

Performance Measurement Protocol External Quality Review of Mental Health Plans

I. Introduction

In response to recent changes in Medicaid managed care regulations, the Department of Mental Health (DMH) must provide for annual external quality review of the quality, outcomes, timeliness of and access to services provided by Mental Health Plans (MHPs). Specifically, MHPs must gather data for the calculation of Performance Measures (PMs) designated by DMH. These PMs must be annually validated and reviewed by an External Quality Review Organization (EQRO).

The purpose of mental health care PMs is to assess and improve care processes and thereby improve outcomes of care. In order for such measures to achieve real improvements in care, and for interested parties to have confidence in the reported improvements, PMs must be designed, conducted and reported in a methodologically sound manner. To achieve this goal, this PM Protocol identifies procedures for an EQRO to use in its validation¹ of MHP PMs.

In California, MHPs claim Federal Financial Participation (FFP) on a cost or negotiated rate basis². Claims are submitted to DMH based on services delivered. DMH pays the county claims and uses approved claims data to calculate performance measures for each MHP. Therefore, in order to validate the accuracy of the PMs, the EQRO will need to validate both the processes and information used by DMH to develop and calculate the performance measures, and the MHP information systems upon which this data is based. This means that the review of performance measurement activities contained in this protocol will take place at both DMH and the MHPs.

For the first year of external quality review, DMH has determined the following PMs will to be validated:

- Total penetration rates for FY 2002/03³
- Penetration rates by three age groups: 0-18, 19-64, and over 65 years of age for FY 2002/03

¹ Validation is defined as the review of information, data and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

² The only exception is the San Mateo MHP, which operates under a separate waiver and receives FFP under a case rate reimbursement basis.

³ Penetration rates for both PMs are calculated by dividing the total number of clients receiving services in the identified category of client and dividing by the average monthly eligible number of persons eligible to receive Medi-Cal services.

In Year One it will also be necessary to verify that the MHP is in compliance with the required elements for a health information system in Medicaid managed care regulations and to develop an appropriate Information System Capabilities Assessment (ISCA) protocol for the MHPs that will include the validation of encounter data⁴. This ISCA protocol will be used to assess the MHP's Information System in future years.

II. Purpose of the PM Protocol

The purpose of the PM Protocol is to assist the EQRO to accomplish the following:

1. Review of the data management processes of DMH and the MHPs
2. Evaluation of the translation of captured data into actual statistics by DMH
3. Verification of the DMH-specified PMs to confirm that the reported results are based on accurate source information
4. Verification that MHPs are in compliance with the basic required elements for a health information system under 42 CFR 438.242
5. Development of an MHP ISCA protocol for DMH approval

The protocol consists of three phases of tasks: Pre-Onsite, Onsite, and Post-Onsite activities. Each of these phases will apply to both DMH and each of the MHPs. For each of these phases, the PM 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 PM Protocol and as attachments.

A. Pre-Onsite

Pre-Onsite activities involve:

1. Communicate with DMH to ensure that the EQRO understands:
 - The measures to be validated.
 - The methodology(ies) DMH has used to calculate and report the performance measures.
2. Develop schedules and preparing DMH and the MHP for onsite activities:

⁴ For purposes of this document, the term "encounter data" means documentation of contacts in a client's chart.

- Communicating with the identified DMH and MHP contact person
 - Indicating, in writing, to DMH and the MHP the EQRO's requirements for the conduct of the assessment including anticipated time on-site, space needs and preliminary data and documentation needs
 - Communicating the EQRO's policies and procedures with respect to safeguarding confidential information
 - Identifying, prior to the site visits, probable key staff to be interviewed
3. Identifying the appropriate stakeholders to be involved in the development of an appropriate assessment protocol for assessing an MHP's underlying information system (IS), and/or reviewing the results of any prior assessment that has been done for an MHP.

B. Onsite Activities

Onsite activities include activities onsite at both DMH and at individual MHPs. They focus on: 1) validating the data for performance measures by DMH through observation of documentation or procedures; and (2) verifying that the MHP is in compliance with the required elements for a health information system and gathering the information necessary in Year One to develop an appropriate MHP "Information System Capabilities Assessment" (ISCA) protocol which will include validation of the encounter data upon which the MHP's claims are based. These activities include:

For DMH:

1. Reviewing and assessing the procedures DMH has in place for integrating eligibility and claims information.
2. Evaluating processes used by the DMH to produce PMs, e.g., calculating denominators and numerators.

For the MHP:

1. Reviewing the procedures the MHP has in place for collecting and/or integrating mental health service, financial, eligibility and service provider information, covering service-related data, from internal and external sources.
2. Verifying that the MHP currently has an Information System that meets the basic required elements of a health information system as described in 42 CFR Section 438.242.

3. Working with the MHP and other stakeholders to develop an appropriate ISCA protocol.

To accomplish these activities, the EQRO reviews DMH and MHP policy and procedure manuals and documents, observes required activities, and conducts interviews with key DMH PM staff and MHP staff such as Information Systems, Fiscal and Quality Improvement staff.

C. Post-Onsite

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, the MHP ISCA protocol and supporting documentation to DMH following its format and time frames. These activities include:

1. Evaluating gathered information and preparing a report of preliminary findings on the validation of PMs and the status of each MHP's compliance with the required basic elements of a health information system.
2. Submitting reports of preliminary findings identifying areas of concern to DMH and the MHPs.
3. Submitting a draft ISCA protocol to DMH and the MHPs.
4. Evaluating DMH and MHP comments concerning the preliminary findings and the draft ISCA protocol to assure accuracy and completeness of findings.
5. Evaluating gathered information and preparation of findings for DMH .
6. Submitting reports and the ISCA protocol to DMH.

The EQRO will submit a summary of its findings along with the completed protocol assessment tools to DMH as supporting documentation.

III. Protocol Activities

A. Pre-Onsite Activities for DMH

Objectives for Pre-Onsite Activities:

The EQRO will:

- Understand the technical specifications for each of the performance measures calculated by DMH.
- Understand DMH's requirements for claims data reporting by the MHP to the State (e.g., report template, electronic submission format, etc.).

Pre-Onsite Activity 1: Review the DMH's requirements for performance measurement and reporting

The EQRO will be responsible for validating PMs that the DMH has calculated from data submitted by the MHPs. The EQRO will need to obtain DMH's specifications and information on how these were calculated.

The EQRO must understand DMH's specifications for each PM, and DMH's instructions to the MHPs for reporting the required data upon which these PMs are based.

The EQRO needs to understand the expected dates and format for DMH and MHP reporting.

DMH has calculated the performance measures to be validated, based on claims submitted by the MHP and paid by DMH. For each measure, the EQRO should create a PM validation worksheet that contains the specifications and components of each PM that is to be validated, including: 1) specifications for the eligible population for the measure; 2) data collection methodology; 3) denominator calculations; 4) numerator calculations; and 5) calculated and reported rates. A generic "Performance Measure Validation Worksheet" is found below containing the components to be validated and the elements to be audited.

Using a performance measure validation worksheet will improve the efficiency of the validation work performed. An example of a completed Performance Measure Validation Worksheet is included as PM Protocol ATTACHMENT I.

GENERIC PERFORMANCE MEASURE VALIDATION WORKSHEET				
<i>For each performance measure to be validated, adapt the generic table shell below to create a validation worksheet for the measure. (An example of a completed Performance Measurement Worksheet is included as ATTACHMENT I).</i>				
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, computer source code			
Denominator	Data sources used to calculate the denominator were appropriate for the time period			
	Calculation of the performance measure adhered to the specifications for all components of the denominator of the performance measure			
Numerator	Data sources used to calculate the numerator were appropriate for the time period			
	Calculation of the performance measure adhered to the specification for all components of the numerator of the performance measure			
Reporting	State specifications for reporting performance measures were followed			

****ASSIGNING A VALIDATION FINDING TO THE MEASURE (See NOTE)**

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 DMH specifications

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

NV = Not Valid - Measure deviated from DMH 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.

AUDIT DESIGNATION	
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NOTE: 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 PM validation worksheet

Pre-Onsite Activity 2: Prepare DMH for EQRO Onsite Activities

Prior to conducting onsite activities, the EQRO will contact DMH to:

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

An introductory letter to DMH should discuss the above issues and explain the EQRO's potential need to interview DMH personnel, so that interviewees are prepared in terms of time and information. Potential interviewees include any DMH and contract staff whose areas of expertise or responsibility relate to PM and whose insights might improve the EQRO's understanding of DMH processes to calculate or report PMs.

In preparation for its onsite activities, the EQRO will provide to DMH a list of the documents and processes that the EQRO may review during the course of the validation activities (PM Protocol ATTACHMENT II). This list is intended to assist DMH in preparing for the validation audit.

B. Pre-Onsite Activities for MHPs

Objectives for Pre-Onsite Activities:

The EQRO will gather information from the MHP and/or review the results of a previously conducted assessment in order to verify that the MHP is in compliance with the required elements for a health information system and to develop an appropriate MHP ISCA protocol to use in future years when assessing the MHP's IS.

Pre-Onsite Activity 1: Prepare the MHP for EQRO Onsite Activities

Prior to conducting onsite activities, the EQRO will contact the MHP to:

- Explain the procedures and time line for working with the MHP regarding the development of a protocol for assessment of the MHP's information system.
- Request identification of personnel within the MHP who will be responsible for responding to EQRO requests for documentation or information, as well as scheduling activities and interviews.
- Communicate the EQRO's policies and procedures with respect to safeguarding confidential information.

An introductory letter to the MHP should discuss the above issues and explain the EQRO's potential need to interview MHP personnel, so that interviewees are prepared in terms of time and information. Potential interviewees include any MHP or contract staff whose areas of expertise or responsibility relate to the MHP's information system.

Also, in preparation for its onsite activities, the EQRO will provide to the MHP a list of the required basic elements of a health information system under 42 CFR Section 438.242. This list is intended to assist the MHP in preparing for the EQRO's verification of the MHPs compliance with these requirements.

Pre-Onsite Activity 2: Develop a representative stakeholder group to work with the EQRO in drafting an appropriate and relevant ISCA protocol for MHPs.

Complete and accurate data is key to valid and reliable PMs. If these two data characteristics are not maintained, then calculated measures become biased, and their validity jeopardized. Therefore it is necessary for the EQRO to assess the integrity of the ISs from which the data is derived. Although performance measures are calculated by DMH rather than the MHPs California, it is based upon claims data that has been submitted to the State by the MHPs; therefore, it is necessary to assess the MHPs ISs. However, because the MHPs are not capitated and do not generate their own performance measures, the ISCA provided in the EQRO protocols by CMS is not appropriate. Therefore, in the first year, the EQRO will need to develop an appropriate protocol for assessing the integrity of the MHPs' IS and the completeness and accuracy of the data produced by that system. Thereafter, the EQRO will conduct an ISCA using the approved protocol or review the results of a prior assessment. Prior to conducting the MHP On-Site Activities, the EQRO will:

- With assistance from the DMH Contract Administrator, contact appropriate stakeholders to identify and select a representative group to work with the EQRO in drafting an appropriate and relevant ISCA protocol for MHPs.

- Hold a preliminary meeting with this group prior to conducting On-Site Activities at the MHPs.

C. Onsite Activities for DMH

Objectives for Onsite Activities

The EQRO will evaluate the extent to which DMH has:

- Adequate data integration and control procedures for accurate production of the DMH-specified PMs.
- Complete and accurate documentation of data and processes used to calculate and report the DMH-specified measures.
- Correctly implemented appropriate processes for calculating and reporting the DMH-specified PMs.

Onsite Activity 1: Assess data integration and control.

This onsite activity assesses: 1) the DMH's ability to link data from multiple sources in order to calculate the required measures; and 2) whether DMH has used these abilities in a manner that ensures the accuracy of the calculated PMs. This assessment will be accomplished through:

1. Review of documentation, procedures, and data pertaining to the PMs
2. Interviews with DMH personnel with knowledge of the source data files and their use in performance measurement

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

1. Examine for accuracy and completeness the details of DMH's processes to transfer data from all data files necessary to calculate PMs and to keep the data until the calculations of the PMs has been completed and validated.

2. Examine samples of data from the data repository and transaction files to assess completeness and accuracy.
3. Investigate the DMH's processes to consolidate diversified files and extract required information from a PM repository or other data consolidation file.
4. Compare actual results of file consolidations or extracts to those that should have resulted according to documented algorithms or specifications.
5. Assess the extent to which proper linkage mechanisms have been employed to join data from all necessary sources.
6. Examine and assess the adequacy of the documentation governing the PM production process, including DMH production activity logs, and DMH staff review of report runs.
7. Review documentation that confirms that prescribed data cutoff dates were followed.
8. If appropriate, request that DMH demonstrate it has retained copies of files or databases used for PM reporting, in the event that results need to be reproduced.
9. Review documentation standards that assure that the PM reporting software program is properly documented with respect to every aspect of the reporting repository, including building, maintaining, managing, testing, and report production.
10. Review DMH's process and documentation to ensure that it complies with specified standards associated with the PM reporting program specifications, code review, and testing.

In addition, as needed, the EQRO should supplement the direct examination of performance measurement policies, procedures, and data with interviews of DMH personnel. DMH personnel who can potentially provide helpful information include all staff involved in the calculation of performance measures. An Interview Guide and suggested questions to ask during these interviews are located at PM Protocol ATTACHMENT IV, Guide for Interviews of DMH Personnel Concerning Data Integration and Control.

The EQRO should document all findings with respect to the adequacy of DMH's data integration and control procedures on a worksheet such as that found in PM Protocol 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.

DMH should have documentation of all steps undertaken in the production of the required PMs, including documentation of: 1) steps taken to integrate the required data into a PM data set or repository; and 2) 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 PMs.

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
- 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 the following information, as appropriate:

- A project or measurements plan, including workflow
- All data sources, including external data and any prior years' data
- 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

- 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. A list of the documentation to be reviewed is located at PM Protocol ATTACHMENT VI, Data and Processes Used to Calculate and Report Performance Measures - Documentation Review Worksheet. In addition, as needed, the EQRO will interview staff involved in the calculation of PMs 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, maps to standard coding) updated and enforced? Who is responsible for this?
2. How are programming specifications for DMH PMs documented? Who is responsible for this?
3. Are the documentation processes up to date?

The results of the EQRO's review of the DMH's documentation of data and processes used to prepare and submit PMs should be recorded on a form such as that found as PM Protocol 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 DMH used the appropriate data (including linked data from separate data sets) to identify the entire eligible population. The "appropriate data" will vary from measure to measure, and may be adjusted to exclude certain clients for reasons identified in the specifications established by DMH for calculating the measure. In conducting this activity, the EQRO will need to refer to the DMH'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 DMH and chosen to be included in the validation activity***, the EQRO will assess the extent to which:

1. All individuals who were eligible to receive the specified services under study were included in the initial population from which the final denominator was produced. This population will include both eligibles that received the services, as well as those who did not. This same validation activity applies to other relevant populations identified in the specifications of each performance measure. The EQRO will evaluate the extent to which DMH used appropriate mathematical operations to determine client age or range.
2. DMH has correctly calculated eligible months and eligible years, if applicable to the PM.
3. DMH has properly evaluated the completeness and accuracy of any codes used to identify events, such as diagnoses and/or services, and that these codes have been appropriately identified and applied as specified in each PM.
4. Time parameters required by the PM specifications are followed.
5. PM specifications or definitions were followed in excluding eligibles from a denominator.

Policies, procedures, data, and information to be reviewed in conducting these activities are listed in PM Protocol ATTACHMENT VIII. Information obtained from a review of these policies, procedures, data, and information should be supplemented and confirmed, as needed, through interviews with DMH personnel involved with the calculation of performance measures. Suggested questions to be asked are located in PM Protocol 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 DMH has correctly identified and evaluated qualifying service events in order to include appropriate

events in the numerator of the performance measure. These “service events” may be identified through approved claims.

As with denominators, accurate and complete data collection is vital to this element of PM calculation. For measures that include sampling in the methodology, the entire eligible population must have an equal chance to be included in the numerator.

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

1. DMH has used the appropriate data, including linked data from separate data sets, to identify the entire population that meets the specified criteria for inclusion in the numerator.
2. DMH’s use of codes to identify service events (such as types of service) 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 individuals for inclusion or exclusion in the numerator.
3. DMH has avoided or eliminated double-counted individuals or numerator events.
4. Codes used by DMH are correctly mapped 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.
5. DMH 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).

Policies, procedures, data, and information to be reviewed in conducting these activities are listed in PM Protocol ATTACHMENT XI. These activities will need to be carried out with respect to each performance measure calculated by DMH 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 PM Protocol ATTACHMENT I.

Information obtained from a review of policies, procedures, data, and information should be supplemented or confirmed, as needed, through interviews with DMH

personnel involved in the calculation of performance measures. Suggested questions are the same as those asked with respect to denominators and are located at PM Protocol ATTACHMENT IX.

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

D. Onsite Activities For The MHP

Objectives for Onsite Activities:

For the first year, the EQRO objectives for MHP onsite activities are:

- To gather the necessary information to develop an ISCA protocol for future MHP IS assessment; and
- To verify that the MHP is currently in compliance with the following basic requirements of a health information system under CFR 438.242:
 - The MHP's collects data on client and provider characteristics as specified by the State, and on services furnished to enrollees in order to generate claims.
 - The MHP ensures that data received from providers is accurate and complete by:
 - Verifying the accuracy and timeliness of the reported data;
 - Screening the data for completeness, logic and consistency; and
 - Collecting service information in standardized formats to the extent feasible and appropriate.
 - The MHP makes all collected data available upon request to the State, and/or CMS.

Onsite Activities will include interactive sessions with MHP staff designed to:

- Get information about the types of data collected.
- Understand the MHPs processes for managing data and developing claims.
- Understand the structural components of the MHPs IS, focusing on the collection and processing of encounter data on which claims submission is based.
- Enable the EQRO to verify the MHP's status regarding compliance with the basic required elements of a health information system.
- Enable the EQRO to develop a relevant and appropriate ISCA protocol to be used to assess the integrity of the MHP's IS in future years.

E. Post-Onsite Activities

Objectives for Post-Onsite Activities:

The EQRO will evaluate all gathered information and submit a report on its validation findings, its findings regarding the status of MHPs' compliance with the required basic elements of a health information system and a proposed ISCA protocol to the State, after review and comment by the DMH and each MHP for any factual errors or omissions.

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 PM. This involves review and analysis of findings and worksheets produced for each PM selected for validation and calculated by DMH including:

- Completed PM validation worksheets for each performance measure to be validated (as in ATTACHMENT I) in conjunction with the Denominator Validation Findings (ATTACHMENT X) and Numerator Validation Findings (ATTACHMENT XII)
- Findings regarding DMH's data integration and control procedures (ATTACHMENT V)

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

Once the EQRO has submitted its preliminary findings regarding PMs to DMH, DMH may offer comments and documentation to support correction of factual errors and omissions in the EQRO's preliminary report.

Once DMH's comments have been appropriately incorporated into the validation findings, the EQRO will submit its findings.

Post-Onsite Activity 2: Submission of validation report to DMH.

In determining the validity of each of the statewide PMs the EQRO will reference a clearly defined set of decision rules for determining if DMH's reported PMs were sufficiently valid; i.e., accurate and complete. DMH will receive the final report and all supporting documentation.

DMH will specify the level of bias that is permissible or allowable in the calculated PMs and encounter data in order for the PMs to be considered "valid measures." The EQRO will need to make an estimate about the cumulative affect of all sources of bias on the validity of the PM.

The format for the final report should follow the format specified by DMH, and will include the following elements:

- A list of measures for validation.
- A description of the DMH 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 PM.
- The validation findings for each PM included in the EQRO validation activities.

- Analysis and findings with respect to DMH's data integration and control procedures for PM calculation documentation.

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

Post-Onsite Activity 3: Submission of report to DMH regarding the status of each MHP with regard to meeting the basic required elements of a health information system under 42 CFR 438.242.

The format for the final report should follow the format specified by DMH, and will include the following elements:

- A list of the required elements of a health information system under 42 CFR Section 438.242
- The findings for each MHP regarding their compliance with the required elements
- In addition, the EQRO might also be asked to submit all or some worksheets and tools as supporting documentation to the report.

Post-Onsite Activity 4: Developing an MHP ISCA protocol to assess the integrity of the MHP's IS and submitting it to DMH for approval.

After identifying and having preliminary meetings with representatives of the appropriate stakeholders to be involved in the development of an appropriate ISCA: protocol for MHPs (MHP Pre-Onsite Activity 2) and the gathering of information from MHPs about their ISs, (MHP On-Site Activity), the EQRO will develop a draft MHP ISCA protocol for review by the stakeholder group.

The EQRO will submit the draft to the stakeholder group for review and comment and incorporate their feedback into a final draft.

Once the stakeholder group's feedback has been appropriately incorporated into the protocol, the EQRO will submit the final MHP ISCA protocol to DMH.

In addition, the EQRO might be asked to submit a description of on-site activities, all or some worksheets, copies of meeting minutes, etc. as supporting documentation for the development of the ISCA protocol.

PM Protocol ATTACHMENT I

Example of a Completed Performance Measure Validation Worksheet

Below is an example of a completed, customized performance measure validation worksheet similar to what the EQRO would prepare prior to its onsite visit. One of the following scoring designations must be checked for each audit element

Met: DMH's measurement and reporting process was fully compliant with specifications

Not Met: DMH's measurement and reporting process was not compliant with specifications. This designation should be used for any audit element that deviates from the 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 DMH's measurement and reporting process

PERFORMANCE MEASURE VALIDATION WORKSHEET				
Performance Measure to be Validated: Penetration Rate Calculations				
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, computer source code			
Denominator	Data sources used to calculate the denominator were appropriate for the time period			
	Calculation of the performance measure adhered to the specifications for all components of the denominator of the performance measure			
Numerator	Data sources used to calculate the numerator were appropriate for the time period			
	Calculation of the performance measure adhered to the specification for all components of the numerator of the performance measure			

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 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 DMH specifications.

SC = Substantially Compliant

Measure was substantially compliant with DMH specifications and had only minor deviations that did not significantly bias the reported rate.

NV = Not Valid

Measure deviated from DMH 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.

AUDIT DESIGNATION	
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PM Protocol ATTACHMENT II

Potential Documents and Processes for Review

In order to assess the validity of reported performance measures, the EQRO will need to review a number of data sources and processes. DMH 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 to consolidate information from disparate transaction files.
- Record and file formats and descriptions, for files used in producing performance measures.
- Source code for data manipulation programs and processes.
- Descriptive documentation for data manipulation programs and processes.
- Documentation of correct time period used in programs.
- Procedures governing process for DMH performance measures.

Collection, Calculation, and Documentation of Performance Measurements

- A project or measurement plan for each performance measure.
- 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.
- Procedures to link member months to member age.
- Description of software or programming languages used to query each database.
- Database record layout and data dictionary.
- Evidence that DMH has counted each member and/or event appropriately.
- Procedures for displaying denominator counts, numerator counts, precision levels, sums and cross-totals.
- 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, 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 calculation of levels of significance of changes.

PM Protocol ATTACHMENT III

IS Data Integration and Control - Documentation Review

Documentation	Reviewed	Not Reviewed	Comments
Procedures to consolidate information from disparate transaction files to support performance measurement			
Record and file formats and descriptions for files used in producing performance measures			
Source code for data manipulation programs and processes			
Descriptive documentation for data manipulation programs and processes			
Comparison of actual results from file consolidation and data abstracts to those which should have resulted according to documented algorithms			
Documentation of correct time periods			
Procedures governing process for DMH measures			

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

Is the required level of coding detail maintained (e.g. all significant digits, primary and secondary diagnoses remain)?

How does DMH test the process used to create the performance measure reports?

PM Protocol ATTACHMENT IV

Guide for Interviews of DMH Personnel Concerning Data Integration

Background Information:

Date:

Location:

Year of First DMH Performance Report:

Auditors:

Names and Titles of Individuals Interviewed:

Has DMH 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:

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 all other reporting is produced from? Are reports created from a vendor software product? If so, how frequently are the files updated? How are reports checked for accuracy?
3. Review the procedure(s) for consolidating claims, member, provider, and other data necessary for performance reporting.
 - How many different sources of data are merged together to create reports?
 - What control processes are in place to ensure that this merger is accurate and complete?
 4. How does DMH test the process used to create the performance measure reports?
 5. Does DMH use any algorithms to check the reasonableness of data integrated to report the DMH performance measures
 6. Does supervisory staff review performance measurement reporting programs?
 7. 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?
 8. What types of authorization are required to be able to access claims/encounter, provider, membership, and performance measure repository data?

Describe Documentation Review and Demonstrations Provided:

PM Protocol ATTACHMENT V

Data Integration and Control Findings – Documentation Worksheet

Data Integration and Control Element	Met	Not Met	N/A	Comments
<i>Accuracy of file consolidations, extracts and derivations</i>				
<ul style="list-style-type: none"> ▪ DMH processes to consolidate diversified files, and to extract required information from the performance measure repository are appropriate 				
<ul style="list-style-type: none"> ▪ Actual results of file consolidations or extracts were consistent with those which should have resulted according to documented algorithms or specifications 				
<i>If DMH uses one, the structure and format of the performance measure data repository facilitates any required programming necessary to calculate and report required performance measures</i>				
<ul style="list-style-type: none"> ▪ Proper linkage mechanisms have been employed to join data from all necessary sources 				
<i>Assurance of effective management of report production and of the reporting software</i>				
<ul style="list-style-type: none"> ▪ Examine and assess the adequacy of the documentation governing the calculation of the performance measures 				
<ul style="list-style-type: none"> ▪ Appropriate time periods are used 				
<ul style="list-style-type: none"> ▪ DMH has retained copies of files or databases used for performance measure reporting, in the event that results need to be reproduced 				
<ul style="list-style-type: none"> ▪ Review documentation to standards to determine the extent to which the reporting software program is properly documented with respect to every aspect of the performance measurement reporting 				

PM Protocol ATTACHMENT VI

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

Documentation	Reviewed	Not Reviewed	Comments
Procedures for displaying denominator counts, numerator counts, precision levels, sums and cross-totals			
Review of reported measures to assess consistency of common elements (e.g., eligible and client counts)			
<i>For Each Measure:</i>			
Programming logic and/or source code for arithmetic calculation			
A project or measurement plan for performance measurement			
Documentation of programming specifications and data sources			
Documentation of the original universe of data including record-level client identifiers that can be used to validate entire programming logic for creating denominators, numerators and samples			
Documentation of computer queries, programming logic, or source code used to create denominators, numerators and interim data files			
Documentation of results of statistical tests and any corrections or adjustment 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 of sources of any supporting external data or prior year's data used in reporting for each performance measure, as appropriate			

Describe Documentation Reviewed and Demonstrations Provided:

PM Protocol ATTACHMENT VII

**Data and Processes Used to Calculate and Report Performance Measures –
 Documentation Worksheet**

Audit Element	Met	Not Met	N/A	Comments
<i>Measurement plans and policies that stipulate and enforce documentation of data requirements, issues, validation efforts and results. These include:</i>				
▪ Data file and field definitions used for each measure				
▪ Statistical testing of results and any corrections or adjustments made after processing				
<i>Documentation of programming specifications (which may be either a schematic diagram or in narrative form) for each measure includes at least the following:</i>				
▪ All data sources and appropriate fiscal years				
▪ Documentation of calculation for changes in performance from previous periods (if applicable) including statistical test of significance				
▪ Data that are related from measure to measure are consistent (e.g., eligible and client counts)				
▪ When determining improvement in performance between measurement periods, appropriate statistical methodology is applied to determine levels of significance of changes				

PM Protocol ATTACHMENT VIII

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

Documentation	Reviewed	Not Reviewed	Comments
Procedures to identify, track and link eligibles by geographic area, age, gender			
Procedures to link eligibility within age group			
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			
Database record layout and data dictionary			

PM Protocol 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 DMH technical specifications as the specifications for the programmers?
4. Are there any manual processes used for calculating denominators and/or numerators?
5. Do you have any concerns about the integrity of the information used to create any of the measures? Please describe.

Other issues:

Names and Titles of Individuals Interviewed:

PM Protocol ATTACHMENT X

Denominator Validation Findings - Reviewer Worksheet

Audit Element	Met	Not Met	N/A	Comments
<i>For each of the performance measures, all members of the relevant populations identified in the performance measure specification are included in the population from which the denominator is produced</i>				
All individuals who were eligible to receive the specified services under study were included in the initial population from which the final denominator was produced. This population will include both clients who received the services, as well as those who did not. This same validation activity applies to other relevant populations identified in the specifications of each performance measure.				
<i>Adequate programming logic or source code exists to appropriately identify all "relevant" members of the specified denominator population for each of the performance measures</i>				
Proper mathematical operations were used to determine client age or range				
Documentation of calculation for changes in performance from previous periods (if applicable) including statistical test of significance				
DMH can explain what classification is used when data are missing, when the missing data are needed to calculate the performance measure(s).				
<i>Correct calculation of eligible months</i>				
DMH has correctly calculated eligible month, if applicable to the performance measure				
<i>Completeness and accuracy of the codes used to identify service events has been identified and the codes have been appropriately applied</i>				
DMH has properly evaluated the completeness and accuracy of any codes used to identify service events, such as diagnoses or type of service, and these codes have been appropriately identified and applied as specified in each performance measure				
<i>Specified time parameters are followed</i>				
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.)				
<i>Exclusion criteria included in the performance measure specifications have been followed</i>				
Performance measure specifications or definitions that exclude eligibles from a denominator were followed. For example, if a measure relates to selected age groups, the denominator may need to be adjusted to reflect only those clients within the age group				

PM Protocol ATTACHMENT XI

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

Documentation	Reviewed	Not Reviewed	Comments
DMH's use of codes to identify service events (such as types of service) were correctly evaluated when classifying individuals for inclusion or exclusion in the numerator			
Evidence that DMH has counted each individual and/or event appropriately			
Programming logic or demonstration that confirms that any data elements used in determining the numerator have been correctly used in a manner that is consistent, complete and reproducible			
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			

PM Protocol ATTACHMENT XII

Numerator Validation Findings - Reviewer Worksheet

Audit Element	Met	Not Met	N/A	Comments
<i>All appropriate data are used to identify the entire at-risk population.</i>				
DMH has used the appropriate data, including linked data from separate data sets, to identify the entire population that meets the specified criteria for inclusion in the numerator				
<i>Qualifying service events (such as types of service) are properly identified and confirmed for inclusion in terms of time and services</i>				
DMH's use of codes to identify service events (such as types of service) are complete, accurate, and specific in correctly describing what has transpired and when.				
DMH correctly evaluated service codes when classifying individuals for exclusion or inclusion in the numerator				
DMH has avoided or eliminated double-counted individuals or numerator events.				
Codes used by DMH are correctly mapped 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 specification 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				

Performance Improvement Project Protocol

External Quality Review of Mental Health Plans

I. Introduction

In response to recent changes in Medicaid managed care regulations, the Department of Mental Health (DMH) must provide for annual external quality review of the quality, outcomes, timeliness of and access to services provided by Mental Health Plans (MHPs). Specifically, MHPs must conduct Performance Improvement Projects (PIPs) and those PIPs must be annually validated and reviewed by an External Quality Review Organization (EQRO).

The purpose of mental health care PIPs is to assess and improve care processes and thereby improve outcomes of care. In order for such projects to achieve real improvements in care, and for interested parties to have confidence in the reported improvements, PIPs must be designed, conducted and reported in a methodologically sound manner. To achieve this goal, this PIP Protocol identifies procedures for an EQRO to use in its validation⁵ of MHP PIPs.

In California, DMH receives claims data from MHPs and utilizes this data to calculate performance measures. MHPs may utilize this DMH claims data in PIPs to determine initial baseline conditions and/or as indicators of improvement. Therefore, validation of a PIP by the EQRO may need to include an assessment of DMH processes for receiving, analyzing and transmitting data from and to the MHPs. Review activities in this Protocol may need to take place at two levels, at DMH and at each MHP.

PIPs will focus primarily on the Medi-Cal client but non-Medi-Cal clients may also be included in the studies. More than one MHP may choose to study the same aspect of care, and MHPs may choose to collaborate on PIP design and implementations.

Only one PIP, in progress or completed, will be evaluated during the annual review of each MHP. PIPs will focus primarily on the Medi-Cal client, but non-Medi-Cal clients may also be included in the studies. More than one MHP may choose to study the same aspect of care, and counties may choose to collaborate on PIP design and implementation.

⁵ Validation is defined as the review of information, data and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

DMH has determined that in Year One of external quality review, a MHP may identify a PIP of its choice that was conducted as part of the MHP's ongoing Quality Improvement (QI) Program. DMH does require that the PIP shall have been initiated no earlier than during FY 2002-2003, and no later than six months before the EQRO site visit. PIP requirements for subsequent years of external quality review (EQR) will be determined in consultation with the EQRO, and other stakeholders and organizations in the public managed care mental health community.

II. Purpose of the Performance Improvement Project (PIP) Protocol

The purpose of the PIP Protocol is to assist the EQRO to accomplish two important activities:

1. Assessment of the MHPs' methodology for conducting the PIP
2. Evaluation of the overall validity and reliability of study results

In order to complete the PIP Protocol and accomplish these activities, the EQRO will need to perform various tasks at various times, before, during and after the on-site review itself. The PIP Protocol refers to these as Pre-onsite, Onsite, and Post-Onsite tasks. For each of these, the PIP Protocol provides:

- Outcomes or objectives
- Lists the specific tasks to be performed
- Suggests possible methods of evaluation
- Provides a sample worksheet is provided as an attachment to the protocol

Pre-Onsite activities involve:

1. Communicating with DMH to be sure the EQRO understands:
 - QI requirements, including those defined in the contract between DMH and MHPs.
 - Requirements, data and other technical assistance provided to MHPs by DMH in preparation for the conduct of a PIP.
2. Reviewing each MHP's preliminary report to DMH on the study question, design and progress of its PIP.

3. Developing schedules and preparing DMH and the MHP for onsite activities:

- Communicating with identified DMH and MHP study contact persons.
- Indicating, in writing, to DMH and MHP, the EQRO's requirements for the conduct of the assessment including anticipated time on-site, space needs, and preliminary data and documentation needs.
- Communicating the EQRO's policies and procedures with respect to safeguarding confidential information.
- Identifying, prior to the site visit, probable key staff to be interviewed.

Onsite activities involve:

1. Evaluating processes used by DMH to obtain, analyze and report data to MHPs if necessary.
2. Evaluating processes used by MHP's to obtain and analyze data pertinent to each PIP.
3. Validating data used in determining the study question (MHP), the specific study focus (MHP) and the findings of the study.
4. Assessing the degree to which the PIP responded to the study question.
5. Assessing the overall reliability and validity of the PIPs.

To accomplish these activities, the EQRO reviews MHP Policies and Procedure Manuals, Quality Improvement Plans and Work Plans, and other documents, as indicated; reviews any information system (IS) analyses at DMH performed in response to the DMH Performance Measurement Protocol; observes required activities; conducts interviews with key DMH and MHP staff such as the Mental Health Director, and with key Information Systems and Quality Improvement staff; interviews staff responsible for the conduct and analysis of the PIP.

Post-Onsite activities involve:

1. Evaluating gathered information and preparing a report of preliminary findings.
2. Submitting reports of preliminary findings identifying areas of concern to DMH and the MHP.
3. Evaluating DMH and MHP comment concerning the preliminary findings to assure accuracy and completeness of findings.
4. Evaluating gathered information and preparation of finding for DMH.

5. Submitting reports to DMH following the format and timeframes established by DMH.

III. Protocol Activities

Activity 1: Assess the study methodology

Assessing the MHP's methodology for conducting a PIP requires the EQRO to have information on the design and implementation of the PIP.

Pre-Onsite: In order to utilize onsite time efficiently, a hardcopy or electronic written description of the PIP design and implementation will be transmitted by MHPs to DMH and through DMH to the EQRO. The EQRO may augment this information with telephonic or electronic interviews with key MHP staff to assure the EQRO has a clear understanding of the intent and design of each PIP prior to the site visit. The EQRO will particularly note the status of the study within the DMH required timelines, so that assessment will be appropriate for studies at all stages of completion.

Onsite: Preliminary summary information will be augmented at the MHP level by complete study documentation. Additional interviews and ad hoc requests for information necessary to clarify the design process and analysis may occur at MHP or DMH levels.

Whatever source(s) of information are used, the EQRO should follow the steps below to assess the methodology of the PIP. Answers to the questions in each of the steps should be recorded on a standardized PIP Validation Worksheet that is provided by DMH and included as Attachment I.

Step 1. Review the Selected Study Topics

All PIPs should target improvement in relevant areas of clinical care or non-clinical services and be reflective of the MHPs' Medi-Cal population in terms of such factors as demographic characteristics, prevalence and potential consequences (risks) of the disease or of unmet needs.

Potential Sources of Supporting Information

To perform this analysis, the EQRO shall utilize, but not be limited to, potential sources of supporting information such as:

- Medi-Cal enrollment files on enrollment characteristics relevant to health risks or utilization of clinical and non-clinical services, such as age, sex, race/ethnicity/language and disability or functional status
- Utilization, diagnostic and outcome information on Medi-Cal outpatient and inpatient encounters, services, procedures, medications and devices, admitting and encounter diagnoses; and patterns of referrals or authorization requests obtained from MHP encounter, claims, or other administrative data
- Data from outside organizations such as local or national public health reports on conditions or risks for specified populations
- Data from other DMH or MHP committees, such as the State and MHP Quality Improvement Committees and Cultural Competency Committees
- Data from surveys, grievance and appeals processes
- Data on appointments and provider networks

Methods of Evaluations

The EQRO will review documentation at the MHP level and, as needed, sources suggested above, to assess the extent to which the MHP selected an appropriate study topic. In general, the issue selected for study should affect a significant portion of the enrollees (or a specified sub-portion of enrollees) and have a potentially significant impact on enrollee mental health, functional status or satisfaction.

The EQRO will review documentation at the MHP level to determine how the study topic was chosen and to evaluate sources of data and findings. It will determine the extent to which the MHP considered enrollee demographics and mental health risks, and the prevalence of the chosen topic among, or the need for a specific service by, enrollees. It will also consider whether a topic may have been selected on the basis of Medicaid enrollee input and/or be of a quality process required by contract with DMH for annual study.

The EQRO will consider the following questions to ascertain the extent to which the MHP choice of study focus reflected an appropriate study topic.

1. Was the topic chosen by the MHP identified by data collection and analysis of comprehensive aspects of enrollee needs, care and services?
2. Was the topic selected based on enrollee input and/or identified for study in the contract between DMH and the MHP?

Step 2. Review the Study Question(s)

The MHP should clearly state, in writing, the question(s) the study is designed to answer. Stating the question(s) helps maintain the focus of the PIP and sets the framework for data collection, analysis and interpretation.

Pre-Onsite: Summary statements reviewed by the EQRO should include the study question(s). The EQRO may request clarification from the MHP prior to the site visit if the study question is not clearly defined.

Onsite: The EQRO will further clarify the study question with key MHP staff, including QI staff and those responsible for the management of the PIP.

Potential Sources of Supporting Information

- QI and other documentation
- MHP level demographic analyses

Methods of Evaluation:

The EQRO will review project documentation to determine whether a study question(s) was clearly defined. The problem to be studied must be stated as clear, simple, answerable questions. For example, in a study of access barriers, the study question might ask, “Does the location of the clinic(s) impact utilization of mental health services by Latino beneficiaries?” or, “Do the opening and closing hours of a mental health clinic have an impact on Older Adult Access?”

Step 3. Review the Selected Study Indicator(s)

A Study Indicator is a quantitative or qualitative characteristic (variable) reflecting a discrete event or a status that is to be measured. Each project should have one or more quality indicators for use in tracking performance and improvement over time. All indicators must be objective, clearly and unambiguously defined, and based on current information. All indicators must be capable of objectively measuring either enrollee outcomes, such as enrollee access or satisfaction, or be valid proxies of these outcomes. Indicators can be few and simple, many and complex or any combination thereof, depending on the study question(s) and the availability of data and resources to gather the data.⁶

As an example, the PIP selected might be a non-clinical study that is focused on assessing and improving the accessibility of services to a specific population, including reducing disparities between services to this population and services to other enrollees. Indicators would be selected in the study design to identify areas of needed improvement and to measure improvement over time. Penetration rates for the population being studied would be measurable indicators in a study of access.

⁶ It has been found, in program evaluation literature, that “outcome measures”, “measures”, and “indicators” appear to be used interchangeably. This protocol has selected the term “Study Indicator”.

Indicator criteria are the set of rules by which the data collector or reviewer determines whether an indicator has been met. These rules would indicate, for the example above, specific definitions of the population(s) studied, how the data for penetration rates are to be derived, and the sources of data providing the numerator and the denominator to establish the rate. Indicator criteria might specify how access will be determined, for example, defining it as a single encounter within a given period of time for average monthly eligibles. As an example, a study of utilization of services, the indicator criteria might define utilization as a minimum number of encounters of a specific type within a given time frame.

Because MHPs will not all be at the same level of completion of the PIPs, some projects will reflect initial collection and analysis of baseline data on a topic. For these PIPs, ongoing work will narrow the study focus and reflect additional measurement, intervention and reevaluation. A portion of the evaluation by the EQRO will be to understand whether the indicator criteria are sufficient and effective and whether additional criteria might be important in follow-up studies. The success of each project will be assessed in terms of the indicators ultimately selected, and not in terms of the in-progress findings.

Potential Sources of Supporting Information

- Clinical and non-clinical practice guidelines
- DMH and other regulatory quality standards
- Administrative data
- Medical records
- Information about the status of the PIP along the required timeline.

Methods of Evaluation

Onsite: The EQRO will review the MHP's project documentation to assess whether appropriate study indicators are used. The EQRO will consider the following questions to help assess study indicators.

1. Did the study use objective, clearly and unambiguously defined, measurable indicators?

When indicators exist that are generally used within the mental health community or the managed care industry, and these are appropriate to the PIP, these should be used in the study. (For example, an indicator of an effective access process could be how soon a clinician sees a beneficiary after initial screening.)

Alternately, indicators may be developed by the MHP on the basis of current clinical practice guidelines and standards, or on mental health services research. When the MHP develops its own indicators, it must be able to document the basis on which it adopted an indicator.

The EQRO will consider the following list of key characteristics to determine if meaningful indicators were used/developed.

- Was/were the indicator(s) related to identified mental health care guidelines pertinent to the study question?
 - Was this an important aspect of care that will make a difference to the MHP's beneficiaries?
 - Were the indicators available either through administrative data, medical records, or other readily available sources?
 - Did limitations on the ability to collect the data skew the results?
 - Did these indicators require explicit or implicit criteria? That is, was the data so complex, or did it require so many people to collect and analyze, that explicit and precise data collection criteria was required to assure inter-reviewer reliability? (For example, a study requiring several people to conduct a large-scale chart review needs to assure that all reviewing staff has been trained in the indicator criteria [i.e., knowing precisely which data they are collecting] and in the use of any data collection tool.)
2. Did the PIP indicators measure changes in mental health status, functional status, or enrollee satisfaction, or valid proxies of these outcomes?

The objective of a PIP should be to improve processes and outcomes. For the purposes of this protocol, "outcomes" are defined as measures of client mental health, functional status or satisfaction following the receipt of care or services. Indicators selected for a PIP in a clinical focus area ideally should include at least some measure of change in mental health status or functional status or process of care proxies for these outcomes. Indicators may also include measures of satisfaction.

Quality indicators do not always need to be outcome measures. Process measures are acceptable as long as it can be shown that there is strong clinical evidence that the process being measured is associated with outcomes. For example, it can be assumed that quality indicators established for a study of procedures to decrease barriers to care for young adult beneficiaries would serve as proxies for improving the mental health of this population.

Step 4. Review the Identified Study Population

Once a topic has been selected, measurement and improvement efforts must be system-wide; i.e., each project must represent the entire Medi-Cal enrolled population to which the PIP study indicators apply. Once that population is identified, the MHP must decide whether to review data for that entire population or

use a sample of that population. Sampling is acceptable so long as the samples are representative of the identified population (see Step 5).

Potential Sources of Supporting Information

- Data on the Medi-Cal enrolled population that enumerates the numbers of enrollees to which the study topic and indicators apply. This would include demographic information available at the DMH or MHP level. It includes data from MHP enrollment files and MHP utilization, diagnostic and outcome information, such as services, procedures, admitting and encounter diagnoses, and patterns of referrals or authorization requests.
- Other data bases, as needed.

Methods of Evaluation

Pre-Onsite: For most PIPs, DMH has provided data that should reflect the entire Medi-Cal enrolled population to which the PIP study indicators apply. The EQRO may need to review data at DMH to validate that MHPs were given comprehensive data on the entire affected population.

Onsite: The EQRO will review the study description and methodology to assess whether the study clearly identified the study population. The EQRO will consider the following questions.

1. How did the MHP define the study's population?
2. Did the MHP clearly define all individuals to whom the identified study question(s) and indicators are relevant?
3. Did the MHP include the entire study population or use a sample in the study?
4. Did the definition of the study population include any requirements for the length of the study populations' members' enrollment in the MHP?
5. If the MHP studied the entire population, did its data collection approach truly capture all enrollees to whom the study question applied? Additional assessment of the MHP's data collection process may be necessary at this point if the EQRO cannot answer question 5 with assurance.

If the MHP used a sample, go to Step 5. If the MHP studied the entire population, skip Step 5 and go to Step 6.

Step 5. Review Sampling Methods

If the MHP used a sample to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided.

Potential Sources of Supporting Information:

- Data on enrollee characteristics relevant to health and mental health risks or utilization of clinical and non-clinical services, including age, sex, race/ethnicity/language and functional status
- Utilization, diagnostic and outcome information, such as services, procedures, admitting and encounter diagnoses, adverse incidents, and patterns of referrals and authorization requests
- Other information needed for the specific study focus

Methods of Evaluation

Onsite: The EQRO will review the study description and methodology. The EQRO will consider the following questions in evaluating the soundness of the MHP's approach to sampling:

1. Did the methods used by the MHP to calculate the needed sample size consider and specify the true (or estimated) frequency of the occurrence of the event, the confidence interval to be used, and the acceptable margin of error?
2. Did the MHP employ valid sampling techniques? (See Attachment II for descriptions of sampling techniques.) The MHP will identify the specific sampling method employed.

Step 6 Review the MHP's Data Collection Procedures

Procedures used by the MHP to collect data for its PIP must ensure that the data collected on the PIP indicators are valid and reliable. Validity is an indication of the accuracy of the information obtained. Reliability is an indication of the repeatability or reproducibility of a measurement. The MHP should have employed a data collection plan that included:

- Clear identification of the data to be collected
- Identification of the data sources and how and when the baseline and repeat indicator data will be collected
- Specification of who will collect the data
- Identification of instruments used to collect the data

When data were collected from automated data systems, specifications for automated retrieval of the data should have been developed. When data were obtained from visual inspection of mental health records or other primary source documents, several steps should have been taken to ensure the data were consistently extracted and recorded:

1. The key to successful manual data collection is in the selection of the data collection staff. Appropriately qualified personnel, with conceptual and organizational skills, should have been used to abstract the data. The specific skills of the data collection staff should vary depending on the nature of the data collected and the amount of professional judgment required. For example, staff with training and expertise in culturally competent service delivery should do chart review for indicators of cultural competence.
2. Clear guidelines for obtaining and recording data should have been established, especially if multiple reviewers were used to perform this activity. Defining a glossary of terms for each project should have been part of the training of abstractors to ensure consistent interpretation among and between the project staff.
3. The number of data collection staff used for a given project affects the reliability of the data. A smaller number of staff promotes inter-rater reliability.

Potential Sources of Supporting Information

- List of sources of data used in the study
- If mental health chart review or other manual data collection was used to produce study data, then review data recording forms and instructions to data collectors
- If automated data collection was used, an algorithm showing the steps in the production of quality indicators and other relevant data collection

Methods of Evaluation

Onsite: Evaluation of the MHP's data collection procedures should include an assessment of the study's approach to data collection (discussed above). The EQRO will consider the answers to the following questions in determining the soundness of data collection procedures.

- Did the study design clearly specify the data to be collected?

Data elements must be carefully specified with unambiguous definitions. When descriptive terms are used (e.g., high, low, normal), numerical definitions are established for each term.

- Did the study design clearly specify the sources of data?

Data sources vary considerably and depend on the selected topic and indicators. Similarly, the topic and indicators will reflect not just the clinical and research considerations, but also the available MHP data sources. Sources can include: beneficiary mental health records, access tracking logs,

encounter and claims systems, provider interviews, beneficiary interviews and surveys.

- Did the study design specify a systematic method of collecting valid and reliable data that represents the entire population to which the study's indicators apply? For example, if the study looked at points of entry for Asian clients, did it include every MHP program and team, whether county or contract, directly admitting clients, including large mental health clinics and smaller specialty programs?

The PIP's design and methodology should include an estimation of the degree of completeness of the automated data used for the PIP study indicators. If the data was collected through the automated information system, the EQRO should consider the completeness of the data captured. During the first annual review of PIPs, it may not be possible to establish with certainty the degree of integrity of the MHPs' Information System. In subsequent years, after the development of an appropriate Information Systems Capabilities Assessment (ISCA), and use of this tool as part of the Performance Measurement Protocol, greater certainty will be possible.

Manual data collection may be the only feasible option for many MHPs and for many topics selected. The mental health record is the most frequently used data source. Other manual systems, which might contain sources of information, include access-tracking logs, complaint logs and manual claims. When evaluating manual data, the following issues should be considered:

- Did the MHP use qualified staff and personnel to collect the data?
- Did the MHP use instruments for data collection that provide for reliable and accurate data collection over the time periods studied?

When assessing non-clinical services such as access, cultural competency or care coordination, a study may utilize information on how the MHP is structured and operates.

- Did the study design prospectively specify a data analysis plan that reflected the following considerations
 - Whether qualitative or quantitative data, or both, were to be collected.
 - Qualitative data describes characteristics or attributes by which persons or things can be classified; for example, sex, race, poverty level, or the presence or absence of a specific mental health diagnosis.

Calculations of proportions and calculations of rates are the two most common qualitative measures.

- Quantitative data are concerned with numerical variables such as age, weight, or blood levels. Quantitative data require, at a minimum, simple descriptive measures of central tendency (i.e., mean, median or mode) and measures of variability (i.e., range or standard deviation).
- Whether the data were to be collected on the entire population or a sample.
- Whether the measurements obtained from the data collection activity were to be compared to the results of previous or similar studies. If so, the data analysis plan should have considered evaluating the comparability of the studies and identified the appropriate statistical tests to be used to compare studies.
- Whether the PIP was to be compared to the performance of an individual MHP, a number of MHPs (for example, a regional average), or different provider sites. Comparing the performance of multiple entities involves greater statistical design and analytical considerations than those required for a study of a single entity.

Step 7. Assess the MHP's Improvement Strategies

Real, sustained improvements in care result from a continuous cycle of measuring and analyzing performance, and developing and implementing system-wide improvements in care. Actual improvements in care depend far more on thorough analysis and implementation of appropriate solutions than on any other steps in the process.

An improvement strategy is defined as an intervention designed to change behavior at an institutional, practitioner or beneficiary level. During the first year of the external quality review, many of the PIPs evaluated may be baseline studies and in-progress activities. The EQRO will explore, in interviews with key MHP staff, the MHP's goals for development and implementation of system-wide improvements based on study findings. The MHP is expected to identify anticipated specific system interventions with a likelihood of improving care in the studied area.

If the study was completed and interventions implemented, the EQRO will review these measure to assess their success in achieving significant improvement. If no improvement attributable to the interventions could be identified, the MHP should be prepared to begin problem-solving process again. This will include data analysis to

identify probable causes, and to propose and implement other solutions. If QI actions were successful, the new processes should be standardized and monitored.

Potential Sources of Supporting Information

- Current project baseline data
- Previous project data (if available)
- Results of clinical and literature research
- Project evaluation results completed by evaluators

Methods of Evaluation

Onsite: The EQRO will consider the answer to the following question to determine the extent to which appropriate interventions were addressed:

Did the MHP undertake interventions related to causes/barriers identified through data analysis and QI processes?

It is expected that interventions associated with improvement on quality indicators will be system interventions, i.e., educational efforts, changes in policies, targeting of additional resources, or other MHP-wide initiatives to improve performance. Interventions that might have some short-term effect, but that are unlikely to induce permanent change (such as a one-time letter to beneficiaries) are insufficient.

To the extent feasible, the MHP should be able to demonstrate that its data have been corrected for any major confounding variables with an obvious impact on the findings. The MHP's interventions should reasonably be determined to have resulted in measured improvement.

Step 8. Review Data Analysis and Interpretation of Study Results

The EQRO will evaluate whether the study was carried out with fidelity to its study plan, using accurate data. It will determine whether the MHP analyzed its findings using appropriate statistical methodologies, and presented the findings in a clear and easy to understand manner. It will focus on determining to what extent the PIP was successful in the studied aspects of its care delivery system, and what follow-up activities are planned to sustain or improve results.

Potential sources of Supporting Information

- Baseline project indicator measurements
- Repeat project indicator measurements
- Industry benchmarks
- Analysis of PIP results by the MHP

Methods of Evaluation

Onsite or Post-onsite: The EQRO will consider the answers to each of the following questions to assess the extent to which MHP PIP data analysis and interpretation was appropriate and valid.

- Did the MHP conduct an analysis of the findings according to the data analysis plan?
- Did the MHP present numerical PIP results and findings data in a way that provides accurate, clear and easily understood information?
- Following the data analysis plan, did the analysis identify:
 - Initial and repeat measurements of the prospectively identified indicators for the project?
 - The statistical significance of any differences between the initial and repeat measurements?
 - Factors that influence the comparability of initial and repeat measurements?
 - Factors that threaten the internal or external validity of the findings?
- Did the MHP's analysis of the study data include an interpretation of the extent to which the PIP was successful and what follow-up activities were planned as a result?

Interpretation and analysis of the study data should be based on continuous improvement philosophies and reflect an understanding that most problems result from failures of administrative or delivery system processes, not failures of individuals within the system. Interpreting the data should involve developing hypotheses about the causes of less-than-optimal performance and collecting data to validate the hypotheses.

Step 9. Assess the Likelihood that Improvement is “Real” Improvement

When an MHP reports a change in its performance, it is important to know whether the reported change represents “real” change or is an artifact of the short-term event related to the intervention (for example, beneficiary participation in a focus group, per se, may increase short-term satisfaction), or random chance. The EQRO will need to assess the probability that reported improvement is actually true improvement. This probability can be assessed in several ways, but is most confidently assessed by calculating the degree to which an intervention is statistically “significant”. While this protocol does not specify a level of statistical

significance that must be met, it does require that the EQRO assess the extent to which any changes in performance reported by an MHP can be found to be statistically significant.

Potential Sources of Supporting Information

- Baseline and repeat measures on quality indicators
- Tests of statistical significance calculated on baseline and repeat indicator measurements
- Benchmarks for quality specified by DMH or found in other industry standards

Onsite: The extent to which this step can be performed during the first annual EQR will depend on the degree of completion of the PIP. While some MHPs will have been able to implement process or other changes in response to study findings, others will not have completed the study in sufficient time to implement indicated interventions. The EQRO will assess the progress of the PIP along the DMH required timeline and will defer this step for subsequent review where studies have not yet implemented or measured change.

Step 10. Assess whether the PIHP has sustained its documented Improvement

Real change results from changes in the fundamental processes of health care delivery. Such changes should result in sustained improvements. In contrast, a spurious “one time” improvement can result from unplanned accidental occurrences or random chance. If real change has occurred, the MHP should be able to demonstrate sustained improvement.

Potential Sources of Supporting Information

- Baseline and first repeated measurements on quality indicators
- Additional measurements on quality indicators made after the first repeat measurement

Methods of Evaluation

Onsite: This step is not required of the EQRO during the first assessment of a specific PIP. In subsequent years, review of the re-measurement documentation will be required to assure that the improvement on a project is sustained. The EQRO will perform step 9 (above) and then will consider the answers to the following question:

- Was the MHP able to demonstrate sustained improvement through repeated measurements over comparable time periods?

The MHP should repeat measurements of the indicators after the first measurement taken after the intervention. It is recognized that because of random, year-to-year variations, population changes, and sampling error, performance on any given individual measure may decline in the second measurement. However, when all of the MHP's repeat measurements for a given review are taken together, this decline should not be statistically significant and should never be statistically significant after two re-measurement periods.

ACTIVITY 2: Evaluate overall validity and reliability of PIP results

After completing Activity One, the EQRO will need to assess the implications of all findings on the likely validity and reliability of the MHP PIP findings and thereby whether or not DMH should have confidence in the reported PIP findings. Because it is almost always impossible to design the "perfect" study or PIP, the EQRO will need to accept some threats to the accuracy and generalizability of the PIP as a routine fact of QI activities. Determining when an accumulation of threats to validity and reliability and PIP design problems reach a point at which the PIP findings are no longer credible is always a judgment call.

Post-onsite: The EQRO will prepare a summary report for DMH on its findings. DMH is interested in common trends, effective study designs, and potentially meaningful interventions.

The EQRO will also provide a short summary of the validation findings along with a summary rating using levels such as the following:

- High confidences in reported MHP PIP results
- Confidence in reported MHP PIP results
- Low confidence in reported MHP PIP results
- Reported MHP PIP results not credible.

PIP PROTOCOL ATTACHMENT I

PERFORMANCE IMPROVEMENT PROJECT (PIP) VALIDATION WORKSHEET

The EQRO will use this worksheet as a guide when validating MHP's Performance Improvement Projects. Answer all questions for each activity. Refer to the protocol for detailed information on each area.

ID of Evaluator _____ Date of Evaluation: ____/____/____

Demographic Information
MHP Name
Project Leader Name:
Telephone Number:
Name of PIP:
Dates in Study Period: ____/____/____ to ____/____/____
____ Number of Medi-Cal Enrollees in PIP ____ Number of other underserved clients in PIP ____ Total number of individuals in PIP

1. ACTIVITY 1: ASSESS THE STUDY METHODOLOGY				
Step 1: REVIEW THE SELECTED STUDY TOPIC				
Component/Standard	Y	N	N/A	Comments
1.1 Was the topic selected through data collection and analysis of comprehensive aspects of beneficiary needs, care and services?				
1.2 Did the MHP, over time, address a key aspect of beneficiary care and services?				
1.3 Did the PIP, over time, include all clients for whom the PIP pertained?				
Step 2: REVIEW THE STUDY QUESTION (S)				
2.1 Was/were the study question(s) stated clearly in writing?				
Step 3: REVIEW SELECTED STUDY INDICATOR (S)				
3.1 Did the study use objective, clearly defined, measurable indicators?				

3.2 Did the indicators measure changes in mental health status, functional status, or beneficiary satisfaction, or process of care with strong associations for improved outcomes?				
Step 4: REVIEW THE IDENTIFIED STUDY POPULATION				
4.1 Did the MHP clearly define all the Medicaid beneficiaries to whom the study question and indicators are relevant?				
4.2 If the MHP studied the entire population, did its data collection approach capture all beneficiaries to whom the study question applied?				
Step 5: REVIEW THE SAMPLING METHODS				
5.1 Did the sampling technique consider and specify the true (or estimated) frequency of occurrence of the event, the confidence interval to be used, and the margin of error that will be acceptable?				
5.2 Did the MHP employ valid sampling techniques that protected against bias? <i>Specify the type of sampling or census used.</i>				
5.3 Did the sample contain a sufficient number of beneficiaries?				
Step 6: REVIEW DATA COLLECTION PROCEDURES				
6.1 Did the study design clearly specify the data to be collected?				
6.2 Did the study design clearly specify the sources of the data?				
6.3 Did the study design specify a systematic method of collecting valid and reliable data that represents the entire population to which the study's indicators apply?				
6.4 Did the instruments for data collection provide for consistent, accurate data collection over the time periods studied?				
6.5 Did the study design prospectively specify a data analysis plan?				
6.6 Were qualified staff and personnel used to collect the data?				
Step 7: ASSESS IMPROVEMENT STRATEGIES				
7.1 Were reasonable interventions undertaken to address causes/barriers identified through data analysis and QI processes undertaken?				
Step 8: REVIEW DATA ANALYSIS AND INTERPRETATION OF STUDY RESULTS				
8.1 Was an analysis of the study findings performed according to the data analysis plan?				

8.2 Did the MHP present numerical PIP results and findings accurately and clearly?				
8.3 Did the analysis identify: initial and repeat measurements, statistical significance, factors that influence comparability of initial and repeat measurements, and factors that threaten internal and external validity?				
8.4 Did the analysis of study data include an interpretation of the extent to which its PIP was successful, and of the success of follow-up activities?				
Step 9: ASSESS WHETHER IMPROVEMENT IS "REAL" IMPROVEMENT				
9.1 Was the same methodology as the baseline measurement used, when measurement was repeated?				
9.2 Was there any documented quantitative improvement of processes or outcomes of care?				
9.3 Does the reported improvement in performance have "face" validity; i.e., does the improvement in performance appear to be the result of the planned quality improvement intervention?				
9.4 Is there any statistical evidence that any observed performance improvement is true improvement?				
Step 10: ASSESS SUSTAINED IMPROVEMENT				
10.1 Was sustained improvement demonstrated through repeated measurements over comparable time periods?				

**ACTIVITY 2: EVALUATE OVERALL VALIDITY AND RELIABILITY OF STUDY RESULTS;
SUMMARY OF AGGREGATE VALIDATION FINDINGS**

Check one:

- High confidence in reported MHP PIP results
- Confidence in reported MHP PIP results
- Low Confidence in reported MHP PIP results
- Reported MHP PIP results not credible

PIP PROTOCOL ATTACHMENT II

Validating Performance Improvement Projects

This listing is intended to present an overview of sampling possibilities and not to provide instructions for implementing a specific sampling technique.

Probability (or random) sampling: Methods that leave selection of population units totally to chance, and not to preference on the part of individuals conducting or otherwise participating in the study. Biases are removed in these methods. There are several types of probability (or random) sampling that can be used by the MHP.

- Simple random sampling – all members of the study population have an equal chance of being selected for the sample. This may be accomplished by numbering all members of the study population and developing the sample by computer generated random number selection.
- Systematic random sampling – the basic principal is to select every n th unit in a list. This can be used when a sampling frame is organized in a way that does not bias the sample. Steps include:
 - Construct a sampling frame (e.g., a list of all beneficiaries).
 - Divide the size of the sampling frame by the required sample size to produce a sampling interval or skip interval (e.g., if there are 250 beneficiaries and a sample of 25 is needed, then divide $250/25=10$).
 - From a random number table, select a random number between 1 and 10.
 - Count down the list to get the n th (i.e., the # identified by using the random number table).
 - Skip down ten names on the list and select a second name. Repeat the process as many times as needed to obtain the required sample.
- Stratified random sampling is used when the target population consists of non-overlapping sub groups or strata. Stratified random sampling requires more information about the population and also requires a larger overall sample than simple random sampling.
- Cluster sampling is used when a comprehensive sampling frame is NOT available. Units in the population are gathered or classified into groups, similar to stratified sampling. This method requires prior knowledge about the population. Once clusters are identified, a random sample of clusters is selected.

Non-probability sampling: Methods based on choice, rather than chance. In non-probability sampling, some bias can be expected. There are several types of non-probability sampling that can be used by the MHP.

- Judgment sampling – constructing a sample based on including units in the sample if they are thought (judged) to be representative of the population. By doing so, the sample is constructed to be a mini-population.
- Convenience sampling – using units that are readily or conveniently available. For example, clients in Spanish-speaking therapy groups might be interviewed if the PIP involved opinions about the services they were receiving.
- Quota sampling – a method to ensure that units in the sample appear in the same proportion as in the population. For instance, if a certain targeted population consisted of 55% female and 45% male, the quota sample would require a similar female/male distribution.