validation worksheets for each performance measure to be validated (ATTACHMENT I) in conjunction with the Denominator Validation Findings (ATTACHMENT X) and Numerator Validation Findings (ATTACHMENT XIII),

- For measures calculated through medical record review, including the hybrid methodology, the completed *Medical Record Review Validation Tool* (ATTACHMENT XII),

- Findings regarding the MCO's/PIHP's data integration and control procedures (ATTACHMENT V), and

- Sampling validation findings (ATTACHMENT XV).

The report of preliminary validation findings identifies any areas of concern for each of the performance measures that were validated by the EQRO and makes suggestions for improvement. In particular, the report indicates precisely which elements of the MCO/PIHP performance measures were invalid (if any). This information provides the MCO/PIHP with specific targets for correction and a tool that can be used to focus MCO/PIHP personnel on the changes necessary to improve the production process. In addition to communicating in writing, the EQRO may participate in meetings with key MCO/PIHP personnel responsible for the calculation and reporting of performance measures.

Once the EQRO has submitted its preliminary findings to the MCO/PIHP, there are two courses of action that the State may have its EQRO pursue with respect to allowing the MCO/PIHP to respond to the EQRO's preliminary findings:

OPTION 1: The MCO/PIHP may offer comments and documentation to support correction of factual errors and omissions in the EQRO's preliminary report, or

OPTION 2: The MCO/PIHP would be allowed to recalculate performance measures based on the findings of the EQRO. The EQRO would then revalidate the revised performance measure(s).

Allowing MCOs/PIHPs to recalculate measures provides States and Medicaid beneficiaries with a greater amount of accurate information on MCO/PIHP performance. However, this option requires greater time and financial resources on the part of the States, EQROs and MCOs/PIHPs. If Option 2 is chosen by the State, depending on the extent of the corrections necessary or assistance that the MCO/PIHP needs to improve its performance measure production processes, the EQRO schedules a time to re-visit the MCO/PIHP as soon as practical, in order to re-evaluate the performance measures before they are reported to the State. This re-evaluation follows the same format and activities as the initial onsite visit, except that the EQRO may focus only on those activities that were found to be problematic during the first validation effort. The EQRO will use worksheets and tools that are identical to those used in the first onsite visit; any areas not re-reviewed should be noted accordingly.

Once Option 1 or Option 2 is completed, and the MCO's/PIHP's comments or revised performance measures validation findings have been appropriately incorporated into the validation findings, the EQRO will submit its findings to the State.

POST-ONSITE ACTIVITY 2: Submission of validation report to State.

A State may choose one of two options for determining the validity of each of the MCO's/PIHP's performance measures:

OPTION 1: The EQRO submits all working papers and a summary of findings to the State. The State would make the final decision on the validity of each performance measure and compliance with reporting requirements.

OPTION 2: The EQRO references a clearly defined set of decision rules for determining if each of the MCO's/PIHP's reported performance measures were sufficiently valid (i.e., accurate and complete). In this instance, the State would still receive the final report and all supporting documentation and would have the final authority to determine acceptable validity and compliance with State conditions.

Regardless of which option a State chooses, the decision rules for compliance should be uniform across MCOs/PIHPs within the State. Because States may differ substantially regarding their requirements for Medicaid MCOs/PIHPs, this protocol provides a framework which the State can use with its own specific "percentage rules" or requirements for determining validity of performance measures.

The State will need to specify the level of bias that is permissible or allowable in the calculated performance measures in order for an MCO's/PIHP's performance measure to be considered "valid measures." Within the industry, levels currently range from 5 percent to 10 percent for commercial and/or Medicare product lines. Bias in reported rates can result from many factors (e.g., sampling bias, coding errors, and in particular, problems with in complete data). For example, is a measure calculated using a data set that is known to be only 50 percent complete a valid measure of performance? What about a measure using data that is 75 or 85 percent complete? Because there is currently no generally accepted standard for data completeness in the industry, each State must specify the extent of data incompleteness it allows in measures before the measure is considered to be "not valid." Data completeness was addressed as part of the *Performance Measure Validation Worksheet* for each performance measure as illustrated in ATTACHMENT I. The EQRO will need to make an estimate about the cumulative affect of all sources of bias on the validity of the performance measure.

The format for the final report should follow the format specified by the State, but should include the following elements:

- A list of measures for validation (it is possible that an MCO/PIHP would be unable to report on all required measures for reasons that would be explained to the EQRO and the State),
- A description of the onsite validation activities including: 1) a list of the EQRO's team members 2) a description of the pre-audit strategy and considerations, 3) a description of the technical methods of data collection and analysis used by the EQRO, 4) a list of interviewees, and 5) any other facts relevant to the onsite process,
- Details, results, and conclusions drawn of the validation process for each performance measure, including any medical record abstractions conducted,
- As directed by the State, the validation findings for each performance measure included in the EQRO validation activities, and
- As directed by the State, analysis and findings with respect to the MCO's/PIHP's data integration and control procedures and performance measure calculation documentation.

In addition to reporting to the State on the extent to which the MCO/PIHP correctly implemented processes to calculate and report individual MCO/PIHP performance measures, other aspects of MCO/PIHP performance measurement that the State may want the EQRO to address in its final report include the extent to which the MCO/PIHP has:

- Adequate data integration and control necessary for accurate reporting of performance measures, and

- Complete and accurate documentation of data and processes used to calculate and report performance measures.

In addition, the EQRO might also be asked to submit all of its worksheets and tools as supporting documentation to the report.

END OF PROTOCOL

ATTACHMENT I

Example of a Completed Performance Measure Validation Worksheet[4]

Below is an example of a completed, customized performance measure validation worksheet similar to what an EQRO would prepare prior to its onsite visit. This worksheet assumes that the State has adopted the HEDIS methodology for this performance measure. One of the following scoring designations must be checked for each audit element:

MET: The MCO's/PIHP's measurement and reporting process was fully compliant with State specifications.

NOT MET: The MCO's/PIHP's measurement and reporting process was not compliant with State specifications. This designation should be used for any audit element that deviates from the State specifications, regardless of the impact of the deviation on the final rate. All audit elements with this designation must include explanation of the deviation in the comments section.

N/A: The audit element was not applicable to the MCO's/PIHP's measurement and reporting process.

PERFORMANCE MEASURE TO BE VALIDATED: BREAST CANCER SCREENING

METHODOLOGY FOR CALCULATING MEASURE: (Check one)	ADMINISTRATIVE	MEDICAL RECORD REVIEW	HYBRID

AUDIT ELEMENTS	AUDIT SPECIFICATIONS	MET	NOT MET	N/A	COMMENTS
DENOMINATOR					
1. Population	• Medicaid population appropriately segregated from commercial / Medicare. • Population defined as effective Medicaid enrollment as of Dec. 31, 2000. • Dual Medicaid and Medicare beneficiaries are included.				
2. Geographic Area	• Includes only those Medicaid enrollees served in the MCO's/PIHP's reporting area.				
3. Age & Sex	• Members aged 52-69 as of 12/31/00 (i.e., born between 1/1/31 & 12/31/48)				

[4]This worksheet is adapted from the IPRO tools used in the audit of the 1997 Medicare HEDIS data.

AUDIT ELEMENTS	AUDIT SPECIFICATIONS	MET	NOT MET	N/A	COMMENTS
	• Only females selected				
4. Enrollment Calculation	• Were members of plan on 12/31/00 • Were continuously enrolled from 1/1/99 to 12/31/00 with one break per year of up to 45 days allowed. • Switches between populations (Medicare, Medicaid, and commercial) were not counted as breaks.				
5. Data Quality	• Based on the IS assessment findings, are any of the data sources for this denominator inaccurate?				
6. Proper Exclusion Methodology in Administrative Data (If no exclusions were taken, check N/A)	• Only members with contraindications or data errors were excluded. • Contraindication exclusions were performed according to current State specifications. • Only the codes listed in specifications as defined by State were counted as contraindications.				
NUMERATOR					
7. Administrative Data: Counting Clinical Events	• Standard codes listed in State specifications or properly mapped internally developed codes were used. (Intended to reference appropriate specifications as defined by State.) • Members were counted only once; double counting of mammograms was prevented.				
8. Medical Record Review Documentation Standards	• Record abstraction tool required notation of the date that the mammogram was performed. • Record abstraction tool required notation of the mammogram result or finding.				
9. Time Period	• Mammogram performed on or between 1/1/99 & 12/31/00.				
10.Data Quality	• Properly identified enrollees.				
AUDIT ELEMENTS	**AUDIT SPECIFICATIONS**	**MET**	**NOT MET**	**N/A**	**COMMENTS**

	• Based on the IS assessment findings, were any of the data sources used for this numerator inaccurate?				
SAMPLING	**IF ADMINISTRATIVE METHOD WAS USED, CHECK "N/A" FOR AUDIT ELEMENTS 11, 12, AND 13.**				
11. Unbiased Sample	• As specified in State specifications, systematic sampling method was utilized.				
12. Sample Size	• After exclusions, sample size is equal to 1) 411, 2) the appropriately reduced sample size, which used the current year's administrative rate or preceding year's reported rate, or 3) the total population.				
13. Proper Substitution Methodology in Medical Record Review (If no exclusions were taken, check NA)	• Only excluded members for whom medical record review revealed 1) contraindications that correspond to the codes listed in appropriate specifications as defined by State or 2) data errors. • Substitutions were made for properly excluded records and the percentage of substituted records was documented.				

ADDITIONAL QUESTIONS

QUESTIONS	**YES**	**NO**
Were members excluded for contraindications found in the administrative data?		
Were members excluded for contraindications found during the medical record review?		
Were internally developed codes used?		

What range defines the impact of data incompleteness for this measure? (Check one.)	
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
Upon what documentation is the above percentage based? (e.g., internal reports, studies, comparison to medical records, etc.	

VALIDATION FINDING

The validation finding for each measure is determined by the magnitude of the errors detected for the audit elements, not by the number of audit elements determined to be "NOT MET". Consequently, it is possible that an error for a single audit element may result in a designation of "NV" because the impact of the error biased the reported performance measure by more than *"x"* percentage points. Conversely, it is also possible that several audit element errors may have little impact on the reported rate and, thus the measure could be given a designation of "SC." The following is a list of the validation findings and their corresponding definitions:

FC **=** ***Fully Compliant***
Measure was fully compliant with State specifications.

SC **=** ***Substantially Compliant***
Measure was substantially compliant with State specifications and had only minor deviations that did not significantly bias the reported rate.

NV **=** ***Not Valid***
Measure deviated from State specifications such that the reported rate was significantly biased. This designation is also assigned to measures for which no rate was reported, although reporting of the rate was required.

NA **=** ***Not Applicable***
Measure was not reported because MCO/PIHP did not have any Medicaid enrollees that qualified for the denominator.

AUDIT DESIGNATION	

ATTACHMENT II

Potential Documents and Processes for Review

In order to assess the MCO's/PIHP's IS and the validity of reported performance measures, the EQRO will need to review a number of data sources and processes. The MCO/PIHP should ensure that the following documents, data, and procedures are available to the EQRO for observation; the EQRO will use its discretion in selecting which ones to review.

Integration and Control of Data

- Procedures and standards for all aspects of the data repository (ies) used in the production of performance measures, including building, maintaining, managing, testing, and production of performance measures.
- Manuals covering application system development methodology, database development, and design and decision support system utilization.
- Control 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 repository (ies).
- Source code data entry, data transfer, and data manipulation programs and processes.
- Descriptive documentation for data entry, transfer, and manipulation programs and processes.
- If applicable, procedures for coordinating activities of multiple subcontractors in a way that safeguards 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 has been proper implementation of procedures for coordinating activities to safeguard the integrity of the performance measure data.
- Documentation of data cutoff 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 MCO/PIHP performance measures, including standards and schedules.

Collection, Calculation, and Documentation of Performance Measurements

- Policies which stipulate and enforce documentation of data requirements, 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 diagrammatic or narrative descriptions.
- Documentation of the original universe of data that includes 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 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; 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 of results of statistical tests 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., Medicare 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 MCO/PIHP).
- 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 sort of population files when sampling (systematic) is used.
- Member database.
- Provider data (including facilities, labs, pharmacies, physicians, etc.).
- Database record layout and data dictionary.
- Survey data.
- 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 (combination of medical records and administrative data) or solely medical record review.
- 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.
- Documentation of "frozen" or archived files from which the samples were drawn, and if applicable, documentation of the MCO's/PIHP's process to re-draw a sample or obtain necessary replacements.
- For performance measures which are easily under-reported, procedures to capture data that may reside outside the MCO's/PIHP'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 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 MCO's/PIHP's use of codes to identify medical events were correctly evaluated when classifying members for inclusion or exclusion in the numerator.
- Evidence that MCO/PIHP 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.).
- 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, timing).
- Documentation that procedures for properly submitting required reports to State were implemented appropriately.

ATTACHMENT III

IS Data Integration and Control - Documentation Review

Worksheet

Documentation	Reviewed	Not Reviewed	Comments
Procedures and standards for all aspects of the data repository (ies), including building, maintaining, managing, testing, and production of performance measures			
Manuals covering application system development methodology, database development and design, and decision support system utilization			
Control system documentation including flow charts and codes for backups, recovery, archiving, and other control functions			
Procedures to consolidate information from disparate transaction files to support performance measurement			
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 repository to produce intended result			
Source code data entry, data transfer, and data manipulation programs and processes			
Descriptive documentation for data entry, data transfer, data manipulation programs and processes			
If applicable, procedures for coordinating activities of multiple subcontractors in a way that safeguards the integrity of the performance measure 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 has been proper implementation of procedures for coordinating activities to safeguard the integrity of the performance measure data			
Documentation of data cutoff 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 of plan-level performance measures, including standards and schedules			

In the comments section, be sure to address the following:

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 plan uses a performance measure repository, review the repository structure. Does it contain all the key information necessary for performance measure reporting?

How does the MCO/PIHP test the process used to create the performance measure reports?

Does the MCO/PIHP use any algorithms to check the reasonableness of data integrated to report the plan-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 a type of version control in place?

ATTACHMENT IV

Guide for Interviews of MCO/PIHP Personnel Concerning Data Integration and Control

Background Information:

Name of MCO/PIHP:

Date:

Location:

Year of First Medicaid Enrollment:

Year of First MCO/PIHP Performance Report:

Auditors:

Names and Titles of Individuals Interviewed:

Has the MCO/PIHP previously undergone an audit of its State performance measure reporting process? If so, when did the audit take place and who conducted it?

Other general issues:

ATTACHMENT IV

Interview Questions:

1. How is performance measure data collection accomplished:

   - By querying the applicable IS 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 submission and processing lags? How is the file creation process checked 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? Are reports created from a vendor software product? If so, how frequently are the files updated? How are reports checked for accuracy?

2. 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?

3. How does the MCO/PIHP test the process used to create the performance measure reports?

4. Does the MCO/PIHP use any algorithms to check the reasonableness of data integrated to report the MCO/PIHP performance measures

5. Are performance measurement reporting programs reviewed by supervisory staff?

6. Is there an internal backup for performance measure programmers - do others know the programming language and the structure of the actual programs? Is there documentation?

7. How does the plan prevent loss of claim and encounter data when systems fail?

8. What administrative data backup systems are in place?

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

ATTACHMENT IV

Describe Documentation Review and Demonstrations Provided:

ATTACHMENT V

Data Integration and Control Findings - Documentation Worksheet

Data Integration and Control Element	Met	Not Met	N/A	Comments
Accuracy of data transfers to assigned performance measure repository.				
• MCO/PIHP 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				
Accuracy of file consolidations, extracts, and derivations.				
• MCO's/PIHP'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 multiple subcontractors 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 necessary to performance measure reporting are lost or inappropriately modified during transfer				
If the MCO/PIHP uses one, the structure and format of the performance measure data repository facilitates any required programming necessary to calculate and report required performance measures.				
• 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)				
Assurance of effective management of report production and of the reporting software.				

• Examine and assess the adequacy of the documentation governing the production process, including MCO/PIHP production activity logs, and MCO/PIHP staff review of report runs				
• Prescribed data cutoff dates were followed				
• The MCO/PIHP has retained copies of files or databases used for performance measure reporting, in the event that results need to be reproduced				
• Review documentation standards to determine the extent to which the 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				
• Review the MCO's/PIHP's processes and documentation to determine the extent to which they comply with the MCO/PIHP standards associated with reporting program specifications, code review, and testing				

ATTACHMENT VI

Data and Processes Used to Calculate and Report Performance Measures - Documentation Review Worksheet

Documentation	Reviewed	Not Reviewed	Comments
Policies which stipulate and enforce documentation of data requirements, issues, validation efforts and results			
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)			
Review of reported measures to assess consistency of common elements (e.g., membership counts, number of pregnancies and births, etc.)			
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 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 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 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 (for each performance measure, as appropriate) showing confidence intervals of calculations when sampling methodology used			
Documentation of sources of any supporting external data or prior years' data used in reporting (for each performance measure, as appropriate)			

Describe Documentation Reviewed and Demonstrations Provided:

ATTACHMENT VII

Data and Processes Used to Calculate and Report Performance Measures - Documentation Worksheet

Audit Element	Met	Not Met	N/A	Comments
Measurement plans and policies which stipulate and enforce documentation of data requirements, issues, validation efforts and results. These include:				
• 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				
Documentation of programming specifications (which may be either a schematic diagram or in narrative form) for each measure includes at least the following:				
• All data sources, including external data (whether from a vendor, public registry, or other outside source), and any prior years' data (if applicable)				
• 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				

ATTACHMENT VII

Audit Element	Met	Not Met	N/A	Comments
• If sampling used, a description of sampling techniques and documentation that assures 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 of 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				

ATTACHMENT VIII

Policies, Procedures, Data and Information Used to Produce Denominators: Review Worksheet

Policies, Procedures, Data, Information 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 MCO/PIHP)			
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			

ATTACHMENT IX

QUESTIONS FOR ASSESSING PROCESSES USED TO PRODUCE DENOMINATORS AND NUMERATORS

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 MCO/PIHP 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 MCO's/PIHP's IS capabilities?

Other issues.

Names and Titles of Individuals Interviewed:

ATTACHMENT X

Denominator Validation Findings - Reviewer Worksheet

Audit Element	Met	Not Met	N/A	Comments
For each of the performance measures, all members of the relevant populations identified in the performance measure specifications are included in the population from which the denominator is produced.				
All members who were eligible to receive the specified services were included in the initial population from which the final denominator was produced. This "at risk" population included both members who received the services, as well as those who did not. This same standard applies to provider groups or other relevant populations identified in the specifications of each performance measure.				
Adequate programming logic or source code exists to appropriately identify all "relevant" members of the specified denominator population for each of the performance measures.				
For each measure, programming logic or source code which identifies, tracks, and links member enrollment within and across product lines (e.g., Medicare and Medicaid), by age and sex, as well as through possible periods of enrollment and disenrollment, has been appropriately applied according to the specifications of each performance measure.				
Calculations of continuous enrollment criteria were correctly carried out and applied to each measure (if applicable).				
Proper mathematical operations were used to determine patient age or range.				
The MCO/PIHP 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 MCO/PIHP can explain what classification is carried out if neither of the required codes is present.				

ATTACHMENT X

Audit Element	Met	Not Met	N/A	Comments
Correct calculation of member months and member years.				
The MCO/PIHP has correctly calculated member months and member years, if applicable to the performance measure.				
Completeness and accuracy of the codes used to identify medical events has been identified and the codes have been appropriately applied.				
The MCO/PIHP 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.				
Specified time parameters are followed.				
Any time parameters required by the specifications of the performance measure are followed (e.g., cut off dates for data collection, counting 30 calendar days after discharge from a hospital, etc.).				
Exclusion criteria included in the performance measure specifications have been followed.				
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.				
Systems to estimate populations, which cannot be accurately counted, exist and are utilized when appropriate.				
Systems or methods used by the MCO/PIHP to estimate populations when they cannot be accurately or completely counted (e.g., newborns) are valid.				

ATTACHMENT XI

Policies, Procedures, Data, and Information Used to Produce Numerators: Review Worksheet

Documentation	Reviewed	Not Reviewed	Comments
For performance measures which are easily under-reported, procedures to capture data that may reside outside the MCO/PIHP'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 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			
MCO's/PIHP's use of codes to identify medical events were correctly evaluated when classifying members for inclusion or exclusion in the numerator			
Evidence that MCO/PIHP 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			

Describe documentation review and any demonstrations provided:

ATTACHMENT XII

Medical Record Review Validation Tools

The purpose of medical record review (MRR) validation is to verify the accuracy of the MRR conducted by each MCO/PIHP. For each of at least three measures for which the hybrid method or solely MRR was used, the EQRO will validate the medical records of 30 enrollees found to meet numerator requirements. Only those members included in a hybrid or solely MRR sample will be selected - the EQRO will not be conducting medical record audits to validate administrative data. Therefore, if an MCO/PIHP used only administrative data for a particular measure, that measure will not be part of the MRR validation process.

For each measure in which the hybrid method or solely MRR was used, the EQRO will request a list of all of the members in the MCO's/PIHP's MRR sample. From that list, the EQRO will identify a sample of 30 members who meet numerator requirements. MCOs/PIHPs 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 MCO/PIHP to gather the required medical record documentation, the EQRO may direct the MCOs/PIHPs 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 prior to completion of the MRR process would allow an MCO/PIHP additional time to retrieve medical record documentation. Soon after receipt of the first list, the EQRO will provide the MCO/PIHP 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 would accept the first list submission approximately one month prior to the scheduled audit. If an MCO/PIHP 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, MCOs/PIHPs 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 MCO's/PIHP'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 will be set for the medical record audit. Rather, onsite auditors will use the MRR results to determine if the hybrid rate or solely MRR rate, as a whole, 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 MCO's/PIHP'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 MCO's/PIHP's Final Audit Designation.

Step 1: Calculation of the Medical Record Review Error Rate

The EQRO will review up to 30 records identified by the MCO/PIHP 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 4, below:

TABLE 4: Summary of Medical Record Review (MRR) Reabstraction 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 to be Compliant	Accuracy Rate (%) (D/B)	Error Rate (%) (100% - E)

Column A: Name of performance measure evaluated.

Column B: Total number of MRR numerator positive records reabstracted 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 MRR Reabstraction 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 4, 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-Onsite activity 3 and Onsite 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 4, 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 MCO's/PIHP's MRR processes on its final reported rate by extrapolating the findings from the audited medical record sample to the universe of all MRR positives. Details on this process are provided in TABLE 5.

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 MCO's/PIHP's MRR process (TABLE 5, 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 MCO's/PIHP's medical review process (TABLE 5, 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.

ATTACHMENT XII

TABLE 5: Impact of MRR Findings

Line #	Description	Measure A	Measure B	Measure C
1	Final Data Collection Method Used (e.g., MRR, hybrid, etc.)			
2	Error Rate (Percentage of records selected for audit that were identified as not meeting numerator requirements, as shown in TABLE 4, column F)			
3	Is error rate < 10%? (Yes or No) --If yes, MCO/PIHP passes MRR validation; no further MRR calculations are necessary --If no, the rest of the spreadsheet will 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 MCO/PIHP)			
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 MCO/PIHP 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)			
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.

ATTACHMENT XIII

Numerator Validation Findings - Reviewer Worksheet

Audit Element	Met	Not Met	N/A	Comments
All appropriate data are used to identify the entire at-risk population.				
The MCO/PIHP has used the appropriate data, including linked data from separate data sets, to identify the entire at-risk population.				
The MCO/PIHP has in place and utilizes procedures to capture data for those performance indicators that could be easily under-reported due to the availability of services outside the MCO/PIHP.				
Qualifying medical events (such as diagnoses, procedures, prescriptions, etc.) are properly identified and confirmed for inclusion in terms of time and services				
The MCO's/PIHP's use of codes used to identify medical events are complete, accurate, and specific in correctly describing what has transpired and when.				
The MCO/PIHP correctly evaluated medical event codes when classifying members for inclusion or exclusion in the numerator.				
The MCO/PIHP has avoided or eliminated all double-counted members or numerator events.				
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 as evidenced by a review of the programming logic or a demonstration of the program.				
Any time parameters required by the specifications of the performance measure are adhered to (i.e., that the measured event occurred during the time period specified or defined in the performance measure).				

ATTACHMENT XIII

Audit Element	Met	Not Met	N/A	Comments
Medical record data extracted for inclusion in the numerator are properly collected.				
Medical record reviews and abstractions have been carried out in a manner that facilitates the collection of complete, accurate, and valid data.				
Record review staff have been properly trained and supervised for the task.				
Record abstraction tools require the appropriate notation that the measured event occurred.				
Record abstraction tools require notation of the results or findings of the measured event (if applicable).				
Data included in the record extract files are consistent with data found in the medical records as evidenced by a review of a sample of medical record for applicable performance measures. **(From Medical Record Review Validation Tools-Table 5, ATTACHMENT XII)**				
The process of integrating administrative data and medical record data for the purpose of determining the numerator is consistent and valid.				

ATTACHMENT XIV

Policies, Procedures, Data, and Information Used to Implement Sampling: Review Worksheet

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/PIHP's process to re-draw a sample or obtain necessary replacements			

Describe Documentation Review and Demonstrations Provided:

ATTACHMENT XV

Sampling Validation Findings - Reviewer Worksheet

Audit Element	Met	Not Met	N/A	Comments
The MCO/PIHP has followed the specified sampling method to produce an unbiased sample which is representative of the entire at-risk population.				
• Each relevant member or provider had an equal chance of being selected; no one was systematically excluded from the sampling.				
• The MCO / PIHP 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 MCO/PIHP 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 MCO/PIHP examined its sampled files for bias, and if any bias was detected, the MCO/PIHP 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.				

Audit Element	Met	Not Met	N/A	Comments
The MCO/PIHP maintains its performance measurement population files/ data sets in a manner which allows a sample to be re-drawn, or used as a source for replacement.				
• The MCO/PIHP 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.				
Sample sizes collected conform to the methodology set forth in the performance measure specifications, and the sample is representative of the entire population.				
• Sample sizes meet the requirements of the performance measure specifications.				
• The MCO/PIHP has appropriately handled the documentation and reporting of the measure if the requested sample size exceeds the population size.				
• The MCO/PIHP properly oversampled in order to accommodate potential exclusions.				
For performance measures which include medical record reviews (e.g., hybrid data collections methodology), proper substitution methodology was followed.				
• 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.				

END OF DOCUMENT