# Quality Improvement Assessment Guide for Medi-Cal Managed Care Plans

Medi-Cal Managed Care Division California Department of Health Care Services

March 2013







1.	QIP BASICS
2.	GETTING STARTED
	Section Organization
3.	SUBMITTING A QIP FOR VALIDATION
	Section Organization
4.	QIP VALIDATION PROCESS
	Section Organization
5.	How to Get Help27
	Technical Assistance
6.	
7.	GLOSSARY
AF	PPENDIX A. QIP SUMMARY FORM
AF	PPENDIX B. QIP SUMMARY FORM (MULTI-COUNTY)
AF	PPENDIX C. QIP SUMMARY FORM COMPLETION INSTRUCTIONS
AF	PPENDIX D. QIP SUMMARY FORM COMPLETION INSTRUCTIONS (MULTI-COUNTY) D-1

## What is a Quality Improvement Project (QIP)?

#### A process of:

- Identifying a target area for improvement (clinical or nonclinical).
- Implementing interventions for improvement.
- Analyzing results.

## Typically, QIPs are conducted in phases:

- Phase One—Study design.
  - Plans target an area they need to improve upon, develop the methodology, and document the process.
- Phase Two—Data analysis and implementation of improvement strategies.
  - Plans analyze data to identify problems and then implement specific actions to correct the problems.
- Phase Three—Remeasurement and evaluation of outcomes.
  - Plans remeasure their performance after they have put their improvement efforts into place and evaluate if they were successful.

# Why do we do QIPs?

- QIPs are a contract requirement for Medi-Cal managed care plans. The California Department of Health Care Services' (DHCS's) Medi-Cal program (referred to herein as "Program") requires each of its contracted managed care plans to conduct two QIPs that DHCS must approve and its external quality review organization (EQRO) must validate.
- *QIPs are a federal requirement.* The Balanced Budget Act of 1997 (BBA), Public Law 105-33, requires that all states that operate a Medicaid managed care program ensure that their contracted plans conduct QIPs in accordance with the Code of Federal Regulations (CFR), at 42 CFR 438.240.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Balanced Budget Act of 1997. Federal Register/Vol. 67, No. 115, June 14, 2002, 2002/Rules and Regulations, p. 41109.

## QIP side effects—the good news

Although the Program's contract and the BBA require all plans to conduct QIPs, plans benefit by conducting QIPs. If conducted effectively, QIPs can:

- Improve performance measurement rates in non-targeted areas.
- Keep plans focused on improving performance.
- Improve member satisfaction.

## What are the responsibilities of plans, DHCS, and the EQRO?

- *Plans* design, document, and conduct the QIPs.
- DHCS requires the QIPs and approves all new QIP proposals. DHCS requires that one of
  the QIPs be either a plan-specific, internal QIP (IQIP) or a small-group collaborative QIP
  (SGC). DHCS requires that the other QIP be the statewide collaborative QIP.
  - Specialty plans are required to conduct two IQIPs, as they are not required to participate in the statewide collaborative QIP.
  - For more details on DHCS's QIP requirements, please refer to the plan contract or the most recent All Plan Letter on quality and performance improvement requirements. (All plan letters for the Program are posted on the DHCS Web site at <a href="http://www.dhcs.ca.gov/services/Pages/Medi-CalManagedCare.aspx.">http://www.dhcs.ca.gov/services/Pages/Medi-CalManagedCare.aspx.</a>)
- EQROs validate the QIPs to ensure that they are methodologically sound and meet all State
  and federal requirements. EQROs provide technical assistance to plans to help interpret
  QIP requirements.

# Where can I find additional help?

Health Services Advisory Group, Inc. (HSAG) provides a list of resources and references in Section 6 of this guide that can aid plans in conducting QIPs.

# **Section Organization**

This section of the Quality Improvement Assessment Guide covers the following:

- The 10 activities outlined by the U.S. Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS) in conducting quality improvement projects
- How to document a QIP using HSAG's QIP Summary Form

# **QIP** Activities

CMS expects QIPs to include 10 activities outlined in its protocols for conducting and validating performance improvement projects.<sup>2</sup>

wassing personnance improvement projection
Activity I - Select the study topic(s)
•
Activity II - Define the study question(s)
Activity III - Select the study indicator(s)
Activity IV - Use a representative and generalizable study population
Activity V - Use sound sampling techniques (if sampling is used)
•
Activity VI - Reliably collect data
Activity VII - Analyze data and interpret study results
Activity VIII - Implement intervention and improvement strategies
•
Activity IX - Assess for "real" improvement
•
Activity X - Assess for sustained improvement

<sup>&</sup>lt;sup>2</sup> Validation of Performance Improvement Projects (PIPs): A Mandatory Protocol for External Quality Review (EQR), Version 2.0, September 2012. Implementation of Performance Improvement Projects (PIPS): A Voluntary Protocol for External Quality Review (EQR), Version 2.0, September 2012.

-

## Activity I: Selecting a Study Topic(s)

DHCS typically allows its managed care plans to select internal QIP (IQIP) and small-group collaborative (SGC) topics, although DHCS or CMS could specify the topic as well. Plans should select a study topic to target improvement in relevant areas of clinical care or nonclinical services. In selecting a topic, plans should consider areas where their performance needs improvement, including Healthcare Effectiveness Data and Information Set (HEDIS®)<sup>3</sup> performance measures that are at or below DHCS's minimum performance levels (MPLs). Plans may also select a topic based on input from members.

# **Key Concepts**

## The study topic:

- Reflects high-volume or high-risk conditions.
- Is selected following collection and analysis of data.
- Addresses a broad spectrum of care and services.
- Includes all eligible populations that meet the study criteria.
- Does not exclude members with special health care needs.
- Has the potential to affect member health, functional status, or satisfaction.

Many QIPs include national benchmarks or cite current literature, but they often neglect to connect the topic to their population. Lack of plan-specific documentation related to the study topic is a common reason a QIP does not fully meet the review criteria for this evaluation element.

Plans need to determine the extent to which they considered specific Medi-Cal enrollee demographic characteristics, prevalence of the chosen topic, or the need for a specific service.

Plans will submit their new QIP topic proposals on the Quality Improvement Project (QIP) Topic Proposal Form. This is a two-page form that the plan must complete and send to DHCS 90 days prior to their current QIP's final submission date. Once DHCS approves the QIP topic, the plan will move forward with submitting the QIP proposal.

-

<sup>&</sup>lt;sup>3</sup> HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).

## Activity II: Defining the Study Question(s)

Defining the study question helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation. The study question should clearly state the question, in writing, that the study is designed to answer.

## **Key Concepts**

#### The study question:

- States the problem to be studied in simple terms.
- Is answerable.

According to the CMS protocol for conducting QIPs, the study question should be in an X/Y format—i.e., *Does doing X result in Y?* A QIP aimed at decreasing the rate of hospital readmissions might pose the study question as follows:

Do targeted interventions reduce the 30-day readmission rate for adults?

## Activity III: Selecting the Study Indicator(s)

A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received an influenza vaccination in the last 12 months) or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time.

# **Key Concepts**

#### The study indicator:

- Is well-defined, objective, and measurable.
- Is based on current, evidence-based practice guidelines, pertinent peer-reviewed literature, or consensus reached by expert panels.
- Allows for the study question to be answered.
- Has data available for collection.

Study indicators need to *answer* the study question; therefore, if HSAG determines that the study indicator does not answer the study question, the QIP would not fully meet the review criteria for this evaluation element.

## Activity IV: Using a Representative and Generalizable Study Population

Plans should ensure that the study population includes all Medi-Cal plan members to which the study question applies. Once the plans identify the population, they should decide whether or not to review data for the entire population or a sample of that population. The plans also need to identify the length of a member's enrollment in the plan for inclusion in the study population.

# **Key Concepts**

#### The study population:

- Is accurately and completely defined.
- Includes requirements for the length of a member's enrollment in the plan.
- Captures all members to whom the study question applies.

QIPs that use HEDIS methodology need to include either a copy of the specifications or cite them completely. Plans that simply cite, for example, "HEDIS 2012" for the study population numerator and denominator do not meet the intent of this review element. Plans need to clearly define inclusions, exclusions, and diagnosis criteria.

## Activity V: Using Sound Sampling Techniques

If a plan decides to use a sample instead of the entire population, the plan should use proper sampling techniques.

# **Key Concepts**

#### Sampling methods use the entire population or:

- Enter the measurement period for the sampling methods used.
- Provide the title of the applicable study indicator(s).
- Identify the population size.
- Identify the sample size.
- Specify the margin of error and confidence level.
- Describe in detail the methods used to select the sample.

Plans that lack resources or expertise regarding sampling can find resources in Section 7 or they can consult with HSAG for guidance.

## Activity VI: Using Valid and Reliable Data Collection Procedures

Plans need to ensure that the data collected on QIP indicators are valid and reliable. Validity means the information collected is accurate. Reliability means the measures and data collected can be reproduced with the same results.

# **Key Concepts**

#### Data collection ensures:

- The identification of data elements to be collected.
- The identification of specified sources of data.
- A defined and systematic process for collecting baseline and remeasurement data.
- A timeline for the collection of baseline and remeasurement data.

#### Manual data collection should include:

- Qualified staff and personnel to abstract manual data.
- A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.
- A manual data collection tool that supports interrater reliability.
- Clear and concise written instructions for completing the manual data collection tool.
- An overview of the study in written instructions.

#### Administrative data should include:

- Algorithms/flow charts that show steps in the production of indicators.
- An estimated degree of administrative data completeness.

The CMS protocol for implementing QIPs guides plans to include a data analysis plan that considers factors related to data collection, such as whether the plan will: use qualitative or quantitative data, include the entire population or a sample, compare the data collected to previous or similar studies, and compare its QIP results to the performance of another plan(s). Plans that compare their QIP results or performance to previous studies or other entities need to include information on appropriate statistical testing and study design.

QIPs that use hybrid methodology need to include the data collection manual *instructions* and data collection *tool* to fully meet this evaluation element.

## Activity VII: Analyzing Data and Interpreting Study Results

Plans determine how they are performing on the study indicators by analyzing the data collected and interpreting the results.

# **Key Concepts**

## Data analysis and interpretation:

- Are conducted according to the data analysis plan in the study design.
- Allow for the generalization of results to the study population if a sample was selected.
- Ensure the identification of factors that threaten internal or external validity.
- Provide an interpretation of findings.
- Are presented in a way that provides accurate, clear, and easily understood information.
- Identify initial measurement and remeasurement of study indicators.
- Identify statistical differences between initial measurement and remeasurement.
- Identify factors that affect the ability to compare the baseline measurement with remeasurement.
- Include an interpretation of the extent to which the study was successful.

The data analysis plan needs to include a description of how the plan will calculate its rates, how the plan will compare its rates with the QIP goals and benchmarks, and which statistical test the plan will use.

HSAG provides guidance and recommendations to plans on generally acceptable statistical methods and rationale.

## Activity VIII: Implementing Improvement Strategies

By picking the right interventions, plans are more likely to have QIPs that result in positive changes. Interventions can be designed to change behavior at an institutional, practitioner, or member level.

# **Key Concepts**

#### Interventions are:

- Related to causes/barriers identified through data analysis and quality improvement (QI) processes.
- System changes that are likely to induce permanent change.
- Revised if the original interventions are not successful.
- Standardized and monitored if interventions are successful.

Once a plan defines a problem using supporting data/evidence, a causal/barrier analysis asks why the problem exists and identifies the causal relationships associated with the problem.

QIP reviewers look for documentation of the process used to conduct the causal/barrier analysis, such as a data analysis process or brainstorming sessions. QIPs that fail to describe the process used for causal/barrier analysis will not fully meet this evaluation element.

QIP reviewers ensure that the interventions address the identified barriers. QIPs that fail to document how an intervention directly affects the barrier and how removing or reducing the barrier will improve QIP outcomes will not fully meet this activity's requirements.

Plans should also document how the effectiveness of the interventions will be evaluated.

# Activity IX: Assessing for "Real" Improvement

Plans need to determine if improved performance is just a one-time chance event or if it is a true and permanent change. To do this, plans calculate the extent to which changes in performance are statistically significant.

Testing for significance allows a plan to show that it is unlikely that improved performance is due to chance. Statistical significance helps to demonstrate that improvement is the result of the targeted interventions.

# **Key Concepts**

#### "Real" improvement is based on:

- Remeasurement methodology that is the same as baseline measurement methodology.
- Documented improvement in processes or outcomes of care.
- Evidence that observed improvement is statistically significant.
- Real improvement that appears to be the result of the intervention(s).

QIP reviewers will determine if the methodology remains the same for the baseline and the remeasurement(s), or if the plan documented any change in methodology and the corresponding rationale. A plan must achieve real improvement over baseline in order to fully meet the criteria for this activity. Plans should provide a discussion of all the study indicators and whether they showed statistically significant improvement. The QIP cannot progress to Activity X until statistically significant improvement over baseline is achieved.

## Activity X: Assessing for Sustained Improvement

Sustained improvement is a demonstration of real change over time rather than a one-time occurrence or an occurrence by chance.

# **Key Concept**

#### Sustained improvement is based on:

 Repeated measurements over comparable time periods that demonstrate that the statistically significant improvement over baseline initially achieved was sustained in a subsequent measurement period.

Plans should provide a discussion of all the study indicators and whether or not they achieved sustained improvement.

## **QIP Activity Additional Resources**

Plans are encouraged to reference the CMS protocol for conducting QIPs for more detailed information on each of the 10 activities. The National Committee for Quality Assurance's (NCQA's) publication, *Health Care Quality Improvement Studies in Managed Care Settings, Design and Assessment: A Guide for State Medicaid Agencies*, provides guidance on each activity, as well. The *How to Get Help* section of this guide includes additional references.

The completion of these activities over time offers the plans a structure in which they can design and conduct quality improvement processes and demonstrate achievement. By following these activities, plans should be able to meet both the CMS protocol for conducting QIPs and DHCS's contractual requirements.

# **Documenting QIP Activities**

#### How to Document a QIP Activity:

- 1. Plans submit the QIP Topic Proposal Form to DHCS for approval.
- 2. Plans submit their QIP study design submissions, annual submissions, and resubmissions using HSAG's QIP Summary Form.
  - a. Appendix A includes a copy of the QIP Summary Form with detailed instructions.
  - b. Appendix B contains a copy of the QIP Summary Form (multi-county), which plans will use to document a single QIP submission for multiple counties.
- 3. Plans should refer to the completion instructions in Appendix C (Appendix D for multiple counties), which outline each evaluation element and the required documentation for their submissions.
- 4. Plans should complete the cover/demographic page.
- 5. Plans should provide thorough QIP documentation.
  - a. Plans should address each element within the sections of the QIP Summary Form.
  - b. Plans should indicate when elements are not applicable to the project and avoid leaving elements blank.
  - c. Plans can include attachments that provide further documentation.
- 6. Plans must maintain the same submission document throughout the study.
  - a. Plans should either use the track changes feature for annual submissions and resubmissions or they may strike through deleted information on the QIP Summary Form and bold, highlight, and date any new information.

#### **DHCS QIP Requirements:**

DHCS requires both regular plans and specialty plans to always maintain two active QIP projects for each county they are operating in unless otherwise specified by the DHCS.

DHCS designates a statewide Medi-Cal collaborative QIP for one of the two required projects for regular plans. The second QIP is either an IQIP or an SGC.

Plans contracting with DHCS after the initiation of the current statewide collaborative are required to develop an IQIP or SGC in place of their participation in the statewide collaborative. New plans contracting with DHCS or existing plans expanding into new counties are typically required to submit their QIP topic proposals to DHCS once they have been in operation for 12 months. This allows plans time to collect data and conduct data analysis to support a QIP. DHCS and its EQRO may adjust reporting requirements to accommodate the particular circumstances of the plan's member population and date of start-up in relation to the reporting cycle. Non-statewide collaborative QIP topics and timelines for initial submissions must be preapproved by the EQRO and DHCS.

For specialty plans, the two QIPs are IQIPs; or, with DHCS approval, specialty plans may replace one of the IQIPs with a plan- or DHCS-facilitated SGC or the statewide collaborative.

# **Section Organization**

This section of the Quality Improvement Assessment Guide will cover the following:

- When to submit a QIP.
- How to submit a QIP.
- When to expect feedback.

## When to Submit a QIP

#### New QIP:

**Topic Proposal:** The plan should begin to consider a new QIP topic after submitting the first remeasurement of its existing project. The plan should select a proposed topic area, complete a QIP Topic Proposal Form, and submit it to DHCS for approval at least 90 days prior to the submission due date of its anticipated final submission for the existing project.

- Note: The final submission usually includes the second remeasurement outcome results. If the EQRO determines that the plan did not achieve statistically significant improvement for its outcome over the baseline rate in the existing QIP, it may require the existing QIP to continue an additional year which would delay the start of the new QIP.
- DHCS will evaluate the QIP topic selection to ensure that plans focus on areas in greatest need of improvement, such as performance measure rates that fall below the MPLs.

**Study Design Submission:** Once DHCS approves the plan's QIP topic, the plan should complete the study design documentation for the new QIP using the CMS protocol for implementing a QIP and document the project on HSAG's QIP Summary Form. The plan should complete the study design through Activity VI and submit the QIP Summary Form to HSAG and DHCS.

**Annual Submission:** DHCS requires plans to submit a QIP status report at least annually using the HSAG QIP Summary Form. The reporting frequency depends on the individual QIP. The EQRO's Validation Tool includes the due date for the next annual status report submission.

**Resubmission:** The EQRO may require plans to resubmit a QIP after validation review if the QIP receives a *Partially Met* or *Not Met* validation status or if HSAG identifies deficiencies that need to be addressed prior to the next annual submission.

## How to Submit a QIP

**QIP Topic Proposal:** The plan must submit its QIP topic proposal to DHCS and receive DHCS approval prior to completing HSAG's QIP Summary Form. The QIP Topic Proposal Form, which will be sent to the plan by the DHCS QIP Coordinator, should be submitted directly to DHCS via its QIPs mailbox at <a href="mailto:qipsmail@dhs.ca.gov">qipsmail@dhs.ca.gov</a>.

**Study Design Submission:** Once the topic is approved by DHCS, the Plan must post the study design documentation, Activities I through VI of the QIP Summary Form, to HSAG's file transfer protocol (FTP) site and e-mail a copy to the DHCS QIPs mailbox (qipsmail@dhs.ca.gov).

Annual Submission: The plan must submit annual status reports on the QIP Summary Form directly to HSAG using HSAG's FTP Web site. The FTP site allows for the secure exchange of files between HSAG and external partners. The FTP site is compliant with the Health Insurance Portability and Accountability Act (HIPAA), although QIPs do not require the submission of member personal health information. In addition, the site allows for large files to be uploaded and downloaded. Plans must also submit a copy of their annual submissions to DHCS via its QIPs mailbox (qipsmail@dhs.ca.gov).

The HSAG FTP Web site can be accessed at <a href="www.hsag.com">www.hsag.com</a> by clicking on the "Partners" tab. The Web site prompts users to enter their username and password. Users can upload QIP files under the "QIPs" folder. To request or change individual access to the FTP site, plans can contact Jenny Montano at <a href="montano@hsag.com">imontano@hsag.com</a>.

HSAG developed the FTP site to exchange information by uploading/downloading information. It is not intended to serve as a storage site; therefore, documents will be posted for a maximum of 60 days.

HSAG logs submitted QIP documents into an internal tracking form for validation review.

# When to Expect Feedback

**New QIP Topic Proposal:** DHCS reviews new QIP topic proposals internally within approximately one month of submission and will provide feedback to the plan regarding the appropriateness and feasibility of the QIP topic selection.

**Study Design Submission:** HSAG reviews the QIP study design submission once it has been approved by DHCS and provides written feedback to the plan and DHCS as to whether the project is likely to produce valid and reliable results. HSAG will then provide validation feedback to the plan and DHCS via e-mail and document the next QIP submission due date.

**Annual Submission:** HSAG reviews QIP Summary Forms within 10 business days of submission or at a time frame designated by DHCS, evaluating the QIPs against CMS protocols and making a judgment about the validity and reliability of the findings. HSAG will then send the validation feedback to the plan and DHCS on the completed QIP Validation Tool via e-mail and document the next QIP submission due date.

**Resubmission:** HSAG reviews each plan's QIP resubmission within 10 business days of submission to determine if the plan has addressed areas of noncompliance or other deficiencies identified in the QIP Validation Tool. HSAG will then send an updated QIP Validation Tool with written feedback to the plan and DHCS via e-mail and document the next QIP submission due date.

# **Section Organization**

This section of the Quality Improvement Assessment Guide will cover HSAG's:

- Ten steps for QIP review.
- QIP validation process.
- QIP Validation Tool.
- Scoring methodology.
- Communication of validation results.

# 10 Steps Used for QIP Review

For each QIP reviewed using the CMS protocol for validating QIPs as a guide, HSAG will, at a minimum, evaluate each activity using the following steps:

Step 1. Review the Selected Study Topic



Step 2. Review the Study Question(s)



Step 3. Review the Selected Study Indicator(s)



Step 4. Review the Identified Study Population



Step 5. Review Sampling Methodology

Step 1. Review the selected study topic(s) to assess if: data collection and analysis of plan member needs, care, and services support the necessity to conduct the QIP; the QIP targets improvement in relevant clinical and nonclinical care and services; the QIP is representative of the plan's Medicaid population; there are sufficient sources for data collection; and the plan can impact change in the area under study. Plans also may identify project topics by evaluating patterns of inappropriate utilization. The State will evaluate the QIP using the QIP Topic Proposal Form, or the State may select a project topic.

Step 2. Review the study question(s) to verify if it is clearly defined and answerable and if it is in the format to meet CMS requirements. The study question(s) will help maintain the focus of the QIP and set the framework for data collection, analysis, and interpretation.

**Step 3. Review the selected study indicator(s)** to determine if it: is measurable, is clearly defined, aligns with the study question(s), has adequate data sources, addresses limitations on collecting data, has clearly defined criteria for data collection, measures processes and outcomes of care, and has realistically set performance goals and benchmarks. Each project should have one or more quality indicators to track performance and improvement over time.

**Step 4. Review the identified study population** to determine: how the study population is defined, if all members relevant to the study question and indicators are included or a sample of these members are included, if there is any defined continuous enrollment criteria, and if the data collection plan ensures the capture of all members in the study population. Once the plan identifies the population, it must determine whether to review data for the entire population or select a sample of that population.

**Step 5. Review sampling methods (if sampling is used)** to determine: if the study sample is derived in accordance with generally accepted principles of research design and statistical analysis, is sufficient to make meaningful conclusions, and will provide valid and reliable results.

Step 6. Review Data Collection Procedures



Step 7. Review
Data Analysis and
Interpretation of
Study Results



Step 8. Assess Improvement Strategies



Step 9. Assess for "Real" Improvement



Step 10. Assess for Sustained Improvement

Step 6. Review data collection procedures to determine if: data collection techniques comply with industry standards; the plan performs data collection in a manner that preserves internal and external validity; the method for calculating indicators is appropriate; the algorithm for extracting automated information system (IS) data is sound/accurate; the manual data collection tool complies with indicator specifications and ensures accurate data collection; the plan provides clearly written instructions for completing the manual data collection tool, specific instructions on how to complete each section, and guidelines on how to handle situations not covered by the instructions; manual data collection staff resources are adequate and staff members are qualified; and the data validation process is effective in verifying the accuracy of the data collected.

Step 7. Review data analysis and interpretation of study results to determine if data analysis techniques comply with industry standards, appropriate statistical tests are used, and accurate/reliable information is obtained. HSAG will also determine if the plan based its interpretation and analysis on continuous improvement philosophies, appropriately attributed causes/barriers to findings, and communicated study results to appropriate internal committees and external entities.

**Step 8.** Assess improvement strategies to determine if the barrier analysis is adequate to identify barriers to improvement, the plan has developed appropriate improvement strategies, and the timeline for implementation of interventions is reasonable. The protocol defines an improvement strategy as "an intervention designed to change behavior at an institutional, practitioner, or beneficiary level." HSAG determines the effectiveness of the intervention activity or activities by reviewing the plan's intervention evaluation and measuring the plan's change in performance.

Step 9. Assess the likelihood that reported improvement is "real" improvement to verify if the plan has achieved significant improvement and if reported improvement in processes or outcomes of care is actual improvement. HSAG will assess the extent to which any changes in performance reported by the plan are statistically significant.

**Step 10. Assess for sustained improvement** to determine if the process can reasonably ensure continued improvement over time and if real change resulted from changes in health care delivery that can be documented by the plan.

#### **QIP Validation Process**

HSAG's approach to QIP validation activities provides a consistent, structured process and a mechanism for providing plans with specific feedback and recommendations for their QIPs. This structured method of assessing QIPs results in the improved reliability and validity of QIPs, supporting the ultimate goal of improving member health outcomes.

HSAG uses the CMS protocol for validating QIPs to develop its QIP validation process, including tools, internal review, and evaluation. HSAG's QIP Review Team routinely evaluates the validation process and makes changes using quality improvement tools and techniques. The team identifies opportunities to streamline the process and develop efficiencies without jeopardizing the integrity of the process, ensuring the validity and reliability of the results.

HSAG reviews and scores each QIP in its entirety with each submission. HSAG reviews the QIP only to the point that the study has progressed.

# **Key Concepts**

#### QIP validation ensures that:

- QIPs are designed, implemented, and reported in a methodologically sound manner.
- QIPs support the achievement of real improvement in the quality of care.
- Documentation complies with CMS protocols for conducting QIPs.
- Stakeholders can have confidence in the reported improvements.

#### **HSAG's QIP Review Team:**

HSAG's QIP Review Team includes a minimum of two reviewers for each study to ensure reliability and appropriate determinations. Each review team consists of a clinician and a statistician.

Clinicians or health care professionals, who typically are registered nurses or licensed social workers, have experience in both mental and physical health and maintain the Certified Professional in Healthcare Quality (CPHQ) certification. Each clinician has validated more than 450 QIPs conducted by Medicaid managed care plans across the country. A health care professional has oversight by a clinician or statistician

and has a Bachelor of Arts or Master of Arts degree with a minimum of three years' experience in health care quality.

**Statisticians** bring a wealth of expertise to the validation process, including experience in study design, sampling, barrier analysis, and statistical testing.

HSAG uses a two-tiered approach to QIP validation. Each reviewer independently assesses the QIP submitted by the plan and then meets to discuss any scoring discrepancies to ensure scoring consistency. HSAG uses a resolution policy and procedure for resolving validation issues.

HSAG uses an internally-developed QIP Validation Tool to document validation findings and provide feedback to the plan on areas that need improvement. HSAG's goal is for the plans to score 100 percent on their QIP validation and to have a strong understanding of the CMS protocol for conducting a QIP and the quality improvement processes.

#### **QIP Validation Tool**

HSAG developed its QIP Validation Tool to assign objective findings to evaluation elements within each activity outlined in the CMS protocols. These evaluation elements are necessary for the successful completion of a valid QIP.

Of the 37 evaluation elements, HSAG designated 10 as critical elements. QIPs must receive a validation finding of *Met* on all critical evaluation elements for the QIP to be determined to be accurate and reliable.

# **QIP Scoring Methodology**

HSAG's scoring methodology is consistent with CMS guidelines as outlined in the CMS publication, Validation of Performance Improvement Projects (PIPs): A Mandatory Protocol for External Quality Review (EQR), Version 2.0, September 2012.

Using the scoring methodology, HSAG evaluates plan QIPs to determine if they are valid and reliable and to what extent they are compliant with the CMS protocol for conducting a QIP.

## Scoring critical and noncritical elements:

During validation, HSAG scores each evaluation element as Met, Partially Met, Not Met, Not Applicable, or Not Assessed.

**Critical elements,** located in the column to the left of the evaluation element, are essential to producing a valid and reliable QIP. Therefore:

- Each critical element must have a score of *Met* for the QIP to receive an overall *Met* validation status
- Critical elements that are *Partially Met* will not invalidate the QIP, but they will affect the overall percentage score
- Any critical element scored as *Not Met* will mean the QIP is not credible

For example, in Review Activity II of the QIP Validation Tool, if the study question could not be answered, then the critical element is scored as *Not Met* and the QIP is not credible.

**Noncritical elements**, individually, are not essential to producing a valid and reliable QIP. Noncritical elements receiving a finding of *Partially Met* or *Not Met* will not invalidate the QIP, but they will affect the overall percentage score, which reflects the degree of the QIP's overall compliance with the CMS protocol for conducting a QIP.

After HSAG scores each QIP evaluation element, a table, such as the Table 4-1 example below, shows total scores for all critical and noncritical elements.

	Table 4-1—Quality Improvement Project Scores for QIP Topic Title for Name of Plan										
	Review Activity	Total Possible Evaluation Elements (Including Critical Elements)	Total <i>Met</i>	Total Partially Met	Total Not Met	Total <i>NA</i>	Total Possible Critical Elements	Total Critical Elements <i>Met</i>	Total Critical Elements Partially Met	Total Critical Elements Not Met	Total Critical Elements <i>NA</i>
I.	Select the Study Topic(s)	2	2	0	0	0	1	1	0	0	0
II.	Define the Study Question(s)	1	1	0	0	0	1	1	0	0	0
III.	Select the Study Indicator(s)	3	2	0	0	1	2	2	0	0	0
IV.	Use a Representative and Generalizable Study Population	1	1	0	0	0	1	1	0	0	0
V.	Use Sound Sampling Methods	6	0	0	0	6	1	1	0	0	0
VI.	Reliably Collect Data	6	6	0	0	0	1	1	0	0	0
VII.	Analyze Data and Interpret Study Results	9	7	1	0	1	2	2	0	0	0
VIII.	Implement Intervention and Improvement Strategies	4	4	0	0	0	1	1	0	0	0
IX.	Assess for Real Improvement	4	4	0	0	0	No Critical Elements				
X.	Assess for Sustained Improvement	1	1	0	0	0	No Critical Elements				
	Totals for All Activities	37	28	1	0	8	10	10	0	0	0

## Calculating the Percentage Scores:

HSAG calculates two percentage scores for QIPs using the critical and noncritical evaluation element scores (see example in Table 4-2):

- The Percentage Score of Evaluation Elements Met
- The Percentage Score of Critical Elements Met

The Percentage Score of Evaluation Elements *Met* is calculated by dividing the total number of elements, both critical and noncritical, that were *Met* by the sum of the total number of elements that were *Met*, *Partially Met*, and *Not Met*. This calculation excludes any elements designated as *Not Applicable* or *Not Assessed*.

The Percentage Score of Critical Elements *Met* is calculated by dividing the total number of critical elements *Met* by the sum of the critical elements *Met*, *Partially Met*, and *Not Met*. This calculation excludes any elements designated as *Not Applicable* or *Not Assessed*.

Table 4-2—Quality Improvement Project Overall Score for QIP Topic Title  for Name of Plan			
Percentage Score of Evaluation Elements Met	96%		
Percentage Score of Critical Elements Met	100%		
Validation Status*	Met		

<sup>\*</sup> Met equals confidence/high confidence that the QIP was valid. Partially Met equals low confidence that the QIP was valid. Not Met equals reported QIP results that were not credible.

## Calculating the Validation Status:

The validation status is based on the percentage scores and whether or not critical elements were *Met*, *Partially Met*, or *Not Met*.

Not Assessed is used when the QIP has not progressed to the remaining activities in the CMS protocol for conducting a QIP. This includes QIP proposals for which plans have not yet implemented interventions, QIP baseline submissions that do not have remeasurement data, or QIP resubmissions that do not include multiple remeasurement periods to assess for sustained improvement.

Points of Clarification are included for evaluation elements with a Met score that need enhanced documentation. Points of Clarification do not affect scores. However, if a plan does not address a Point of Clarification in future submissions, HSAG will negatively score the evaluation element in the next validation cycle.

Overall scores determine the overall QIP validation status as follows:

Met

- All critical elements were Met and -
- 80 to 100 percent of all elements were *Met* across all activities.

Partially Met

- All critical elements were Met and 60 to 79 percent of all elements were Met across all Activities -or-
- One or more critical element(s) were Partially Met and the percentage score for all elements across all activities was 60 percent or more.

Not Met

- All critical elements were Met and less than 60 percent of all elements were Met across all activities -or-
- One or more critical element(s) were Not Met.

 Not Applicable elements (including critical elements) were removed from all scoring.

Not Assessed

 Not Assessed elements (including critical elements) were removed from all scoring.

Point of Clarification • Points of Clarification occur when documentation for an evaluation element has the basic components described in the narrative of the QIP to meet the evaluation element; however, enhanced documentation would demonstrate a stronger understanding of the CMS protocol.

HSAG designed the scoring methodology to ensure that critical elements are must-pass evaluation elements. If one critical evaluation element is Not Met, the overall validation status is Not Met. In addition, the methodology addresses the potential situation in which HSAG scores all critical elements as Met, but finds suboptimal performance in the noncritical elements. HSAG bases the final outcome of the QIP's validation on the percentage score of critical elements met.

# Evaluation of the Overall Validity and Reliability of QIP Results

For each QIP completed, HSAG assesses the validity and reliability of the findings based on the CMS protocol for validating QIPs and informs plans and the DHCS of the confidence level of the reported findings. HSAG assesses threats to the validity and reliability of the QIP findings and determines when an accumulation of threats reaches the point at which the findings are no longer credible. Using the QIP Validation Tool and standardized scoring methodology, HSAG reports overall validity and reliability to the DHCS.

March 2013

HSAG reports validity and reliability as follows:

- *Met* = Confidence/high confidence in the reported QIP results
- Partially Met = Low confidence in the reported QIP results
- *Not Met* = Reported QIP results that were not credible

#### Communication of Validation Results

HSAG communicates QIP validation results via the QIP Validation Tool, which includes validation scoring and an overall validation status. The validation tool includes HSAG's feedback through *Points of Clarification* and comments related to evaluation elements receiving a Partially Met or Not Met score. The completed validation tool displays areas in which the plans need to provide additional documentation and the specific documentation needed to achieve a Met finding.

The Next Steps section provides direction to plans related to the findings.

#### Next Steps for Valid and Reliable QIPs:

- Plans will proceed with the QIP study and submit baseline results.
- Plans will continue the QIP for the next annual submission.
- HSAG will instruct plans to address all Partially Met and Not Met scores and Points of Clarification prior to the next submission.
- Approximately 10 months prior to the closure of an existing QIP, DHCS will instruct the plan to identify its next QIP topic.
- If HSAG validates the QIP through all 10 activities and the plan achieved sustained improvement, HSAG considers the QIP final. For QIPs that do not achieve the desired statistically significant and/or sustained improvement, HSAG in consultation with DHCS and the plan will determine whether to close out the existing project or have the plan continue the QIP for additional remeasurement periods.

#### A new methodology for Activity IX was implemented as of July 1, 2012.

Activity IX will be scored annually after remeasurement data have been reported. When statistically significant improvement is achieved from baseline to the current measurement period for a study indicator, that study indicator will receive a *Met* score. Once a study indicator achieves statistically significant improvement, the score for that study indicator will remain Met for the duration of the QIP. Evaluation Element 3 will be scored Partially Met if not all of the study indicators achieved statistically significant improvement. If all study indicators achieve statistically significant improvement, Evaluation Element 3 will be scored Met.

#### A new methodology for Activity X was also implemented as of July 1, 2012.

Statistically significant improvement must be achieved (i.e., Activity IX, Evaluation Element 3 receives a Partially Met or Met score) for at least one study indicator before Activity X will

March 2013

be validated for the study indicators achieving statistically significant improvement. This means that the QIP may report several measurement periods before Activity X will be scored. DHCS and HSAG will determine when a study indicator or the entire QIP is complete based on the study indicators that have achieved sustained improvement.

#### Next Steps for Invalid or Unreliable QIPs:

 HSAG directs plans to resubmit a revised QIP addressing all Partially Met and Not Met scores and Points of Clarification.

#### **Communication with Plans and the DHCS**

HSAG provides a completed QIP Validation Tool to plans and MCMC. Plans can contact the EQRO directly to discuss validation findings or request technical assistance.

As required by its DHCS contract, HSAG prepares a Quarterly QIPs Status Report that includes a list of all QIPs validated during the quarter. The report documents:

- Aggregate validation findings for the quarter.
- Strengths and opportunities for improvement identified through the validation process.
- Recommendations provided to the DHCS and the plans.
- A list of all active QIPs conducted by the plans.
- Key findings and best practices.

#### **Technical Assistance**

HSAG is available to provide technical assistance to plans to ensure that their QIPs are sound and valid and result in real improvements in the care and/or services provided to Medi-Cal managed care plan members. HSAG also provides technical assistance to help plans comply with CMS protocol requirements.

HSAG's approach to providing technical assistance focuses on several key areas:

- Providing information to DHCS and plans regarding the validation process, criteria, and related federal requirements/protocols.
- Providing information to DHCS and plans regarding supporting materials that plans should submit to meet validation requirements.
- Assisting in the development and monitoring of a statewide collaborative QIP to ensure that all QIP components meet CMS requirements.
- Providing information on industry standard practices for conducting QIPs.
- Providing meaningful and timely feedback to plans regarding each QIP.
- Conducting follow-up conference calls with plans to discuss evaluation results if requested and/or approved by DHCS.
- Assisting plans in determining the possible reasons that QIPs have not achieved improvement and providing recommendations for improvement to the DHCS and the plans.
- Identifying best practices, common issues, and performance trends and conveying this information to DHCS and the plans.
- Assisting in educating DHCS and the plans regarding pertinent quality improvement project study areas.

HSAG provides technical assistance through e-mails, conference calls, and/or Webinars. With DHCS approval, HSAG may provide Webinars to respond to global questions with answers that would benefit all the plans. Plans may request technical assistance through the DHCS and HSAG points of contact.

HSAG provides the following list of resources and references to help plans conduct QIPs. These sites offer protocols, literature, guidelines, and tools used for quality improvement projects.

- Agency for Healthcare Research and Quality (AHRQ)—The nation's leading federal
  agency for research on health care quality, costs, outcomes, and patient safety.
   www.ahrq.gov
- AHRQ Health Care Innovations Exchange—Health plans send AHRQ the innovations and/or tools they used to improve services provided to their members. Information includes innovations that did not work and why, and the level of evidence (strong, moderate, low, insufficient). <a href="https://www.innovations.ahrq.gov">www.innovations.ahrq.gov</a>
- Center for Healthcare Strategies—A nonprofit health policy resource center dedicated to improving the quality and cost effectiveness of health care services for low-income populations and people with chronic illnesses and disabilities. <a href="www.chcs.org">www.chcs.org</a>
- Centers for Medicare & Medicaid Services (CMS)—The U.S. Department of Health and Human Services agency responsible for administering the Medicare, Medicaid, CHIP (Children's Health Insurance Program), and several other health-related programs.
   www.cms.gov
  - Validation of Performance Improvement Projects (PIPs): A Mandatory Protocol for External Quality Review (EQR), Version 2.0, September 2012. (This document is downloadable within the EQR protocols.) www.medicaid.gov
  - Implementation of Performance Improvement Projects (PIPS): A Voluntary Protocol for External Quality Review (EQR), Version 2.0, September 2012. (This document is downloadable within the EQR protocols.) www.medicaid.gov
- The National Committee for Quality Assurance (NCQA)—A private, nonprofit organization dedicated to improving health care quality. NCQA has been a central figure in driving improvement throughout the health care system, helping to elevate the issue of health care quality to the top of the national agenda. <a href="www.ncqa.org">www.ncqa.org</a>
  - Health Care Quality Improvement Studies in Managed Care Settings—Design and Assessment: A
    Guide for State Medicaid Agencies.
- Institute for Healthcare Improvement (IHI)—An independent, nonprofit organization helping to lead the improvement of health care throughout the world. IHI works to accelerate improvement by building the will for change, cultivating promising concepts for improving patient care, and helping health care systems put those ideas into action.

  www.ihi.org

- National Guideline Clearinghouse (NGC)—A public resource for evidence-based clinical practice guidelines, NGC is an initiative of AHRQ, U.S. Department of Health and Human Services. AHRQ originally created NGC in partnership with the American Medical Association and the American Association of Health Plans (now America's Health Insurance Plans [AHIP]). <a href="https://www.guidelines.gov">www.guidelines.gov</a>
- **Sampling Calculator**—An online calculator that can be used to determine sample sizes. <a href="http://www.surveysystem.com/sscalc.htm">http://www.surveysystem.com/sscalc.htm</a>
- **Statistical Testing Calculator**—An online statistical calculator that can be used to perform statistical testing. <a href="www.graphpad.com/quickcalcs/index.cfm">www.graphpad.com/quickcalcs/index.cfm</a>

#### **CMS**

Centers for Medicare & Medicaid Services (CMS) is the federal agency responsible for administration of the Medicare and Medicaid programs. This agency was formerly known as the Health Care Financing Administration (HCFA).

#### **CMS Protocols**

A written instructional document for conducting specific EQR-related activities, including conducting and validating QIPs.

#### Critical Element

Elements within the EQRO QIP Validation Tool that have been identified as essential for producing a valid and reliable QIP. All critical elements must be *Met* for a QIP to receive an overall validation status of *Met*.

#### **EQRO**

An external quality review organization (EQRO) is a peer review organization (PRO)-like entity or accrediting body that has expertise in reviewing the quality of health care provided to Medicaid beneficiaries in a state's Medicaid managed care plans. CMS requires state Medicaid managed care programs to contract with an EQRO to receive enhanced federal financial participation.

#### Noncritical Element

Elements within the EQRO QIP Validation Tool that have been identified as nonessential for producing a valid and reliable QIP. Noncritical elements are included in the total sum to produce an overall QIP validation percentage score.

#### **Outcome Measure**

Variables that measure the end results of health care—e.g., elimination of disease, improvement of functioning or perceived well-being, birth weight, or death.

# Performance Improvement Project (PIPs)

The federal term for QIPs. A structured process of identifying and measuring a targeted area (clinical or nonclinical), analyzing the results, implementing interventions for improvement, and remeasuring to determine if improvement in performance was achieved.

#### **Points of Clarification**

Comments provided by the EQRO on the QIP Validation Tool to indicate that documentation for an evaluation element has the basic components; however, enhanced documentation would demonstrate a stronger understanding of the CMS protocols.

## **Quality Improvement Projects (QIPs)**

A structured process of identifying and measuring a targeted area (clinical or nonclinical), analyzing the results, implementing interventions for improvement, and remeasuring to determine if improvement in performance was achieved.

## Reliability

The degree to which a measure is reproducible—i.e., whether the measure has the same result when applied repeatedly.

## Sampling

The process of selecting a representative part of an overall population to study characteristics or test a hypothesis.

## Statistical Significance

Quantifies the degree to which chance variability may account for the results observed in a particular study.

#### Technical Assistance

The process of providing information on specific technical content related to EQR activities to address an identified need.

#### Validation

An objective review of a QIP by an EQRO to determine compliance with the CMS requirements for conducting a valid QIP.

## Validity

The extent to which the data collected for a QIP accurately measure what they were intended to measure and whether the conclusions made from the QIP were appropriate and justifiable.



# Appendix A. California 2012–2013 QIP Summary Form: <QIP Topic> for <Health Plan Full Name>

DEMOGRAPHIC INFORMATION				
Plan Name: <health full="" name="" plan=""></health>	Submission Date:			
Study Leader Name:	Title:			
Telephone Number:	E-Mail Address:			
Name of Project/Study: < QIP Topic>				
Name(s) of the Study Outcome(s):				



# Appendix A. California 2012–2013 QIP Summary Form: <QIP Topic> for <Health Plan Full Name>

**Activity I: Select the Study Topic(s).** QIP topics should target improvement in relevant areas of care/services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. The goal of the project should be to improve processes and/or outcomes of health care or services.

#### The study topic should:

- Be selected following the collection and analysis of plan-specific data.
- ➤ Have the potential to improve member health, functional status, or satisfaction.
- > Be based on a high-volume, high-risk, or problem-prone area for which improvement is needed.

20 Sacra on a high volume, mgr. nen, er presiem prene area ier innen imprevenient ie necaca.
Study Topic Rationale:
Provide plan-specific data:
Describe how the study topic has the potential to improve member health, outcomes of care, functional status, or satisfaction:



# Appendix A. California 2012–2013 QIP Summary Form: <QIP Topic> for <Health Plan Full Name>

**Activity II: Define the Study Question(s).** Stating the question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation.

#### The study question(s) should:

- ➤ Be structured in an X/Y format: "Does doing X result in Y?"
- > State the problem in clear and simple terms.
- Be answerable based on the data collection methodology and study indicator(s) provided.

Study Question(s):



**Activity III: Select the Study Indicator(s).** The selected indicator(s) should track performance or improvement over time. The study indicator(s) should be objective, completely and clearly defined, measurable, and based on current clinical knowledge or health services research.

- Include the complete title of the study indicator.
- > Include complete descriptions of the numerators and denominators, defining the terms used.
- Include the rationale for selecting the study indicator(s).
- ➤ If indicators are based on nationally recognized measures (e.g., HEDIS), include the year of the HEDIS technical specifications used for the applicable measurement year and update the year annually, as appropriate.
- Include complete dates for all measurement periods (with the day, month, and year).
- Include plan-specific goals for the remeasurement periods and the State-designated goal, if applicable.

Study Indicator 1 Title:	Provide a narrative description and the rationale for selecting the study indicator:
Numerator (no numeric value)	
Denominator (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal (if applicable)	



**Activity III: Select the Study Indicator(s).** The selected indicator(s) should track performance or improvement over time. The study indicator(s) should be objective, completely and clearly defined, measurable, and based on current clinical knowledge or health services research.

- Include the complete title of the study indicator.
- Include complete descriptions of the numerators and denominators, defining the terms used.
- Include the rationale for selecting the study indicator(s).
- If indicators are based on nationally recognized measures (e.g., HEDIS), include the year of the HEDIS technical specifications used for the applicable measurement year and update the year annually, as appropriate.
- Include complete dates for all measurement periods (with the day, month, and year).
- Include plan-specific goals for the remeasurement periods and the State-designated goal, if applicable.

Study Indicator 2 Title:	Provide a narrative description and the rationale for selecting the study indicator:
Numerator (no numeric value)	
Denominator (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal (if applicable)	



**Activity III: Select the Study Indicator(s).** The selected indicator(s) should track performance or improvement over time. The study indicator(s) should be objective, completely and clearly defined, measurable, and based on current clinical knowledge or health services research.

- Include the complete title of the study indicator.
- Include complete descriptions of the numerators and denominators, defining the terms used.
- Include the rationale for selecting the study indicator(s).
- If indicators are based on nationally recognized measures (e.g., HEDIS), include the year of the HEDIS technical specifications used for the applicable measurement year and update the year annually, as appropriate.
- Include complete dates for all measurement periods (with the day, month, and year).
- Include plan-specific goals for the remeasurement periods and the State-designated goal, if applicable.

Study Indicator 3 Title:	Provide a narrative description and the rationale for selecting the study indicator:
Numerator (no numeric value)	
Denominator (no numeric value)	
Baseline Measurement Period	
(include date range)	
Remeasurement 1 Period	
(include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period	
(include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal	
(if applicable)	
Additional information about the study indicators:	



Activity IV: Use a Representative and Generalizable Study Population. The study population(s) should be clearly defined to represent the population(s) to which the study question(s) and indicator(s) apply, without excluding members with special health care needs.

#### The study population(s) definition should:

- > Include the requirements for the length of enrollment, defining continuous enrollment, new enrollment, and allowable gaps in enrollment.
- > Include the complete age range of the study population and the anchor dates used to identify age criteria, if applicable.
- > Clearly define the inclusion, exclusion, and diagnosis criteria.
- Include a list of diagnosis/procedure/pharmacy/billing codes used to identify members, if applicable.
- Capture all members to whom the study question(s) applies.

Study Population:	
Member enrollment requirements:	
Member age criteria (if applicable):	
Inclusion, exclusion, and diagnosis criteria:	
Diagnosis/procedure/pharmacy/billing codes (if applicable):	



Activity V: Use Sound Sampling Techniques. If sampling is used to select members of the study, proper sampling techniques are necessary to support study results generalizable to the entire study population. The sampling methods should consider and specify the true or estimated frequency of occurrence of the event, the confidence interval used, and the acceptable margin of error. The sampling methods should also protect against bias and identify a sufficient number of members.

#### The description of the sampling methods should:

- Include components identified in the table below.
- > Be updated annually for each measurement period and for each study indicator.
- Include a detailed narrative description of the methods used to select the sample.

Measurement Period	Study Indicator	Population Size	Sample Size	Margin of Error and Confidence Level

Describe in detail the methods used to select the sample:



Activity VI: Use Valid and Reliable Data Collection Procedures. The data collection methods must ensure that data collected on the QIP indicators are valid and reliable.

#### Data collection methodology should include the following:

- Identification of data elements and data sources.
- When and how data are collected.
- How data are used to calculate the study indicators.
- How data are analyzed.

#### **Data Sources (Select all that apply)**

[ ] Hybrid—Both medical/treatment records (manu	al data collection) and administrative data collection processes are used	
[ ] Medical/Treatment Record Abstraction     Record Type     [ ] Outpatient     [ ] Inpatient     [ ] Other  Other Requirements     [ ] Data collection tool attached     [ ] Data collection instructions attached     [ ] Summary of data collection training attached     [ ] IRR process and results attached     [ ] Other Data	Data Source  [ ] Programmed pull from claims/encounters [ ] Complaint/Appeal [ ] Pharmacy data [ ] Telephone service data/call center data [ ] Appointment/access data [ ] Delegated entity/vendor data [ ] Other	Fielding Method  [ ] Personal interview [ ] Mail [ ] Phone with CATI script [ ] Phone with IVR [ ] Internet [ ] Other  Other Requirements [ ] Number of waves [ ] Response rate [ ] Incentives used
Description of manual data collection staff, including training, experience, and qualifications:	Estimated percentage of administrative data completeness: percent.  Describe the process used to determine data completeness and accuracy:	



Determine the data collection cycle.	ermine the data analysis cycle.
[ ] Twice a year [ [ ] Once a season [ ] Once a quarter [	] Once a year ] Once a season ] Once a quarter ] Once a month ] Continuous ] Other (list and describe):



#### Data analysis plan and other pertinent methodological features.

- Include how the rates or means are calculated, the type of statistical testing to be used to compare study results between measurement periods and to the baseline, and details of how data will be analyzed.
- > Documentation should include clear definitions of the data elements to be collected.
- Documentation should include a systematic process with an ordered sequence of steps. Each step depends on the outcome of the previous step. This can be defined in a narrative or with algorithms/flow charts.

Describe the data analysis plan:	
Describe the data collection process:	
Describe the data collection process:	



Activity VII: Data Analysis and Interpretation of Results. Clearly present the results of the study indicator(s). Describe the data analysis performed, the results of the statistical analysis, and an interpretation of the findings. Through data analysis and interpretation, real improvement as well as sustained improvement can be determined.

Enter results for each study indicator—including the goals, statistical testing with complete *p* values, and the statistical significance—in the table provided.

#### **Study Indicator 1 Title:**

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test, Statistical Significance, and <i>p</i> value
	Baseline					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					

#### **Study Indicator 2 Title:**

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test, Statistical Significance, and <i>p</i> value
	Baseline					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results for each of the study indicator(s). Describe the data analysis performed and the results of the statistical analysis, and interpret the findings. Through data analysis and interpretation, real improvement as well as sustained improvement can be determined.

The data analysis and interpretation of each study indicator's results should include the following for each measurement period:

- A description of the data analysis process conducted on each study indicator, including the statistical testing performed and the p values calculated.
- A description of the results for the statistical analysis, an interpretation of the findings, and a comparison of the results/changes from measurement period to measurement period as well as from baseline to the current measurement period. Discuss any statistically significant increase or decrease for each study indicator. Additionally, include a comparison to the goal for each study indicator.
- ldentification of any factors that could influence the comparability of measurement periods or the validity of the findings for each measurement period.
- Discussion of any random, year-to-year variations, population changes, sampling errors that may have occurred during the remeasurement process.
- A discussion of the extent to which each study indicator and the overall QIP was successful and any follow-up activities planned.

Describe the data analysis process and provide an interpretation of each study indicator's results for each measurement period.

Describe the data analysis process and provide an interpretation of each study indicator's results for each measurement period.
Baseline:
Remeasurement 1:
Remeasurement 2:



Activity VIII: Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through data analysis and quality improvement (QI) processes. Causal/barrier analysis identifies root causes and barriers to efficient care/service processes and from which appropriate interventions can be developed.

The causal/barrier analysis and QI processes should include the following for each measurement period:

- Detailed steps of the specific analysis performed and processes used.
- Description of the process conducted by committee(s), team(s), and/or work group(s).
- Description of the QI tools used (e.g., a fishbone diagram).
- Description of the identification and prioritization of the barriers.

Describe the causal/barrier analyses and QI processes used to develop, revise, and/or standardize the interventions for each measurement period.

Causal/barrier analysis process:

Barriers identified and prioritized:

New interventions planned/implemented during the Remeasurement 1 period:

#### Remeasurement 1

**Baseline** 

Causal/barrier analysis process:

Barriers identified and prioritized:

Revised, standardized, and/or new interventions planned/implemented during the Remeasurement 2 period:



Activity VIII: Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through data analysis and quality improvement (QI) processes. Causal/barrier analysis identifies root causes and barriers to efficient care/service processes and from which appropriate interventions can be developed.

#### The causal/barrier analysis and QI processes should include the following for each measurement period:

- > Detailed steps of the specific analysis performed and processes used.
- Description of the process conducted by committee(s), team(s), and/or work group(s).
- Description of the QI tools used (e.g., a fishbone diagram).
- Description of the identification and prioritization of the barriers.

#### Remeasurement 2

Causal/barrier	anal	vsis	process:
		,	p

Barriers identified and prioritized:

Revised, standardized, and/or new interventions planned/implemented during the Remeasurement 3 period, if necessary:



**Activity VIII: Improvement Strategies (implement interventions and improvement strategies).** Real, sustained improvements in care result from a continual cycle of measuring and analyzing performance, as well as developing and implementing effective interventions. Appropriate interventions that directly address identified barriers and consider the characteristics of the targeted population are essential to improving outcomes. Each intervention should be evaluated throughout the measurement period to determine effectiveness.

#### Interventions should:

- Directly address barriers identified.
- > Consider the characteristics of the targeted member and/or provider population and available resources.
- Affect behavior or processes at a member, practitioner, and/or system level.
- Include an evaluation plan.

Describe each intervention in detail, including the intervention category (member, provider, or system), the barrier addressed, the targeted population, and the date interventions were implemented. For each intervention, describe all evaluation outcomes during the measurement period and the resulting intervention status (i.e., its revision, standardization, or discontinuation):

measurement period and the resulting intervention status (i.e., its revision, standardization, or discontinuation):
<u>Baseline</u>
Intervention description:
Remeasurement 1
Intervention description:
Intervention evaluation, interpretation, and status:



Activity VIII: Improvement Strategies (implement interventions and improvement strategies). Real, sustained improvements in care result from a continual cycle of measuring and analyzing performance, as well as developing and implementing effective interventions. Appropriate interventions that directly address identified barriers and consider the characteristics of the targeted population are essential to improving outcomes. Each intervention should be evaluated throughout the measurement period to determine effectiveness.

#### Interventions should:

- Directly address barriers identified.
- Consider the characteristics of the targeted member and/or provider population and available resources.
- Affect behavior or processes at a member, practitioner, and/or system level.
- Include an evaluation plan.

Remeasurement 2	
ntervention description:	
ntervention evaluation, interpretation, and status:	



DEMOGRAPHIC INFORMATION		
Plan Name: <health full="" name="" plan=""></health>	Submission Date:	
Study Leader Name:	Title:	
Telephone Number:	E-Mail Address:	
Name of Project/Study: < QIP Topic>		
Name(s) of the Study Outcome(s):		



**Activity I: Select the Study Topic(s).** QIP topics should target improvement in relevant areas of care/services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of disease. The goal of the project should be to improve processes and/or outcomes of health care or services.

#### The study topic should:

- Be selected following the collection and analysis of plan-specific data.
- > Have the potential to improve member health, functional status, or satisfaction.
- Be based on a high-volume, high-risk, or problem-prone area for which improvement is needed.

Study Topic Rationale:
Provide plan-specific data (please provide plan-specific data for each county):
County 1:
County 2:
County 3:
Describe how the study topic has the potential to improve member health, outcomes of care, functional status, or satisfaction:



Activity II: Define the Study Question(s). Stating the question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation.

#### The study question(s) should:

- Be structured in an X/Y format: "Does doing X result in Y?"
- > State the problem in clear and simple terms.
- Be answerable based on the data collection methodology and study indicator(s) provided.

Study Question(s):	



**Activity III: Select the Study Indicator(s).** The selected indicator(s) should track performance or improvement over time. The study indicator(s) should be objective, completely and clearly defined, measurable, and based on current clinical knowledge or health services research.

- Include the complete title of the study indicator.
- Include complete descriptions of the numerators and denominators, defining the terms used.
- Include the rationale for selecting the study indicator(s).
- If indicators are based on nationally recognized measures (e.g., HEDIS), include the year of the HEDIS technical specifications used for the applicable measurement year and update the year annually, as appropriate.
- Include complete dates for all measurement periods (with the day, month, and year).
- Include plan-specific goals for the remeasurement periods and the State-designated goal, if applicable.

Study Indicator 1 Title:	Provide a narrative description and the rationale for selecting the study indicator:
Numerator (no numeric value)	
Denominator (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal (if applicable)	



**Activity III: Select the Study Indicator(s).** The selected indicator(s) should track performance or improvement over time. The study indicator(s) should be objective, completely and clearly defined, measurable, and based on current clinical knowledge or health services research.

- Include the complete title of the study indicator.
- Include complete descriptions of the numerators and denominators, defining the terms used.
- Include the rationale for selecting the study indicator(s).
- If indicators are based on nationally recognized measures (e.g., HEDIS), include the year of the HEDIS technical specifications used for the applicable measurement year and update the year annually, as appropriate.
- Include complete dates for all measurement periods (with the day, month, and year).
- Include plan-specific goals for the remeasurement periods and the State-designated goal, if applicable.

Study Indicator 2 Title:	Provide a narrative description and the rationale for selecting the study indicator:
Numerator (no numeric value)	
Denominator (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal (if applicable)	



**Activity III: Select the Study Indicator(s).** The selected indicator(s) should track performance or improvement over time. The study indicator(s) should be objective, completely and clearly defined, measurable, and based on current clinical knowledge or health services research.

- Include the complete title of the study indicator.
- Include complete descriptions of the numerators and denominators, defining the terms used.
- Include the rationale for selecting the study indicator(s).
- If indicators are based on nationally recognized measures (e.g., HEDIS), include the year of the HEDIS technical specifications used for the applicable measurement year and update the year annually, as appropriate.
- Include complete dates for all measurement periods (with the day, month, and year).
- > Include plan-specific goals for the remeasurement periods and the State-designated goal, if applicable.

Study Indicator 3 Title:	Provide a narrative description and the rationale for selecting the study indicator:
Numerator (no numeric value)	
Denominator (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal (if applicable)	
Additional information about the study indicators:	



Activity IV: Use a Representative and Generalizable Study Population. The study population(s) should be clearly defined to represent the population(s) to which the study question(s) and indicator(s) apply, without excluding members with special health care needs.

#### The study population(s) definition should:

- > Include the requirements for the length of enrollment, defining continuous enrollment, new enrollment, and allowable gaps in enrollment.
- > Include the complete age range of the study population and the anchor dates used to identify age criteria, if applicable.
- > Clearly define the inclusion, exclusion, and diagnosis criteria.
- Include a list of diagnosis/procedure/pharmacy/billing codes used to identify members, if applicable.
- Capture all members to whom the study question(s) applies.

Study Population:
Nember enrollment requirements:
Member age criteria (if applicable):
nclusion, exclusion, and diagnosis criteria:
Diagnosis/procedure/pharmacy/billing codes (if applicable):



**Activity V: Use Sound Sampling Techniques.** If sampling is used to select members of the study, proper sampling techniques are necessary to support study results generalizable to the entire study population. The sampling methods should consider and specify the true or estimated frequency of occurrence of the event, the confidence interval used, and the acceptable margin of error. The sampling methods should also protect against bias and identify a sufficient number of members.

#### The description of the sampling methods should:

- Include components identified in the table below.
- > Be updated annually for each measurement period and for each study indicator.
- Include a detailed narrative description of the methods used to select the sample.

County	Measurement Period	Study Indicator	Population Size	Sample Size	Margin of Error and Confidence Level

Describe in detail the methods used to select the sample:



Activity VI: Use Valid and Reliable Data Collection Procedures. The data collection methods must ensure that data collected on the QIP indicators are valid and reliable.

#### Data collection methodology should include the following:

- Identification of data elements and data sources.
- When and how data are collected.
- How data are used to calculate the study indicators.
- How data are analyzed.

ta Sources (Select all that apply)  ] Hybrid—Both medical/treatment records (manual)  ] Medical/Treatment Record Abstraction Record Type  [ ] Outpatient [ ] Inpatient [ ] Other  Other Requirements [ ] Data collection tool attached [ ] Data collection instructions attached [ ] Summary of data collection training attached [ ] IRR process and results attached [ ] Other Data	al data collection) and administrative data collection processes are used  [ ] Administrative Data  Data Source     [ ] Programmed pull from claims/encounters     [ ] Complaint/Appeal     [ ] Pharmacy data     [ ] Telephone service data/call center data     [ ] Appointment/access data     [ ] Delegated entity/vendor data     [ ] Other  Other Requirements     [ ] Codes used to identify data elements (e.g., ICD-9, CPT codes)  [ ] Data completeness assessment attached     [ ] Coding verification process attached     [ ] Quality control process attached	[ ] Survey Data  Fielding Method  [ ] Personal interview [ ] Mail [ ] Phone with CATI script [ ] Phone with IVR [ ] Internet [ ] Other  Other Requirements [ ] Number of waves [ ] Response rate [ ] Incentives used
Description of manual data collection staff, including training, experience, and qualifications:	Estimated percentage of administrative data completeness: percent.  Describe the process used to determine data completeness and accuracy:	



Determine the data collection cycle.	Determine the data analysis cycle.
[ ] Once a year [ ] Once a season [ ] Once a quarter [ ] Once a month [ ] Once a week [ ] Once a day [ ] Continuous [ ] Other (list and describe):	<ul> <li>Once a year</li> <li>Once a season</li> <li>Once a quarter</li> <li>Once a month</li> <li>Continuous</li> <li>Other (list and describe):</li> </ul>



#### Data analysis plan and other pertinent methodological features.

- Include how the rates or means are calculated, the type of statistical testing to be used to compare study results between measurement periods and to the baseline, and details of how data will be analyzed.
- Documentation should include clear definitions of the data elements to be collected.
- Documentation should include a systematic process with an ordered sequence of steps. Each step depends on the outcome of the previous step. This can be defined in a narrative or with algorithms/flow charts.

Describe the data analysis plan:	
Describe the data collection process (by county if applicable): County 1: County 2: County 3:	



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, the results of the statistical analysis, and an interpretation of the findings. Through data analysis and interpretation, real improvement as well as sustained improvement can be determined.

Enter results for each study indicator—including the goals, statistical testing with complete *p* values, and the statistical significance—in the table provided.

#### **Study Indicator 1 Title:**

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test, Statistical Significance, and <i>p</i> value
	Baseline					
	County 1					
	County 2					
	County 3					
	Remeasurement 1					
	County 1					
	County 2					
	County 3					
	Remeasurement 2					
	County 1					
	County 2					
	County 3					
	Remeasurement 3					
	County 1					
	County 2					
	County 3					



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, the results of the statistical analysis, and an interpretation of the findings. Through data analysis and interpretation, real improvement as well as sustained improvement can be determined.

Enter results for each study indicator—including the goals, statistical testing with complete *p* values, and the statistical significance—in the table provided.

#### **Study Indicator 2 Title:**

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test, Statistical Significance, and <i>p</i> value
	Baseline					
	County 1					
	County 2					
	County 3					
	Remeasurement 1					
	County 1					
	County 2					
	County 3					
	Remeasurement 2					
	County 1					
	County 2					
	County 3					
	Remeasurement 3					
	County 1					
	County 2					
	County 3					



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results for each of the study indicator(s). Describe the data analysis performed and the results of the statistical analysis, and interpret the findings. Through data analysis and interpretation, real improvement as well as sustained improvement can be determined.

The data analysis and interpretation of each study indicator's results should include the following for each measurement period:

- A description of the data analysis process conducted on each study indicator, including the statistical testing performed and the *p* values calculated.
- A description of the results for the statistical analysis, an interpretation of the findings, and a comparison of the results/changes from measurement period to measurement period as well as from baseline to the current measurement period. Discuss any statistically significant increase or decrease for each study indicator. Additionally, include a comparison to the goal for each study indicator.
- Identification of any factors that could influence the comparability of measurement periods or the validity of the findings for each measurement period.
- Discussion of any random, year-to-year variations, population changes, sampling errors that may have occurred during the remeasurement process.
- A discussion of the extent to which each study indicator and the overall QIP was successful and any follow-up activities planned.

Describe the data analysis process and provide an interpretation of each study indicator's results for each measurement peri	od.
Baseline:	

County 1:

County 2:

County 3:

#### Remeasurement 1:

County 1:

County 2:

County 3:

#### **Remeasurement 2:**

County 1:

County 2:

County 3:



Activity VIII: Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through data analysis and quality improvement (QI) processes. Causal/barrier analysis identifies root causes and barriers to efficient care/service processes and from which appropriate interventions can be developed.

The causal/barrier analysis and QI processes should include the following for each measurement period:

- Detailed steps of the specific analysis performed and processes used.
- Description of the process conducted by committee(s), team(s), and/or work group(s).
- Description of the QI tools used (e.g., a fishbone diagram).
- Description of the identification and prioritization of the barriers.

# Describe the causal/barrier analyses and QI processes used to develop, revise, and/or standardize the interventions for each measurement period. Baseline Causal/barrier analysis process: County 1: County 2: County 3: Barriers identified and prioritized: County 1: County 2: County 3: New interventions planned/implemented during the Remeasurement 1 period: County 1: County 1: County 2: County 3:



Activity VIII: Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through data analysis and quality improvement (QI) processes. Causal/barrier analysis identifies root causes and barriers to efficient care/service processes and from which appropriate interventions can be developed.

#### The causal/barrier analysis and QI processes should include the following for each measurement period:

- Detailed steps of the specific analysis performed and processes used.
- Description of the process conducted by committee(s), team(s), and/or work group(s).
- Description of the QI tools used (e.g., a fishbone diagram).

Remeasurement 1	
Causal/barrier analysis p	process:
County 1:	
County 2:	
County 3:	
Barriers identified and p	rioritized:
County 1:	
County 2:	
County 3:	
Revised, standardized, a	and/or new interventions planned/implemented during the Remeasurement 2 period:
County 1:	
County 2:	
County 3:	



Activity VIII: Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through data analysis and quality improvement (QI) processes. Causal/barrier analysis identifies root causes and barriers to efficient care/service processes and from which appropriate interventions can be developed.

#### The causal/barrier analysis and QI processes should include the following for each measurement period:

- Detailed steps of the specific analysis performed and processes used.
- Description of the process conducted by committee(s), team(s), and/or work group(s).
- Description of the QI tools used (e.g., a fishbone diagram).
- Description of the identification and prioritization of the barriers.

### Remeasurement 2 Causal/barrier analysis process:

deal/burrior unaryolo processi
ounty 1:
ounty 2:
ounty 3:
rriers identified and prioritized:
ounty 1:
ounty 2:
ounty 3:
evised, standardized, and/or new interventions planned/implemented during the Remeasurement 3 period, if necessary:
ounty 1:
ounty 2:
ounty 3:



Activity VIII: Improvement Strategies (implement interventions and improvement strategies). Real, sustained improvements in care result from a continual cycle of measuring and analyzing performance, as well as developing and implementing effective interventions. Appropriate interventions that directly address identified barriers and consider the characteristics of the targeted population are essential to improving outcomes. Each intervention should be evaluated throughout the measurement period to determine effectiveness.

#### Interventions should:

- Directly address barriers identified.
- Consider the characteristics of the targeted member and/or provider population and available resources.
- Affect behavior or processes at a member, practitioner, and/or system level.
- Include an evaluation plan.

Describe each intervention in detail, including the intervention category (member, provider, or system), the barrier addressed, the targeted population, and the date interventions were implemented. For each intervention, describe all evaluation outcomes during the

#### measurement period and the resulting intervention status (i.e., its revision, standardization, or discontinuation): **Baseline** Intervention description: County 1: County 2: County 3: Remeasurement 1 Intervention description: County 1: County 2: County 3: Intervention evaluation, interpretation, and status: County 1: County 2:

County 3:



**Activity VIII: Improvement Strategies (implement interventions and improvement strategies).** Real, sustained improvements in care result from a continual cycle of measuring and analyzing performance, as well as developing and implementing effective interventions. Appropriate interventions that directly address identified barriers and consider the characteristics of the targeted population are essential to improving outcomes. Each intervention should be evaluated throughout the measurement period to determine effectiveness.

#### Interventions should:

- Directly address barriers identified.
- > Consider the characteristics of the targeted member and/or provider population and available resources.
- Affect behavior or processes at a member, practitioner, and/or system level.
- Include an evaluation plan.

Remeasurement	2
---------------	---

County 3:

Intervention description:
County 1:
County 2:
County 3:
Intervention evaluation, interpretation, and status:
County 1:



## Appendix C. State of California QIP Summary Form Completion Instructions

These instructions should be used as a guide during the completion of the QIP Summary Form. Each section provides detailed information on the documentation requirements for each activity.

DEMOGRAPHIC INFORMATION				
Plan Name: <health full="" name="" plan=""></health>	Submission Date:			
Study Leader Name:	Title:			
Telephone Number:	E-mail Address:			
Name of Project/Study: <qip topic=""></qip>				
Name(s) of the Study Outcome(s): (Specifically state the outcome being measured.)				



## Appendix C. State of California QIP Summary Form Completion Instructions

Activity I: Choose the Selected Study Topic. QIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPCS codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; local or national data related to Medicaid risk populations; etc. The goal of the project should be to improve processes and/or outcomes of health care or services in order to have a positive impact on member health, functional status, or satisfaction. The topic may be specified by the State Medicaid agency or CMS and be based on input from members. Topics should represent high-volume or high-risk problem-prone populations. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

#### Study topic rationale:

Clearly state the study topic. Specify if the topic was assigned by the State or is a statewide or small group collaborative QIP topic. Explain how the study topic was selected, addressing the following required HSAG evaluation elements:

#### 1. Is selected following collection and analysis of data.

- Provide plan-specific historical data and analysis to support the selection of the study topic. For example, if the study topic is Well-Child
  Visits in the First 15 Months of Life, the documentation should provide the recent well-child visit rates to support the selection of the study
  topic for a QIP.
- If no historical plan-specific data were available, provide rationale for why these data were not included.

#### 2. Has the potential to positively affect member health, outcomes of care, functional status, or satisfaction.

- Explain how the study topic has the potential to affect member health, functional status, or satisfaction.
- Explain the link between the study topic and outcomes of care.



## Appendix C. State of California QIP Summary Form Completion Instructions

Activity II: Define the Study Question(s). Stating the question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation.

#### Study question(s):

Enter study question(s) here. Ensure the study question(s) address the following HSAG evaluation element:

#### 1. States the problem to be studied in simple terms.

- The study question(s) should be stated in the recommended format of, "Does doing X (the interventions) result in Y (desired improvement)?"
- Define terms used in the study question(s) that may be unclear.
- The study question(s) must be answerable through the proposed data collection methodology and study indicator(s) provided.



Activity III: Select the Study Indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

#### Study indicator(s):

Enter the study indicator(s) in the table for Activity III, ensuring that the following evaluation elements are addressed:

- 1. The indicator(s) are well-defined, objective, and measure changes (outcomes) in health or functional status, member satisfaction, or valid process alternatives.
  - Provide the complete title(s) of the study indicator(s) in the shaded gray box.
  - Provide complete narrative descriptions of the numerators and denominators.
  - Provide the rationale for each study indicator.
  - Include all starting and ending dates of each measurement period (month, day, and year format).
  - Include plan-specific goals for remeasurement periods and the State-designated goal, if applicable. If a State goal was not determined, enter "Not Applicable" or "NA."
- 2. Include the basis on which the study indicator(s) were adopted.
  - The rationale and explanation why each study indicator was chosen. Study indicator(s) should be based on current clinical practice guidelines or health services research, and these sources should be specified in the QIP documentation.
  - When appropriate, nationally recognized measures (e.g., HEDIS), should be used. Include the year of the HEDIS technical specifications used for the applicable measurement year, and update annually as appropriate.
  - If the study indicator(s) are nationally recognized measures, this should be explained in the QIP documentation. The year of the specifications should also be included, and updated annually.
  - If the study indicator(s) were provided by the State, the documentation in Activity III should reflect this.
- 3. The indicator(s) allow for the study question to be answered.
  - The study indicator(s) should provide data to answer the reported study question(s).
  - The study indicator(s) and study question(s) should align.



Activity III: Select the Study Indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study Indicator 1 Title: Enter the complete title of the study indicator here	Provide a narrative description and the rationale for selection of the study indicator:
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal	
Study Indicator 2 Title: Enter the complete title of the study indicator here	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator here	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator here  Numerator: (no numeric value)	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator here  Numerator: (no numeric value)  Denominator: (no numeric value)  Baseline Measurement Period (include date	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator here  Numerator: (no numeric value)  Denominator: (no numeric value)  Baseline Measurement Period (include date range)  Remeasurement 1 Period (include date	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator here  Numerator: (no numeric value)  Denominator: (no numeric value)  Baseline Measurement Period (include date range)  Remeasurement 1 Period (include date range)	Provide a narrative description and the rationale for selection of the study indicator:
complete title of the study indicator here  Numerator: (no numeric value)  Denominator: (no numeric value)  Baseline Measurement Period (include date range)  Remeasurement 1 Period (include date range)  Plan-Specific Remeasurement 1 Goal  Remeasurement 2 Period (include date	Provide a narrative description and the rationale for selection of the study indicator:



Activity III: Select the Study Indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study Indicator 3 Title: Enter the complete title of the study indicator here	Provide a narrative description and the rationale for selection of the study indicator:
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal	
If the plan has additional information about	out the study indicators it would like to provide, use this area to document the information.



Activity IV: Use representative and generalizable study population(s). The study population(s) should be clearly defined to represent the entire population to which the study question and indicators apply. The length of member enrollment should be considered and defined. All selection criteria should be listed here. Once the population(s) are identified, a decision must be made whether to review data for the entire population or a sample of that population.

#### Study population(s):

Describe the population(s) and methods for identifying the study population(s). Identify the study population(s), addressing the following components of the HSAG evaluation element: The study population should not exclude members with special health care needs. If these members were excluded, the plan must provide the rationale.

#### The study population(s) are accurately and completely defined and capture all members to whom the study question(s) apply.

- Clearly define inclusion, exclusion, and diagnosis criteria.
- Include a list of diagnosis codes, pharmacy codes, billing codes, procedure codes, and/or other system codes used to identify members.
- Include the complete age range and any anchor dates used to identify age criteria, if applicable.
- Include actual HEDIS technical specifications used in the study to define the study population (may provide as an attachment).
- Define continuous enrollment, new enrollment, and allowable gaps in enrollment.
- Any dates used to identify continuous enrollment criteria should be included.
- Include how race/ethnicity will be identified, if applicable.



**Activity V: Use Sound Sampling Techniques.** If sampling is to be used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. Sampling techniques should be in accordance with generally accepted principles of research design and statistical analysis. Representative sampling techniques should be used to ensure generalizable information.

#### Sampling Methods:

Enter sampling techniques used to select members for the study. Please ensure that the responses address all of the items highlighted below. If the entire eligible population was used, document this in the table in Activity V of the QIP Summary Form. The sampling information should be updated annually for each measurement year and for each study indicator.

For each measurement period and study indicator, enter the following information in the table provided:

- 1. Enter the measurement period for the sampling methods used (e.g., baseline, Remeasurement 1, etc.)
- 2. Provide the title of the applicable study indicator(s).
- 3. Identify the population size.
- 4. Identify the sample size.
- 5. Specify the margin of error and confidence level.
- 6. Below the table, describe in detail the methods used to select the sample.
  - If NCQA certified software was used to select the sample, document this and include the certified software seal.

Measurement Period	Study Indicator	Population Size	Sample Size	Margin of Error and Confidence Level

#### Describe the methods used to select the sample:



**Activity VI: Use Valid and Reliable Data Collection Procedures.** Data collection must ensure that the data collected on QIP 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.

#### **Data Collection:**

Enter data collection techniques. When using hybrid data collection, both manual data collection and administrative items should be addressed. Make sure that the responses address all of the evaluation items listed below:

#### 1. Identification of data elements to be collected and specified sources of data.

- Documentation should include clear definitions of the data elements to be collected.
- Include codes, such as ICD9, CPT codes that are used to identify and pull administrative data for the study indicators.
- If using HEDIS, submit the Final HEDIS Audit Report.
- The sources of data should be clearly specified by checking all appropriate boxes, providing descriptive information when necessary, and by attaching required information when appropriate.

#### 2. A defined and systematic process for collecting and remeasuring data.

- A systematic method for data collection should be specified.
- Documentation should include a systematic process of an ordered sequence of steps. Each step depends on the outcome of the previous step. This can be defined in a narrative, or with algorithms/flow charts.
- If an NCQA certified vendor or software was used to collect data, document this and include the vendor's name and the certified software seal.
- Identify the timing of data collection and data analysis by checking appropriate boxes and providing additional narrative information if necessary.

### IF MANUAL DATA COLLECTION WAS USED, PROVIDE:

#### 3. Qualifications of staff members collecting manual data.

- The relevant education, experience, and training of all manual data collection staff should be described in the QIP Summary Form.
- Training of the staff members should be updated annually.



**Activity VI: Use Valid and Reliable Data Collection Procedures.** Data collection must ensure that the data collected on QIP 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.

#### 4. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.

- Include the manual data collection tool and instructions for completing the tool with the QIP submission.
- For mailed surveys, include the cover letter and survey.
- For telephone surveys, include the script, as well as the monitoring and training process for the telephone survey staff.
- Include a discussion of the IRR process and the results of the process. Include a detailed discussion of the steps for conducting interrater reliability in medical record review.

#### IF ADMINISTRATIVE DATA WERE COLLECTED, PROVIDE:

#### 1. An estimated percentage of administrative data completeness and quality.

- Percentage of administrative data completeness and a description of the process used to determine the percentage should be included.
- Include a description of the quality process used for data collection. For example, how is the quality of administrative data ensured in the data collection procedures, and what are the steps to ensure valid and reliable data are produced?

### 2. Data analysis plan. (Include in every submission, even the initial study design submission.)

- Describe the data analysis plan. The essential components of a data analysis plan include how the study indicator rate or mean will be
  calculated, how the study indicator rate or mean will be compared to a goal or benchmark, and what statistical test will be used to compare
  study indicator rates or means between measurement periods. If subgroup analysis will be conducted, the data analysis plan should
  identify those subgroups and what comparisons will be done as well as what statistical testing will be done on the subgroup level.
- HSAG recommends a two-tailed statistical test (e.g., Chi-square, z test for proportions, or Fisher's exact test). The QIP should conduct statistical testing to determine if the change for each study indicator was statistically significant from baseline to Remeasurement 1 and from Remeasurement 1 to Remeasurement 2. If the QIP includes additional measurement periods beyond Remeasurement 2, it will need to provide statistical testing results for the additional measurement period results.



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.

Enter the results for each study indicator, including goals and statistical testing with complete *p* values, and statistical significance in the table provided.

Study Indicator 1 Title: Enter the title of the study indicator here.

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test Significance and <i>p</i> value
Month, Day, Year Format	Baseline					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					
	Remeasurement 4					
	Remeasurement 5					

Study Indicator 2 Title: Enter the title of the study indicator here.

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test Significance and <i>p</i> value
Month, Day, Year Format	Baseline					
	Remeasurement 1					
	Remeasurement 2					
	Remeasurement 3					
	Remeasurement 4					
	Remeasurement 5					



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.

**Analysis and Interpretation of the Results.** Describe the data analysis performed on each of the study indicators and the interpretation of the results addressing the following:

- Include statistical analysis techniques used (e.g., Chi-square, Fisher's exact test, *t* test). Perform all statistical testing using a two-tailed approach to calculate the *p* value. Please include the *p* value to four decimal places (i.e., 0.0235). If the *p* value is less than 0.0001, please indicate the *p* value ≤ 0.0001. For HEDIS-based QIPs, the data reported in the QIP should match the data reported in the plan's NCQA Interactive Data Submission System (IDSS). All data reported should be accurate and consistent throughout the QIP.
- Identify statistical differences between measurement periods and between baseline and the current measurement period.
- Describe the results of the statistical analysis, interpret the findings, and compare and discuss results/changes from measurement period to measurement period as well as from baseline to the current measurement period.
- Discuss any statistically significant increase or decrease for each study indicator. Additionally, include a comparison to the goal for each study indicator.
- Identify factors that threaten internal or external validity of the findings. Examples of factors would be a change in demographic population, acquiring another health plan's members, or a change in health plan staff. If there were factors identified, their impact and resolution should be discussed.
- Identify factors that affect the ability to compare measurements. An example would be a change in the study methodology. If there was a change in methodology, the issue, impact, and resolution should be discussed to justify the needed changes.
- If there are no identified factors that threatened the validity of the findings or that affected the ability to compare measurement, this information should be documented in the QIP Summary Form.
- Discuss any random, year-to-year variations, population changes, sampling errors that may have occurred during the remeasurement process.
- Include a discussion about the extent to which each study indicator and the overall QIP was successful and follow-up activities planned as a result. This can also include success identified by the plan throughout the QIP process, which may or may not be related to indicator(s) improvement. The interpretation should include lessons learned.



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.

Describe the data analysis process and provide an interpretation of each study indicator's results for each measurement period.
Baseline:
Remeasurement 1:
Remeasurement 2:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

#### **Causal/Barrier Analyses:**

Describe the causal/barrier analyses and quality improvement (QI) processes used to develop, revise, and/or standardize the interventions for each measurement period. Make sure the description addresses the items listed below:

Causal/Barrier analyses and/or QI processes described should include the following descriptions for each measurement period:

- Steps and specific processes used.
- Process conducted by committee(s), team(s), and/or work group(s).
- QI tools used and provided as attachments (e.g., fishbone diagram, Plan-Do-Study-Act (PDSA) Worksheet).
- Data mining activities. Data mining analysis can be performed to gain further insights for barriers to receiving care/services. For example, member subgroups (by provider, county, and/or zip code, etc.) could be identified that did not receive care/services.
- Identification and prioritization of the barriers.
- Analysis conducted on the interventions after each measurement period.

#### **Baseline**

Causal/barrier analysis process:

**Barriers identified and prioritized:** 

New interventions planned/implemented during the Remeasurement 1 period:

### Remeasurement 1

Causal/barrier analysis process:

**Barriers identified and prioritized:** 

Revised, standardized, and/or new interventions planned/implemented during the Remeasurement 2 period:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

Remeasurement 2
Causal/barrier analysis process:
Barriers identified and prioritized:
Revised, standardized, and/or new interventions planned/implemented during the Remeasurement 3 period, if necessary:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

The interventions target causes/barriers identified through data analysis and quality improvement processes.

Describe interventions/improvement strategies, and the evaluation and interpretation of each intervention for each measurement period. The narrative discussion about the interventions/improvement strategies and their evaluation results and interpretation should address the following:

- Include the date the interventions were implemented (month/year format).
- Provide the category of the intervention (member, provider, system).
- Describe how the interventions directly address the identified barriers. Each intervention should be linked with a specific barrier.
- Describe how the interventions consider the characteristics of the targeted member and/or provider population and available resources.
- Discuss the evaluation results for each intervention conducted during the measurement period. The evaluation should include analysis of the intervention's effectiveness. For example, if a member intervention included postcard visit reminders, discuss how many members required a visit and then compare to how many members scheduled and/or kept appointments after receiving the reminder postcard. Include any issues/concerns with the implementation of the intervention.
- Based on the evaluation results, describe the revision, standardization, and/or discontinuation of the intervention.

Describe	interventions.	

### Baseline

Intervention description (including category and date implemented):

### Remeasurement 1

Intervention description (including category and date implemented):

Intervention evaluation, interpretation, and status:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

causes and barriers to efficient care processes from which appropriate interventions can be developed.
Remeasurement 2
Intervention description (including category and date implemented):
Intervention evaluation, interpretation, and status:



**Activities IX and X: Real and Sustained Improvement.** There are no additional documentation requirements for Activities IX and X. These activities will be scored based on documentation provided in prior activities.

For improvement strategy planning purposes only, please note the following:

Activity IX: Assessing for Real Improvement

For each study indicator, Activity IX will be scored annually until statistically significant improvement (Evaluation Element 3) is achieved from baseline to the current remeasurement period. Once a study indicator receives a *Met* score for Evaluation Element 3, it will remain *Met* for the duration of the QIP. The actual score for Evaluation Element 3 will be based on the scores for all study indicators.

Activity X: Assessing for Sustained Improvement

HSAG will not validate Activity X until statistically significant improvement has been achieved in Activity IX for at least one study indicator. After a study indicator achieves statistically significant improvement, it will be evaluated annually to determine if the statistically significant improvement has been sustained in the subsequent remeasurement period. Once a study indicator achieves sustained improvement, additional data are no longer required to be reported in the QIP.



These instructions should be used as a guide during the completion of the QIP Summary Form. Each section provides detailed information on the documentation requirements for each activity.

DEMOGRAPHIC INFORMATION		
Plan Name: <h><b><b><b><b><b><b><b><b><b><b< td=""><td>Submission Date:</td></b<></b></b></b></b></b></b></b></b></b></h>	Submission Date:	
Study Leader Name:	Title:	
Telephone Number:	E-mail Address:	
Name of Project/Study: < <u>QIP Topic&gt;</u>		
Name(s) of the Study Outcome(s):(Specific	cally state the outcome(s) being measured.)	



Activity I: Choose the Selected Study Topic. QIP topics should target improvement in relevant areas of services and reflect the population in terms of demographic characteristics, prevalence of disease, and the potential consequences (risks) of the disease. Topics may be derived from utilization data (ICD-9 or CPT coding data related to diagnoses and procedures; NDC codes for medications; HCPCS codes for medications, medical supplies, and medical equipment; adverse events; admissions; readmissions; etc.); grievances and appeals data; survey data; provider access or appointment availability data; member characteristics data such as race/ethnicity/language; other fee-for-service data; local or national data related to Medicaid risk populations; etc. The goal of the project should be to improve processes and/or outcomes of health care or services in order to have a positive impact on member health, functional status, or satisfaction. The topic may be specified by the State Medicaid agency or CMS and be based on input from members. Topics should represent high-volume or high-risk problem-prone populations. Over time, topics must cover a broad spectrum of key aspects of member care and services, including clinical and nonclinical areas, and should include all enrolled populations (i.e., certain subsets of members should not be consistently excluded from studies).

#### Study topic rationale:

Clearly state the study topic. Specify if the topic was assigned by the State or is a statewide or small group collaborative QIP topic. Explain how the study topic was selected, addressing the following required HSAG evaluation elements:

#### 1. Is selected following collection and analysis of data.

- Provide plan-specific historical data and analysis to support the selection of the study topic. For example, if the study topic is Well-Child Visits in the First 15 Months of Life, the documentation should provide the recent well-child visit rates to support the selection of the study topic for a QIP.
- If no historical plan-specific data were available, provide rationale for why these data were not included.

### 2. Has the potential to positively affect member health, outcomes of care, functional status, or satisfaction.

- Explain how the study topic has the potential to affect member health, functional status, or satisfaction.
- Explain the link between the study topic and outcomes of care.



**Activity II: Define the Study Question(s)**. Stating the question(s) helps maintain the focus of the QIP and sets the framework for data collection, analysis, and interpretation.

#### Study question(s):

Enter study question(s) here. Ensure the study question(s) address the following HSAG evaluation element:

#### 1. States the problem to be studied in simple terms.

- The study question(s) should be stated in the recommended format of, "Does doing X (the interventions) result in Y (desired improvement)?"
- Define terms used in the study question(s) that may be unclear.
- The study question(s) must be answerable through the proposed data collection methodology and study indicator(s) provided.



**Activity III: Select the Study Indicator(s).** A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

### Study indicator(s):

Enter the study indicator(s) in the table for Activity III, ensuring that the following evaluation elements are addressed

- 1. The indicator(s) are well-defined, objective, and measure changes (outcomes) in health or functional status, member satisfaction, or valid process alternatives.
  - Provide the complete titles of the study indicator(s) in the shaded gray box.
  - Provide complete narrative descriptions of the numerators and denominators.
  - Provide the rationale for each study indicator.
  - Include all starting and ending dates of each measurement period (month, day, and year format).
  - Include plan-specific goals for remeasurement periods and the State-designated goal, if applicable. If a State goal was not determined, enter "Not Applicable" or "NA."
- 2. Include the basis on which the study indicator(s) were adopted.
  - The rationale and explanation why each study indicator was chosen. Study indicator(s) should be based on current clinical practice guidelines or health services research, and these sources should be specified in the QIP documentation.
  - When appropriate, nationally recognized measures (e.g., HEDIS), should be used. Include the year of the HEDIS technical specifications used for the applicable measurement year, and update annually as appropriate.
  - If the study indicator(s) are nationally recognized measures, this should be explained in the QIP documentation. The year of the specifications should also be included, and updated annually.
  - If the study indicator(s) were provided by the State, the documentation in Activity III should reflect this.
- 3. The indicator(s) allow for the study question to be answered.
  - The study indicator(s) should provide data to answer the reported study question(s).
  - The study indicator(s) and study question(s) should align.



Activity III: Select the Study Indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study Indicator 1 Title: Enter the complete title of the study indicator here	Provide a narrative description and the rationale for selection of the study indicator:
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal	
Study Indicator 2 Title: Enter the complete title of the study indicator	Provide a narrative description and the rationale for selection of the study indicator:
here	
•	
here	
here Numerator: (no numeric value)	
here Numerator: (no numeric value) Denominator: (no numeric value) Baseline Measurement Period (include date	
here Numerator: (no numeric value) Denominator: (no numeric value) Baseline Measurement Period (include date range) Remeasurement 1 Period (include date	
here  Numerator: (no numeric value)  Denominator: (no numeric value)  Baseline Measurement Period (include date range)  Remeasurement 1 Period (include date range)	
here Numerator: (no numeric value) Denominator: (no numeric value) Baseline Measurement Period (include date range) Remeasurement 1 Period (include date range) Plan-Specific Remeasurement 1 Goal Remeasurement 2 Period (include date	



Activity III: Select the Study Indicator(s). A study indicator is a quantitative or qualitative characteristic or variable that reflects a discrete event (e.g., an older adult has not received a flu shot in the last twelve months), or a status (e.g., a member's blood pressure is/is not below a specified level) that is to be measured. The selected indicators should track performance or improvement over time. The indicators should be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research.

Study Indicator 3 Title: Enter the complete title of the study indicator here	Provide a narrative description and the rationale for selection of the study indicator:
Numerator: (no numeric value)	
Denominator: (no numeric value)	
Baseline Measurement Period (include date range)	
Remeasurement 1 Period (include date range)	
Plan-Specific Remeasurement 1 Goal	
Remeasurement 2 Period (include date range)	
Plan-Specific Remeasurement 2 Goal	
State-Designated Goal	
If the plan has additional information about	out the study indicators it would like to provide, use this area to document the information.



Activity IV: Use representative and generalizable study population(s). The study population(s) should be clearly defined to represent the entire population to which the study question and indicators apply. The length of member enrollment should be considered and defined. All selection criteria should be listed here. Once the population(s) are identified, a decision must be made whether to review data for the entire population or a sample of that population.

#### Study population(s):

Describe the population(s) and methods for identifying the study population(s). Identify the study population(s), addressing the following components of the HSAG evaluation element: The study population should not exclude members with special health care needs. If these members were excluded, the plan must provide the rationale.

### The study population(s) are accurately and completely defined and capture all members to whom the study question(s) apply.

- Clearly define inclusion, exclusion, and diagnosis criteria.
- Include a list of diagnosis codes, pharmacy codes, billing codes, procedure codes, and/or other system codes used to identify members.
- Include the complete age range and any anchor dates used to identify age criteria, if applicable.
- Include actual HEDIS technical specifications used in the study to define the study population (may provide as an attachment).
- Define continuous enrollment, new enrollment, and allowable gaps in enrollment.
- Any dates used to identify continuous enrollment criteria should be included.
- Include how race/ethnicity will be identified, if applicable.



Activity V: Use Sound Sampling Techniques. If sampling is to be used to select members of the study, proper sampling techniques are necessary to provide valid and reliable information on the quality of care provided. Sampling techniques should be in accordance with generally accepted principles of research design and statistical analysis. Representative sampling techniques should be used to ensure generalizable information.

### **Sampling Methods:**

Enter sampling techniques used to select members for the study. Please ensure that the responses address all of the items highlighted below. If the entire eligible population was used, document this in the table in Activity V of the QIP Summary Form. The sampling information should be updated annually for each measurement year and for each study indicator.

\*Plans to provide sampling methodology for each county, if applicable.

For each measurement period and study indicator, enter the following information in the table provided:

- 1. Enter the measurement period for the sampling methods used (e.g., Baseline, Remeasurement 1, etc.)
- 2. Provide the title(s) of the applicable study indicator(s).
- 3. Identify the population size.
- 4. Identify the sample size.
- 5. Specify the margin of error and confidence level.
- 6. Below the table, describe in detail the methods used to select the sample.
  - If NCQA certified software was used to select the sample, document this and include the certified software seal.

County*	Measurement Period	Study Indicator	Population Size	Sample Size	Margin of Error and Confidence Level

#### Describe the methods used to select the sample:



**Activity VI: Use Valid and Reliable Data Collection Procedures.** Data collection must ensure that the data collected on QIP 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.

#### **Data Collection:**

Enter data collection techniques. When using hybrid data collection, both manual data collection and administrative items should be addressed. Make sure that the responses address all of the evaluation items listed below:

\*Plans to provide data collection procedures used at the county-specific level, if applicable.

#### 1. Identification of data elements to be collected and specified sources of data.

- Documentation should include clear definitions of the data elements to be collected.
- Include codes, such as ICD9, CPT codes that are used to identify and pull administrative data for the study indicators.
- If using HEDIS, submit the Final HEDIS Audit Report.
- The sources of data should be clearly specified by checking all appropriate boxes, providing descriptive information when necessary, and by attaching required information when appropriate.

#### 2. A defined and systematic process for collecting and remeasuring data.

- A systematic method for data collection should be specified.
- Documentation should include a systematic process of an ordered sequence of steps. Each step depends on the outcome of the previous step. This can be defined in a narrative, or with algorithms/flow charts.
- If an NCQA certified vendor or software was used to collect data, document this, and include the vendor's name and the certified software seal.
- Identify the timing of data collection and data analysis by checking appropriate boxes and providing additional narrative information if necessary.

#### IF MANUAL DATA COLLECTION WAS USED, PROVIDE:

### 3. Qualifications of staff members collecting manual data.

- The relevant education, experience, and training of all manual data collection staff should be described in the QIP Summary Form.
- Training of the staff members should be updated annually.



**Activity VI: Use Valid and Reliable Data Collection Procedures.** Data collection must ensure that the data collected on QIP 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.

#### 4. A manual data collection tool that ensures consistent and accurate collection of data according to indicator specifications.

- Include the manual data collection tool and instructions for completing the tool with the QIP submission.
- For mailed surveys, include the cover letter and survey.
- For telephone surveys, include the script, as well as the monitoring and training process for the telephone survey staff.
- Include a discussion of the IRR process and the results of the process. Include a detailed discussion of the steps for conducting interrater reliability in medical record review.

#### IF ADMINISTRATIVE DATA WERE COLLECTED, PROVIDE:

#### 1. An estimated percentage of administrative data completeness and quality.

- The estimated percentage of administrative data completeness and a description of the process used to determine the percentage should be included.
- Include a description of the quality process used for data collection. For example, how is the quality of administrative data ensured in the data collection procedures, and what are the steps to ensure valid and reliable data are produced?

### 2. Data analysis plan. (Include in every submission, even the initial study design submission.)

- Describe the data analysis plan. The essential components of a data analysis plan include how the study indicator rate or mean will be
  calculated, how the study indicator rate or mean will be compared to a goal or benchmark, and what statistical test will be used to compare
  study indicator rates or means between measurement periods. If subgroup analysis will be conducted, the data analysis plan should
  identify those subgroups and what comparisons will be done as well as what statistical testing will be done on the subgroup level.
- HSAG recommends a two-tailed statistical test (e.g., Chi-square, z test for proportions, or Fisher's exact test). The QIP should conduct statistical testing to determine if the change for each study indicator was statistically significant from baseline to Remeasurement 1 and from Remeasurement 1 to Remeasurement 2. If the QIP includes additional measurement periods beyond Remeasurement 2, it will need to provide statistical testing results for the additional measurement period results.



Activity VII: Data Analysis and Interpretation of Results. Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.

Enter the results for each study indicator, including goals and statistical testing with complete *p* values, and statistical significance in the table provided.

Study Indicator 1 Title: Enter the title of the study indicator here.

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test, Statistical Significance, and <i>p</i> Value
	Baseline					
	County 1					
	County 2					
	County 3					
	Remeasurement 1					
	County 1					
	County 2					
	County 3					
	Remeasurement 2					
	County 1					
	County 2					
	County 3					
	Remeasurement 3					
	County 1					
	County 2					
	County 3					



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.

Study Indicator 2 Title: Enter the title of the study indicator here.

Time Period Measurement Covers	Indicator Measurement	Numerator	Denominator	Rate or Results	Goal	Statistical Test, Statistical Significance, and <i>p</i> Value
	Baseline					
	County 1					
	County 2					
	County 3					
	Remeasurement 1					
	County 1					
	County 2					
	County 3					
	Remeasurement 2					
	County 1					
	County 2					
	County 3					
	Remeasurement 3					
	County 1					
	County 2					
	County 3					



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.

**Analysis and Interpretation of the Results:** Describe the data analysis performed on the study indicators and the interpretation of the results addressing the following:

\*Plans to provide interpretation and analysis at the county-specific level for each measurement period.

- Include statistical analysis techniques used (e.g., Chi-square, Fisher's exact test, t test). Perform all statistical testing using a two-tailed approach to calculate the p value. Please include the p value to four decimal places (i.e., 0.0235). If the p value is less than 0.0001, please indicate the p value ≤ 0.0001. For HEDIS-based QIPs, the data reported in the QIP should match the data reported in the plan's NCQA Interactive Data Submission System (IDSS). All data reported should be accurate and consistent throughout the QIP.
- Identify statistical differences between measurement periods and between baseline and the current measurement period.
- Describe the results of the statistical analysis, interpret the findings, and compare and discuss results/changes from measurement period to measurement period as well as from baseline to the current measurement period.
- Discuss any statistically significant increase or decrease for each study indicator. Additionally, include a comparison to the goal.
- Identify factors that threaten internal or external validity of the findings. Examples of factors would be a change in demographic population, acquiring another health plan's members, or a change in health plan staff. If there were factors identified, their impact and resolution should be discussed.
- Identify factors that affect the ability to compare measurements. An example would be a change in the study methodology. If there was a change in methodology, the issue, impact, and resolution should be discussed to justify the needed changes.
- If there are no identified factors that threatened the validity of the findings or that affected the ability to compare measurement, this information should be documented in the QIP Summary Form.
- Discuss any random, year-to-year variations, population changes, sampling errors that may have occurred during the remeasurement process.
- Include a discussion about the extent to which each study indicator and the overall QIP was successful and follow-up activities planned as a result. This can also include success identified by the plan throughout the QIP process, which may or may not be related to indicator(s) improvement. The interpretation should include lessons learned.



**Activity VII: Data Analysis and Interpretation of Results.** Clearly present the results of the study indicator(s). Describe the data analysis performed, results of the statistical analysis, and an interpretation of the findings.



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

#### **Causal/Barrier Analysis:**

Describe the causal/barrier analyses and quality improvement (QI) processes used to develop, revise, and/or standardize the interventions for each measurement period. Make sure the description addresses the items listed below:

\*Plans to provide the causal/barrier process and barriers at the county-specific level if applicable.

#### Causal/Barrier analyses and/or QI processes described should include the following descriptions for each measurement period:

- Steps and specific processes used.
- Process conducted by a committee(s), team(s), and/or work group(s).
- QI tools used and provided as attachments (e.g., fishbone diagram, Plan-Do-Study-Act [PDSA] Worksheet).
- Data mining activities. Data mining analysis can be performed to gain further insights for barriers to receiving care/services. For example, member subgroups (by provider, county, and/or zip code, etc.) could be identified that did not receive care/services.
- Identification and prioritization of the barriers.
- Analysis conducted to evaluate the interventions after each measurement period.

### **Baseline**

County 1:

County 2: County 3:
Barriers identified and prioritized:
County 1:
County 2:
County 3:
New interventions planned/implemented during the Remeasurement 1 period:
County 1:
County 2:
County 3:

Causal/barrier analysis process:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

es and barriers to efficient care processes from which appropriate interventions can be developed.
easurement 1
sal/barrier analysis process:  aty 1:  aty 2:  aty 3:
iers identified and prioritized: aty 1: aty 2: aty 3:
sed, standardized, and/or new interventions planned/implemented during the Remeasurement 2 period: aty 1: aty 2: aty 3:
easurement 2
sal/barrier analysis process: htty 1: htty 2: htty 3:
iers identified and prioritized: htty 1: htty 2: htty 3:
sed, standardized, and/or new interventions planned/implemented during the Remeasurement 3 period, if necessary: htty 1: htty 2: htty 3:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

The interventions target causes/barriers identified through data analysis and quality improvement processes.

Describe interventions/improvement strategies, and the evaluation and interpretation of each intervention for each measurement period. The narrative discussion about the interventions/improvement strategies and their evaluation results and interpretation should address the following:

### \*Plans to provide the interventions at the county-specific level if applicable.

- Include the date the interventions were implemented (month/year format).
- Provide the category of the intervention (member, provider, system).
- Describe how the interventions directly address the identified barriers. Each intervention should be linked with a specific barrier.
- Describe how the interventions consider the characteristics of the targeted member and/or provider population and available resources.
- Discuss the evaluation results for each intervention conducted during the measurement period. The evaluation should include analysis of
  the intervention's effectiveness. For example, if a member intervention included postcard visit reminders, discuss how many members
  required a visit and then compare to how many members scheduled and/or kept appointments after receiving the reminder postcard.
  Include any issues/concerns with the implementation of the intervention.
- Based on the evaluation results, describe the revision, standardization, and/or discontinuation of the intervention

• based on the evaluation results, describe the revision, standardization, and/or discontinuation of the intervention.
Describe interventions.
Baseline Company of the Company of t
ntervention description (including category and date implemented):
County 1:
County 2:
County 3:
Remeasurement 1
ntervention description (including category and date implemented):
County 1:
County 2:
County 3:



Activity VIII: Include Improvement Strategies (interventions for improvement as a result of analysis). Interventions are developed to address causes/barriers identified through a continuous cycle of data measurement and data analysis. Causal/barrier analysis identifies root causes and barriers to efficient care processes from which appropriate interventions can be developed.

Remeasurement 1 (cont.)	
ntervention evaluation, interpretation, and status: County 1: County 2: County 3:	
Remeasurement 2	
ntervention description (including category and date implemented):	
County 1:	
County 2:	
County 3:	
ntervention evaluation, interpretation, and status:	
County 1:	
County 2:	
County 3:	



**Activities IX and X: Real and Sustained Improvement.** There are no additional documentation requirements for Activities IX and X. These activities will be scored based on documentation provided in prior activities.

### For improvement strategy planning purposes only, please note the following:

Activity IX: Assessing for Real Improvement

For each study indicator, Activity IX will be scored annually until statistically significant improvement (Evaluation Element 3) is achieved from baseline to the current remeasurement period. Once a study indicator receives a *Met* score for Evaluation Element 3, it will remain *Met* for the duration of the QIP. The actual score for Evaluation Element 3 will be based on the scores for all study indicators.

Activity X: Assessing for Sustained Improvement

HSAG will not validate Activity X until statistically significant improvement has been achieved in Activity IX for at least one study indicator. After a study indicator achieves statistically significant improvement, it will be evaluated annually to determine if the statistically significant improvement has been sustained in the subsequent remeasurement period. Once a study indicator achieves sustained improvement, additional data are no longer required to be reported in the QIP.