

Quality Assessment and Performance Improvement (QAPI) Project Completion Report

INSTRUCTIONAL GUIDE



Prepared by the Medicare+Choice
Quality Review Organizations for the
Centers for Medicare & Medicaid Services (CMS)
Revised: November 2002

Contents: Instructional Guide

Page

- 1 Introduction**
- 7 Medicare+Choice Organization Identifiers**
- 15 Review Element 1:**
Project Title, Type, Focus Area
- 20 Review Element 2:**
Topic Relevance
- 25 Review Element 3:**
Quality Indicator(s)
- 38 Review Element 4:**
Baseline Study and Analysis
- 46 Review Element 5:**
Baseline Study Population and Baseline Measurements/Performance
- 56 Review Element 6:**
Interventions Aimed at Achieving Demonstrable Improvement
- 65 Review Element 7:**
Demonstrable Improvement
- 69 Review Element 1S:**
Subsequent or Modified Interventions Aimed at Achieving Sustained Improvement
- 79 Review Element 2S:**
Sustained Improvement
- 83 External Consultation and Lessons Learned**
- 88 Glossary of Terms**

Introduction

Purpose of the Instructional Guide

The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), requires Medicare+Choice Organizations (M+COs) to document the results (i.e., demonstrable and sustained improvements) of their projects on the Quality Assessment and Performance Improvement (QAPI) Project Completion Report. The intent of this report is to reflect your efforts in complying with CMS QAPI standards and to serve as an effective tool for ensuring continual improvement in the quality of services to your Medicare+Choice beneficiaries.

The purpose of the Instructional Guide is to assist you in completing the QAPI Project Completion Report by providing specific instructions and relevant information, as applicable, for each review element.

Content of the Instructional Guide

The Instructional Guide follows the outline of the QAPI Project Completion Report, covering Review Elements 1-7 for reporting on demonstrable improvement and Review Elements 1S and 2S for reporting on sustained improvement.

The content is organized into three distinct areas:

1. Listing of each review element, as stated in the QAPI Completion Report
2. *Instructions* (italicized) giving the M+CO clear directions (e.g., how to enter, select, describe or provide required information)
3. Relevant information (boxed) providing definitions, descriptions, background information, QAPI standards interpretation, and examples.

A glossary of terms appears at the end of the Guide.

QAPI Project Reporting Criteria

The M+CO must submit a QAPI Project Completion Report when it:

1. Achieves demonstrable improvement, completing Review Elements 1-7 with all required project results and analysis.
2. Has not yet achieved improvement at the end of the three-year cycle, completing Review Elements 1-7 with all required project results and analysis. The Medicare+Choice Quality Review Organizations (M+CQROs) will evaluate the project and make recommendations to CMS on how the M+CO can best achieve the required improvements.
3. Achieves sustained improvement, completing Review Elements 1S and 2S of the report with all required project results and analysis.
4. Has a multi-year project. After obtaining approval and establishing the intermediate target goals, the M+CO will report on the pre-established time frame, which has been agreed upon by both the M+CO and CMS. Refer to the QAPI standards that address multi-year projects for more information.

Timeframe for Reporting on QAPI Projects

The M+CO will have 90 days from the completion of its project to electronically submit a Project Completion Report to the M+CQRO. The completion date of a project is generally the date on which the last data run of the project was completed that demonstrated improvement. CMS expects this date to be by the end of the 3-year project cycle. M+CO determines the actual date of project completion.

For organizations that are using CMS standardized measurements, such as HEDIS, CAHPS, or HOS, allowances will be made to accommodate these predetermined reporting timeframes. For instance, if an organization used HEDIS measurements in its 2000 project, typically, CMS would expect that the project would be completed by the end of 2002. However, in this case, the Project Completion Report will be accepted after the audited HEDIS results are announced in June of 2003. The assumption is that during year 2003, the M+CO will be working on sustaining its improvement for reporting in 2004.

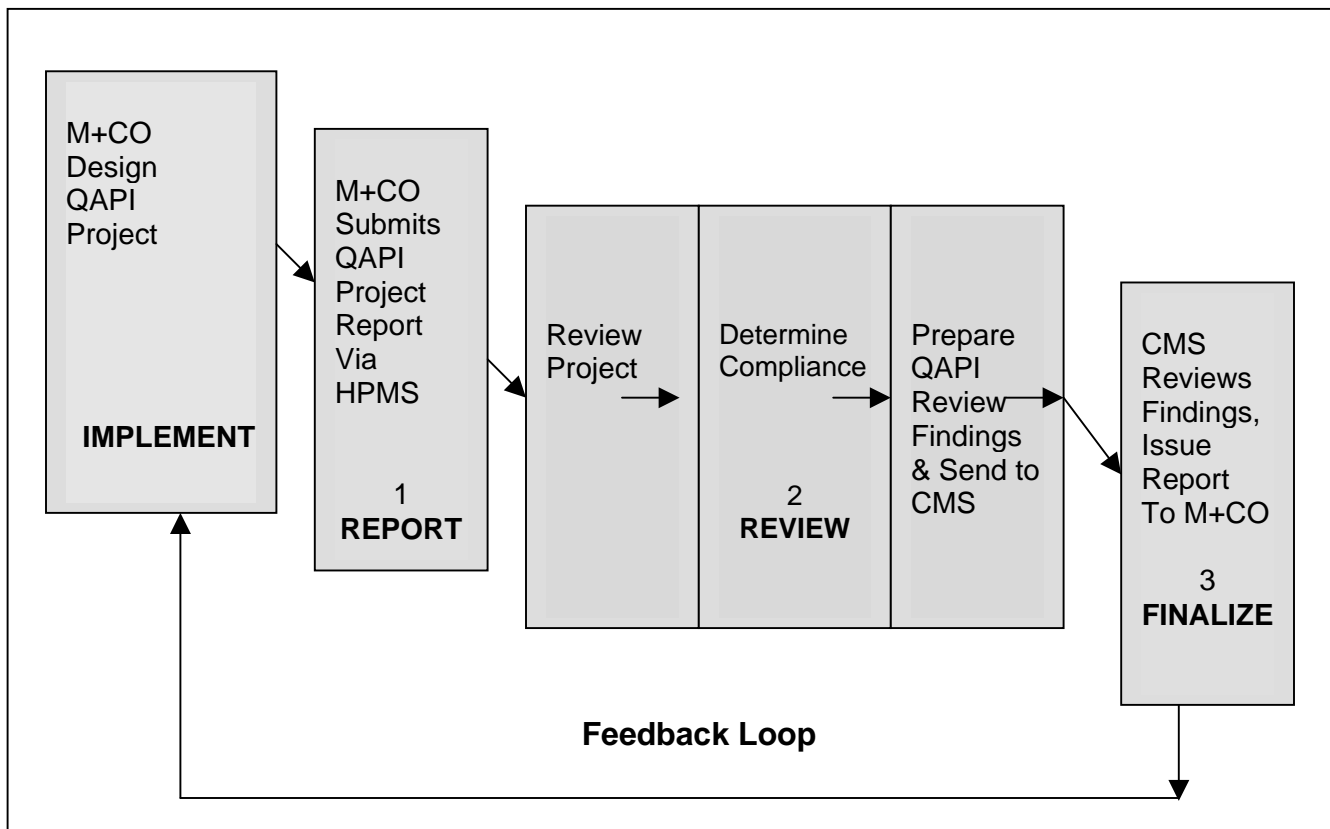
Reporting on Quality Indicators and Interventions

The QAPI standards require that a M+CO only report on one indicator and intervention for each QAPI project, unless otherwise determined by CMS. (The 2001 CMS National Project for CHF requires that the M+CO report on two CMS-defined quality indicators for CHF.) However, if a M+CO chooses to report on more than one indicator, it will be evaluated only on the indicator for which it has achieved improvement. CMS will not penalize the M+CO for reporting on more than one indicator and encourages *the full reporting of all indicators and interventions*.

QAPI Review Process

CMS has contracted with three Quality Improvement Organizations (QIOs), formerly known as Peer Review Organizations (PROs), designated as the Medicare+Choice Quality Review Organizations (M+CQROs) to review all QAPI Project Completion Reports during the years 2002-2005.

Exhibit 1: Overview of QAPI Review



Implement

The M+CO, with the help of its state QIO or other consultant, designs and implements a QAPI project each year to meet the requirements, as delineated by the QAPI standards. The M+CO must do two projects each year for projects initiated in 1999 and 2000. For projects started in and after 2001, only one project is required.

QAPI Review Process (1-3)

1. **Report:** Upon completion of a project, the M+CO completes and submits the QAPI Project Completion Report with supporting data, via the CMS web-based tool.
2. **Review:** Upon receipt of the QAPI Project Completion Report from the M+CO, the reviewers have 90 days to review and submit report findings and recommendations to CMS.
3. **Finalize:** CMS will review the findings, recommendations, and summary report from the M+CQRO reviewers and issue a final report to the M+CO.

Submission of the QAPI Project Completion Report

The project review and evaluation process is based solely on the electronic submission of the QAPI Project Completion Report with no on-site review. The M+CO must address all requested review elements. The electronic completion report will not allow a submission of the report unless all the required fields are complete.

For further details, please contact assigned M+CQRO reviewer of your Region.

**Regions: (Region I-New York State only, VII, VIII, IX-Except California & X)
M+CQRO: Lumetra (Formerly known as CMRI)**

Contact: Saleema S. Hashwani, MS, RN
Project Manager, M+CQRO
Lumetra
One Sansome Street, Suite 600
San Francisco, California 94104
Tel: 415-677-2008
Fax: 415-677-2191
E-mail: shashwani@caqio.sdps.org

**Regions: (Region IV, V-Except Chicago & VI)
M+CQRO: Delmarva Foundation**

Contact: Kay Satchell, R.N., CPHQ
Project Manager, M+CQRO
Delmarva Foundation
9240 Centreville Road
Easton, MD 21601-7098
Tel: 410-769-6249
Fax: 410-822-7971
E-mail: ksatchell@dfmc.org

**Regions: (Region I-Except New York State, II, III, V-Only Chicago & IX-Only
California)
M+CQRO: IPRO**

Contact: Rosemarie Farrell, RN, BS
Project Manager, Managed Care
IPRO
1979 Marcus Avenue
Lake Success, NY 11042
Tel: 516-326-7767, ext. 253
Fax: 516-326-6177
E-mail: rfarrell@ipro.org

Accessing the Online QAPI Project Completion Report

The web-based Project Completion Report is located in CMS Health Plan Management System (HPMS) database. All M+COs have controlled access to this site, although not every person in a M+CO has access. To gain access to the Project Completion Report (which is also called the QAPI module in HPMS), a M+CO must apply for HPMS access codes by completing and submitting the “Application for Access to CMS Computer Systems” form, available online at <http://www.cms.hhs.gov/mdcn/access.pdf>.

Print out and complete the form, sign the privacy agreement on page 2, and mail the original, signed copy to:

Centers for Medicare & Medicaid Services
Attention: Neetu Balani
7500 Security Boulevard
Mailstop Central 4-14-21
Baltimore, Maryland 21244-1850

Call Neetu Balani at (410) 786-2548 with any questions regarding the process for applying for an HPMS account.

Note: You do not need to obtain CMS approval signatures prior to submitting the application. CMS will obtain the necessary signatures. It takes about two weeks to process an application and to issue by mail a user ID, password, and instructions on how to access HPMS.

Upon receipt of the user ID and password from CMS, try to log on immediately into HPMS. If you have access problems, call Don Freeburger at (410) 786-4586.

Medicare+Choice Organization Identifiers

All fields must be completed before the M+CO can move to the next section.

The M+CO is encouraged to contact its Regional Office (RO) Managed Care staff for assistance on the completion of this report. The M+COs also can e-mail the Central Office at qapi@cms.hhs.gov.

If you find any error(s) in the information, notify your contact at the CMS Regional Office (RO) for guidance and assistance. In order to facilitate timely submission of your report, we encourage you to continue completing the report while the error is being resolved.

1. H# _____

[select your H# from the drop-down list, based on HPMS login]

→ **Instructions:** Select your H# from the drop-down list. The available H# is based on the HPMS login. If you do not see your H#, please notify CMS. The name of the M+CO, State, and the CMS Regional Office will be filled in, based on the H# selected.

2. Are you reporting on a sub-unit?

Yes [complete 2a]

No [continue to 3]

2a. Please identify the counties in the sub-unit [from list, based on H#]

→ **Instructions:** If you are reporting on a sub-unit, select “Yes,” then identify the counties in the sub-unit from the list. Select more than one county by holding down the CTRL key while clicking on the counties. If you are not reporting on a sub-unit level of reporting, click “No” and then select “continue.”

RELEVANT INFORMATION

2. Sub-unit Level of Reporting

In some instances, M+COs have stated that they would like to report on projects that do not encompass their entire contract (H) number. This is especially relevant for large organizations that conduct their business in a geographically defined manner within their larger H number. These sub-units are determined by county. It is not expected that many plans will be reporting on sub-units, and those M+COs that do will report on more than one project, since all counties/members served within the H number must be accounted for.

3. Name of Managed Care Organization _____
[prefilled, based on H#]

4. State _____ [prefilled, based on H#]

5. CMS Regional Office _____ [prefilled, based on H#]

6. Project title [maximum 200 characters]

RELEVANT INFORMATION

6. Project Title Examples

- Management of Diabetes Mellitus
- Access to home health care services
- Timeliness of response to complaints
- Influenza immunization rates

7. Select the project type

- CMS National Project - Diabetes (1999)
- CMS National Project - Pneumonia (2000)
- CMS National Project - CHF (2001)
- CMS National Project - Breast Cancer Screening (2002)
- CMS National Project - Clinical Health Care Disparities (2003)
- CMS National Project - Cultural & Linguistically Appropriate Services (2003)
- CMS National Project – Diabetes (2004)
- M+CO-Selected Project 1999 2000
- Local Marketplace Initiative
- Other CMS-Directed Special Project Specify year: _____

Instructions: Select one project type from the list. You should complete a separate report form for each project.

RELEVANT INFORMATION

7. Project Type

The M+CO must initiate two projects each year for projects initiated in 1999 and 2000. For projects initiated in and after 2001, M+COs are expected to submit one (1) project.

- **CMS National Projects:** CMS identifies national topics and indicators for the M+COs to use. The national projects and topics for years 1999-2004 are provided.
- **M+CO-Selected Projects:** M+CO chooses a topic, based on its relevance to its Medicare population. For 2001, the M+CO must identify its project area and baseline, but does not have to maintain its projects for improvement. Information is reported via e-mail to gapi@cms.hhs.gov. The subject line should read “2001 Project” and include the H# of the M+CO. The body of the e-mail should contain the project area/title and the baseline rates. **The M+CO does not enter this project into the HPMS system.**

- **Local Marketplace Initiative:** CMS has encouraged local marketplace initiatives, under which several contracting organizations undertake a joint QAPI project addressing a common topic. This project type will become an option beginning in 2004. Parameters for an acceptable local marketplace initiative require that:
 - It must be a community-wide initiative in which most or all M+COs participate and be initiated, facilitated, approved or required by a private purchaser group, QIO, State Medicaid Agency or other state government agency. This does not preclude M+C organizations from the role of facilitator, initiator or requestor so long as one or more of the other organizations function in these roles;
 - The topic must be relevant to the Medicare population;
 - Medicare enrollees must be in the population sample for the project; and
 - The M+C organization must report on M+C organization specific data although Medicare data does not need to be separated from the other purchasers (Medicaid/commercial) unless separation of data is necessary for other reporting purposes such as Medicare HEDIS requirements.
 - M+C organizations must follow QAPI requirements such as the use of baseline measurement, interventions, and re-measurement.
- **Other CMS-Directed Special Project:** In some instances, CMS may direct a M+CO to conduct a special project to improve its performance on some aspect of care or to focus its attention on a special needs population. M+COs that have received exemptions from national projects and are conducting a project focusing on a different topic, as approved by CMS, can choose this option. However, they will be expected to provide documentation on the CMS official's name, exemption date, and other corresponding information.

HEDIS Data

The M+CO may choose a HEDIS indicator for a project that will use HEDIS data to measure performance. Therefore, for a 2003 QAPI project, the M+CO may use either 2003 HEDIS (data year 2002) or 2004 HEDIS (data year 2003). (**Note:** The calendar year 2001 data would not be accepted as baseline data for a project required to be initiated in 2003.)

For new health plans, CMS allows the M+CO to initiate its projects in the second contract year to allow time for the enrollment of members. For example, if a new plan signs its contract in 2002 (i.e., its first contract year), the M+CO must initiate its QI project in 2003 (i.e., the second contract year).

8. Project initiation year

- 1999 2000 2001 2002 2003
 2004 2005 2006 2007 2008

RELEVANT INFORMATION

8. Project Initiation Year This option will only be available if the M+CO selects Local Marketplace Initiative, M+CO-Selected Project, or Other CMS-Directed Special Project.

9. Enter the principal contact information

[person responsible for completion of this report]

Last name First name Middle Initial

Title

Phone Fax E-mail

Instructions: Provide the name, phone, fax, and e-mail of the principal contact. CMS Regional Office staff and/or the project reviewers may need to contact the M+CO for additional information regarding the project. Please provide the person most appropriate for this role.

10. Select the reporting level

- Standard QAPI Project (Demonstrable and/or Sustained Improvement)
- Multi-Year Project

If multi-year selected:

- A. Project approved by [name]
- B. Date project approved [MM/DD/YYYY]
- C. Date approved from [MM/DD/YYYY]
- D. Date approved through [MM/DD/YYYY]

► **Instructions:** Select the reporting level: standard or multi-year.

If multi-year is selected, enter the name of CMS Central Office (CO) representative who provided written authorization for the multi-year project, the date of written authorization from CMS CO to M+CO, and the approved start and end dates for the project.

RELEVANT INFORMATION

10. Reporting Level

Standard QAPI Project

Standard QAPI projects include those submitted for demonstrable or sustained improvement.

Demonstrable Improvement: To report demonstrable improvement at the end of the three-year project cycle, the M+CO must submit a completed report with all required project information for Review Elements 1-7. If at the end of the three-year cycle, the M+CO has not achieved demonstrable improvement, the M+CO **must** still submit a completed report with all required project results and analysis.

Sustained Improvement: To report on sustained improvement, the M+CO **must** continue the project for **twelve months after demonstrable improvement** to show improvement from **baseline** and submit a completed report for Review Elements 1S and 2S.

Multi-year Project

A multi-year project is considered a more complex or difficult project. Generally, it is not expected to achieve demonstrable improvement for several years (i.e., more than three years). The national projects and M+CO-selected projects are not considered multi-year projects, in this context, even though they are conducted over several years.

continued

Approval to conduct a multi-year project must be obtained prior to the implementation of the project. A “standard” national or M+CO-selected project cannot be converted into a multi-year project without prior approval from CMS. Additional requirements for multi-year project submission include the following:

- The M+CO must provide a **clear and defensible reason** for defining a project as a multi-year project.
- There must be **significant, ongoing activity** related to the project during each of the review years for which the indicator is to be re-measured. In order to meet this, there should be continuous data collection throughout the project period and ongoing efforts to identify and implement system changes aimed at improving the long-term outcome(s).
- There must be **quantifiable interim goals** or intermediate outcomes for each project year, so that it is possible to monitor the continuing progress of the project.

For example, an organization conducting a project on breast cancer survival rates might track a process of care (e.g. mammography screening rates) or an intermediate outcome (e.g., stage of breast cancer at detection) and set goals for each year of the project.

A multi-year project may be:

- A project that an organization may continue and that has already been determined to have achieved demonstrable improvement. If further improvement occurs, the project may again be considered to have achieved demonstrable improvement. However, the improvement will not be measured relative to the original baseline, but relative to the improved performance level previously scored.

For example, a M+CO might have an ongoing project to improve beta-blocker use after myocardial infarction to prolong life in this population. It's possible that the M+CO had been working to improve this measure for the past five years and moved from a baseline measure of 20% in 1994 to a measure of 50% in 2000. By 2000, however, the M+CO was unable to ascertain whether the lifespan in this group had been prolonged. CMS might approve this study as a multi-year project to prolong life after myocardial infarction. If so, the QAPI baseline measure of beta-blocker use after MI would be 50%.

- A project in which a M+CO may undertake a particularly complex or difficult project that is not expected to achieve demonstrable improvement for several years (i.e., more than three years). This might occur because:

continued

- Improvement in the targeted outcome cannot be measured for a long period (e.g., the organization wishes to improve five-year survival rates for breast cancer).
- Improvement in outcomes can occur only after process improvements that are not closely linked to outcomes can be met.
- Improvement will require multiple system interventions that cannot be implemented over a short period.

Approval Process for Multi-year Projects

Approval from CMS is only required on multi-year projects. M+CO should identify its intention to do a multi-year project significantly in advance of the proposed implementation date. The M+CO should e-mail CMS at the qapi@cms.hhs.gov address and request consideration of the proposed multi-year project.

[On the Web-based Project Completion Report you will be prompted to]
SAVE AND CONTINUE TO REVIEW ELEMENT 1

Review Element 1: Project Title, Type, Focus Area

All elements must be completed before the M+CO can submit Demonstrable Improvement.

The Project Title, Type, Project Initiation year, and Sub-unit(s) of reporting are automatically entered from previous information.

1. Project title

→ **Instructions:** You can return to the M+CO Identifiers/Project Identifiers screen to revise the project title, but you must save the information before returning to this screen.

2. Project type

- CMS National Project - Diabetes (1999)
- CMS National Project - Pneumonia (2000)
- CMS National Project - CHF (2001)
- CMS National Project - Breast Cancer Screening (2002)
- CMS National Project - Clinical Health Care Disparities (2003)
- CMS National Project - Cultural & Linguistically Appropriate Services (2003)
- CMS National Project – Diabetes (2004)
- M+CO-Selected Project (1999-2000)
- Local Marketplace Initiative
- Other CMS-Directed Special Project Specify year: _____

→ **Instructions:** You cannot change the project type once you select it on the M+CO Identifiers/Project Identifiers screen, since it is a key field that uniquely identifies a project.

3. Project initiation year

- | | | | | |
|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| <input type="checkbox"/> 1999 | <input type="checkbox"/> 2000 | <input type="checkbox"/> 2001 | <input type="checkbox"/> 2002 | <input type="checkbox"/> 2003 |
| <input type="checkbox"/> 2004 | <input type="checkbox"/> 2005 | <input type="checkbox"/> 2006 | <input type="checkbox"/> 2007 | <input type="checkbox"/> 2008 |

RELEVANT INFORMATION

3. Project Initiation Year This option will only be available if the M+CO selects Local Marketplace Initiative, M+CO-Selected Project, or Other CMS-Directed Special Project.

4. Project focus area

[select all that apply]

Clinical focus area

- Primary, Secondary, and/or Tertiary Prevention of Acute Conditions
- Primary, Secondary, and/or Tertiary Prevention of Chronic Conditions
- Care of Acute Conditions
- Care of Chronic Conditions
- High-Volume Services
- High-Risk Services
- Continuity and Coordination of Care

Non-clinical focus area

- Availability, Accessibility, Cultural Competency of Services
- Appeals, Grievances, and other Complaints

Instructions: Identify which of the clinical or non-clinical focus area(s) the project addresses. More than one focus area that relates to the project topic may be selected. Previously, standards required that projects address all of the focus areas before repeating a focus area; however, projects may now repeat focus areas.

RELEVANT INFORMATION

4. Project Focus Area

CMS no longer mandates a distributive requirement in the focus area category. The M+CO may repeat focus areas as necessary to meet the goals and objectives, as determined by the organization.

The QAPI standards on focus areas were developed to encourage M+COs to undertake a variety of quality improvement projects, including those that address issues concerning large numbers of enrollees and high-risk conditions and those that address the needs of special or vulnerable populations, such as the mentally ill.

continued

Selection of a focus area should consider the following key requirement: The M+CO should consider focus areas that encompass aspects of both physical health and mental health/substance abuse, unless the benefit structure does not include such coverage.

The M+CO should carefully assess the selected focus area(s) to be sure that the entire project supports the chosen indicator(s). Also, it's possible that more than one focus area may apply to a project.

For example, a M+CO conducting a immunization project could select a:

- Clinical focus area, such as prevention of an acute condition, and
- Non-clinical focus areas, such as availability, accessibility, and cultural competency of services for those projects that targets Medicare members with disparities in immunization rates due to cultural or linguistic issues.

Important Reminders about Focus Areas

- A review and approval process is not required for choosing focus areas.
- A M+CO should not limit its projects to those that address only certain subsets of the population due to utilization data, high costs, or quality indicators that are easy to measure.
- The M+CO may choose to assess member experiences with care received from specialized providers inside, as well as outside, its network (e.g., burn centers, transplant centers, and cardiac surgery centers).

Examples of Clinical and Non-Clinical Focus Areas

Clinical Focus Areas:

1. Primary, secondary, and/or tertiary prevention of acute conditions

Examples:

- Prevention of influenza (e.g., influenza immunization rate)
- Prevention of pneumococcal pneumonia (e.g., Pneumovax immunization rate)

continued

2. Primary, secondary, and/or tertiary prevention of chronic conditions

Examples:

- Prevention of complications of colon cancer (e.g., colon cancer screening rate)
- Prevention of arrhythmia and cardiac mortality following acute myocardial infarction (e.g., prescription for beta-blockers)
- Prevention of blindness in diabetes mellitus (e.g., diabetic retinal eye exam),
- Prevention of amputation in diabetes mellitus (e.g., diabetic foot exam))
- Prevention of cardiac decompensation in CHF (e.g., prescription for ACE inhibitor for members with CHF)

3. Care of acute conditions

Examples:

- Care of pneumonia (e.g., speed/timeliness of prescription for antibiotic)
- Care of acute myocardial infarction (e.g., timeliness of administration of TPA)

4. Care of chronic conditions

Example:

- Improved exercise ability and decreased hospitalizations in persons with CHF (e.g., prescription for ACE inhibitor for CHF patients who have been assessed for left ventricular function)

5. High-volume services

Example:

- Echocardiograms in the Medicare population (e.g., rate of appropriate use)

6. High-risk services

Examples:

- CABG (e.g., complication rate),
- Heart/organ transplantation (e.g., complication rate)

7. Continuity and coordination of care

Examples:

- CHF (e.g., rate of appropriate follow-up post hospitalization for CHF)
- AMI (e.g., rate of appropriate follow-up post hospitalization for AMI)

continued

Non-clinical Focus Areas:

1. Availability, accessibility, and cultural competency of services

Examples:

- Availability and accessibility of CHF support services (e.g., CHF Disease Management Program where LVF testing, as well as prescription for ACE inhibitor, is managed)
- Barriers to obtain a mammography examination (e.g., mammography rates before and after culturally-focused interventions) in the M+CO's most prevalent cultural minority
- Improving the effectiveness of communication with enrollees who are non-English speaking
- Reduction of inpatient admissions for ambulatory sensitive conditions (e.g., asthma) by improving access to care
- Timeliness of referral services in response to a positive result on a given diagnostic test

2. Appeals, grievances, and other complaints

Examples:

- Identifying areas of concern from complaint, grievance, and appeals files (e.g., telephone answering time of member services department)
- Improving the grievance process, so that grievances are resolved quickly
- Improving the coverage determination process
- Improving the authorization process if the M+CO has a high rate of adverse determinations overturned
- Improving member/provider education regarding covered benefits of a service that has a high rate of grievances

[On the Web-based Project Completion Report you will be prompted to]

SAVE AND CONTINUE TO REVIEW ELEMENT 2

Review Element 2: Topic Relevance

This Review Element must be completed for the M+CO Selected project or other CMS directed special project before the M+CO can submit Demonstrable Improvement.

1. Topic relevance to your Medicare population determined by

[select all that apply and describe each]

- Literature review [complete 1a, 1b, 1c, 1d, and 1e, if applicable]
- Comparisons with comparable organizations (Maximum 4000 Characters)
- Cost analysis (Maximum 4000 Characters)
- Adverse events: Errors (Maximum 4000 Characters)
- Adverse events: Omissions (Maximum 4000 Characters)
- Adverse events: Sentinel events (Maximum 4000 Characters)
- HEDIS data: Health Employers Data Information System (Maximum 4000 Characters)
- Enrollee survey: CAHPS (Consumers Assessment Health Plan Survey) (Maximum 4000 Characters)
- Enrollee survey: HOS (Health Outcome Survey) (Maximum 4000 Characters)
- Enrollee survey: Interviews (Maximum 4000 Characters)
- Enrollee survey: Focus groups (Maximum 4000 Characters)
- Enrollee survey: Other (Maximum 4000 Characters)
- Provider survey: Physician (Maximum 4000 Characters)
- Provider survey: Other provider (Maximum 4000 Characters)
- External Quality Review Organization (EQRO) (Maximum 4000 Characters)
- Quality Improvement Organization (QIO) (Maximum 4000 Characters)
- Other (Describe) (Maximum 4000 Characters)

1a. Literature review topic [Maximum 4000 Characters up to four citations]

1b. Citation #1 [enter the citation]

1c. Citation #2 [enter the citation]

1d. Citation #3 [enter the citation]

1e. Citation #4 [enter the citation, if desired; not required]

→ **Instructions:** These are possible data sources that you may have used to select the project topic. Select all that apply and describe briefly. You are not required to fill out the literature citations unless you chose "Literature review."

2. Topic prioritization to Medicare population

[briefly describe your organization's prioritization process for selecting this specific topic, in one page or less- Maximum 4000 characters]

Instructions: *If this is a M+CO-selected project, local marketplace initiative, or other CMS-directed special project, use the text box to describe how the project topic was determined to be relevant to your own Medicare population and how you determined that this project was a priority over other potential topics. Include a description of the prioritization and selection process used to determine the project's relevance to your own Medicare population. The description should explain why the chosen topic has special relevance to your own Medicare members and **not** just why the topic is relevant to the Medicare population in general. You **must** document the relevance of the project topic to your Medicare population.*

RELEVANT INFORMATION

1. & 2. Topic Relevance and Prioritization

The QAPI standards require that the documentation of completed projects shows the basis on which the organization selected project topics (i.e., continuing monitoring of population needs and preferences and organizational performance; identification of areas of concern; and clear criteria, identified by the organization for prioritizing the areas to be addressed).

Topic Selection and Prioritization Process

The QAPI standards state that the selection and prioritization process for a project topic should be systematic and data-driven and include:

- Information on the use of continuous data collection;
- An analysis of comprehensive aspects of patient care and member services;
- A process that considers the greatest practical benefit for enrollees;
- The prevalence of a condition among, or need for a specific service by, the organization's enrollees;
- Enrollee demographic characteristics and health risks;
- The interest of consumers in the topics addressed; and
- Network provider input.

The Monitoring Process

The M+CO's QAPI program should have a system in place to routinely collect and interpret information from all parts of the organization to identify areas of clinical concern, health delivery systems issues, and member services issues.

continued

M+COs with physician incentive plans that include substantial financial risk for a physician for the care of Medicare enrollees must include in their QAPI program a continuous monitoring of the potential effects of the incentive plan.

Collected information should include:

- Population information (i.e., age, gender, race/ethnicity/language, disability or functional status that influences health risks, and utilization of clinical and non-clinical services)
- Utilization information on services, procedures, medications, and devices
- M+CO program information about adverse incidents (i.e., deaths, avoidable admissions, re-admissions, patterns of referrals, and authorization requests)
- Enrollee information on experiences with care, gathered from surveys, grievance and appeals processes, and databases for tracking provider changes and disenrollment. The CAHPS survey is a standardized methodology used to capture this information. Populations with special needs, such as linguistic minorities or the disabled, may be underrepresented in general population surveys. Assessment of satisfaction for some groups may require over-sampling or other methods, such as focus groups or enrollee interviews.

M+COs, especially newly formed M+COs, may use data from outside the organization (external data), other M+COs, or local or national public health reports.

Prioritizing Topics

In general, a clinical or non-clinical issue selected for study should affect a significant portion of the M+CO's Medicare enrollees and have a potentially significant impact on enrollee health, functional status, or satisfaction.

The M+CO should provide clear criteria for prioritizing the topics that are beneficial to the Medicare population and consider the following issues:

- Projects should focus on deficiencies in care or services that, for example, lead to inappropriate utilization rather than on the cost and utilization issues alone.
- There may be instances when infrequent conditions or services warrant study (e.g., when data show a pattern or unexpected adverse outcomes).

continued

- Projects should focus on areas in which meaningful improvement can be effected by system interventions by the M+CO.
- The organization's affiliated providers and enrollees must have formal opportunities to participate in the selection and prioritization of projects.

To the extent possible, input should be obtained from enrollees who are users of, or concerned with, specific focus areas.

Possibilities for input include:

- Enrollee representation on a quality assurance committee
 - Routine discussion of QAPI issues by a general advisory committee
 - Member survey
 - Focus groups
- The M+CO must explicitly take into account quality-of-care concerns identified by a quality improvement organization (QIO). If these organizations raise certain concerns, and a QAPI project is not initiated to address these concerns, the M+CO should document what alternative action was taken to address them.

3. Aspect of Clinical Care Related to Focus Area

[select all that **apply** and **describe** each]

- Prevalence of a clinical condition (specify data source(s) and analysis used to determine) (Maximum 4000 Characters)
- Performance against a guideline (acceptable sources recognized by industry) (Maximum 4000 Characters)
- Enrollee identified need (Maximum 4000 Characters)
- Enrollee demographic characteristics (Maximum 4000 Characters)
- Identified special health risks in population (e.g., asbestosis, sickle cell anemia) (Maximum 4000 Characters)
- Consumer interest/advocacy (Maximum 4000 Characters)
- Significant variation in practice (compared against standardized measures) (Maximum 4000 Characters)
- High-volume service/procedure (Maximum 4000 Characters)
- High-risk service/procedure (Maximum 4000 Characters)
- Other aspect of clinical care (Maximum 4000 Characters)
- Not applicable [disables other options]

4. Aspect of non-clinical service

[select all that **apply** and **describe** each]

- Customer satisfaction (complaints, grievances, appeals) (Maximum 4000 Characters)
- Internal surveillance [select all that apply]
 - Disparities identified for vulnerable population(s) (Maximum 4000 Characters)
 - Over- or under-utilization adversely impacting health outcomes (Maximum 4000 Characters)
 - Patterns of referrals (Maximum 4000 Characters)
 - Timeliness of care (Maximum 4000 Characters)
- Access, availability of service (Maximum 4000 Characters)
- Access, language (Maximum 4000 Characters)
- Organizational support for Cultural & Linguistically Appropriate Services (Maximum 4000 Characters)
- Other aspect of non-clinical service (Maximum 4000 Characters)
- Not applicable [disables other options]

→ **Instructions:** These are lists of possible data sources and rationales for identifying opportunities for improvement and prioritizing a topic for both clinical and non-clinical project topics. Select all that were used to prioritize this project topic and describe.

[On the Web-based Project Completion Report you will be prompted to]

SAVE AND CONTINUE TO REVIEW ELEMENT 3

Review Element 2

Review Element 3: Quality Indicator(s)

All elements must be completed before the M+CO can submit Demonstrable Improvement. Only one indicator is required. Reporting additional indicators is optional. Exceptions to this will be determined by CMS. (For example, if reporting on the CMS National Project CHF 2001, reporting of two indicators is required.)

1. Indicator defined by

- CMS [prefilled if Project Type is one of the CMS National Projects; describe]
 - Medicaid agency [describe]
 - M+CO [describe]
 - HEDIS [reported]
 - HEDIS [not reported]
- Describe: _____
[provide details of specifications and/or modifications used for project development]
- Other:
Describe: _____
[provide details of specifications used for project development]

If either HEDIS option selected

- HEDIS 3.0 1998 - data year 1997
- HEDIS 1999 - data year 1998
- HEDIS 2000 - data year 1999
- HEDIS 2001 - data year 2000
- HEDIS 2002 - data year 2001
- HEDIS 2003 - data year 2002

Instructions: Select the source/reference that provided the indicator definition and describe the sources/references used to define the indicator. If the project type is a CMS National project, enter 'CMS National Project' in the text box. If HEDIS is selected, indicate which HEDIS technical specification year and version was used, including the page numbers. You do not need to rewrite the indicator verbatim. If you used HEDIS specifications as a basis but modified them in any way OR received NR (Not Reported) for the measure, provide a detailed description of the specifications and/or modifications. The review team will evaluate the project as one developed by the M+CO, NOT as a HEDIS measure. If the quality indicator was defined by any organization other than those listed, select "Other" and provide the relevant information in this section.

RELEVANT INFORMATION

1. Defined Indicator Sources

CMS

CMS-defined indicators are those indicators that were originated from CMS, such as the indicators for the 2001 CHF National project.

State Medicaid Agency

The State Medicaid Agency defines the topic and indicator. For example, a State Medicaid Agency may initiate a mandatory project on provider access, based upon problems identified by access and availability studies conducted by the External Quality Review (EQR) agent. A possible indicator for this project is the proportion of members who receive a visit for an urgent problem within 24 hours.

M+CO

The topic and indicator are defined by the M+CO. For example, the M+CO may choose to reduce the dropped call rate on the member service line in response to member complaints of slow or no answer. Other possible sources of M+CO-defined indicators are further described below.

HEDIS

The topic and indicator are based on HEDIS technical specifications. In many instances this option may be selected even for a National QAPI project since HEDIS indicators may be an option in that project. The M+CO may choose an indicator deemed “Report” or “Not Reported” by the audit firm.

M+CO-Defined Indicator Sources

Possible sources of M+CO-defined indicators are described below.

Clinical Evidence: Sources may include clinical guidelines and practice parameters from professional societies (e.g., the AMA and other professional or medical specialty associations), data sets with national acceptance (e.g., HEDIS Quality Compass and government agencies, such as AHCPH/AHRQ, and NIH), and state health departments.

Expert Consensus: Local experts or panels convene to review literature and reflect on local treatment practices, identify a need, and recommend a topic for a quality improvement project.

continued

Enrollee Consultation: Focus group or enrollee survey identifies an enrollee satisfaction issue.

Prior M+CO Project: Identified continuing opportunities for improvement in certain areas of care. For example, a M+CO studies breast cancer screening rates. A logical next step would be to measure follow-up for positive results on mammography.

Provider Consultation (physician or other provider): Involving stakeholders, such as network physicians, early in the process often yields practical advice, as well as physician buy-in, and compliance. A M+CO could include network providers in a quality assurance steering committee. The entire group or a sub-group of specialist could identify a process-of-care need.

Other Organization: For example, alcohol misuse defined by the Foundation for Accountability (FACCT).

Each QAPI project must establish one or more quality indicators to track performance and improvement over time. The M+CO should exercise caution when making a decision about the number of indicators, as the project may fail without a clear focus. Choosing only one indicator does not provide an alternative if it does not reach demonstrable improvement. However, choosing too many indicators may divert resources and energy.

Definition and Description of Quality Indicators

A quality indicator is a measurement tool or statement that:

- Assesses a characteristic of quality
- Reflects an aspect of care, not simply a measurement
- Focuses on desired outcomes and/or key processes
- Is derived from clinical practice guidelines or treatment guidelines
- Is measured before interventions are implemented
- Should be developed and written using precise operational definitions for terms

Characteristics of Quality Indicators

Objective: Subject to objective measurement of patient health, functional status, or enrollee satisfaction. Measures of costs or other administrative results do not constitute outcomes.

Clearly and unambiguously defined: Terms are operationally defined. This includes such statements as the numerator, denominator, and inclusion and exclusion criteria, which would assist a reviewer in clearly understanding the quality indicator and its relationship to the aspect of quality being measured.

continued

Based on current clinical knowledge or health services research: There has to be evidence supporting them.

Types of Quality Indicators

Process of Care: Indicators in which a medical decision or clinical intervention is performed for an individual patient or group in the course of managing or preventing a disease. They are acceptable, as long as the M+CO can show strong clinical evidence that the process being measured is meaningfully associated with eventual outcomes. This determination should be based on published guidelines that support the association and that cite evidence from randomized and clinical trials, case control studies, or cohort studies. Although published evidence is generally required, empirical evidence of the process/outcome linkage may be limited for certain areas of practice.

Important points regarding process-of-care indicators:

- A M+CO may furnish its own or similar evidence of association between a process and an outcome, as long as this association is demonstrable and not contradicted by valid studies.
- At a minimum, the M+CO must be able to show that a consensus exists among practitioners with expertise in the defined area as to the importance of a given process.
- Outcomes of QAPI projects cannot be expressed as measures of costs or cost savings.

Outcome of Care: Indicators in which simply the results of care are measured (i.e., a measurement of health, utilization, or economic benefit or harm that results from the operation of a healthcare system). Relatively few standardized performance measures actually address outcomes. Even when outcome measures are available, their utility as quality indicators for QAPI projects may be limited, because uncontrollable factors (i.e., poverty, genetic variability, and environment) can significantly affect outcomes. Sometimes, outcome improvement is possible, but not within the project timeline. Therefore, this QAPI standard does not require that quality indicators be outcome measures.

2. Indicator Statement (Maximum 255 Characters)

Instructions: This field must be completed before continuing to the next Review Element.

Note: If using a HEDIS indicator, you may cite the specifications used (e.g., HEDIS 2000, Volume 2 – Technical Specifications, pp. 24 – 27) to complete the numerator, denominator, and inclusion and exclusion criteria. You **must** describe and justify any variations to HEDIS specifications (e.g., addition or omission of codes, use of different age groups than specified, etc.).

RELEVANT INFORMATION

2. Indicator Statement

Indicators should include three key elements:

- i. **Who** is being measured (e.g., proportion of diabetic members)?
- ii. **What** is being measured (e.g., test, visit, procedure, and treatment such as retinal eye exams)?
- iii. What is the **timeframe** for measurement (e.g., a one year reporting period)?

Examples of Complete and Incomplete Indicators

- Proportion of members with diabetes who had two or more visits with a PCP or endocrinologist (Incomplete: missing timeframe)
- Proportion of members with diabetes who received two or more HbA1c tests during the measurement year (Complete: all elements present)
- Number of diabetic eye exams (Incomplete: missing eligible population and timeframe)
- Proportion of members with diabetes who received two or more HbA1C tests during January 1, 2000 through December 31, 2000 (Complete: all elements present)

3. Indicator numerator statement (Maximum 255 Characters)

Instructions: Describe the numerator (criterion). Examples: Number of diabetic enrollees with hypertension who were prescribed ACE inhibitors during the measurement year. Number of diabetic enrollees who received two or more HbA1c's during the measurement year.

Note: If using a HEDIS indicator you may cite the specifications used (e.g., HEDIS 2000, Volume 2 – Technical Specifications, pp. 24 – 27) to complete the numerator, denominator, and inclusion and exclusion criteria). You **must** describe and justify any variations to HEDIS specifications (e.g., addition or omission of codes, use of different age groups than specified, etc.).

RELEVANT INFORMATION

3. Indicator Numerator Statement

The numerator statement should indicate that it is a subset of the denominator for indicators that are proportions. Numerators contain a description of what is considered to be an adequate quality criterion (or criteria).

Examples of Unacceptable Numerator Statements:

- The numerator statement "The number of members with congestive heart failure discharged from the hospital" DOES NOT specify any quality criteria and, therefore, is not an adequate numerator statement.
- The numerator statement "The number of prescriptions for ACE inhibitor provided" is NOT acceptable with the denominator statement "Congestive heart failure patients who are discharged from the hospital," since these do not have the same units of analysis (i.e., the numerator measures prescriptions, while the denominator measures patients).

This indicator would be acceptable if the numerator read "The number of patients who received prescriptions for ACE inhibitors," since patients would be the unit of analysis for both numerator and denominator.

Rates are most commonly used to describe outcomes that are standardized per unit of population at risk. At a minimum, for rate indicators, the numerator statement should clearly state the outcome of interest. The objective of the QAPI program is to improve outcomes, defined as objective measures of patient health, functional status, or satisfaction following the receipt of care or services.

continued

Examples of Acceptable Outcome Measures

- Mortality
- Admission/readmission rates
- Utilization/access/availability of services, functional status, quality of life measures, or enrollee satisfaction

An important caveat regarding the use of utilization and cost issues as indicators is that "the project must be clearly focused on identifying and correcting deficiencies in care or services that might have led to this pattern, such as inadequate access to primary care, rather than on utilization and cost issues alone."

4. Indicator denominator statement (Maximum 255 Characters)

Instructions: Describe the denominator (# of eligible cases), including information about age, eligibility, and appropriate codes (e.g., CPT, ICD-9, and NDC codes), where applicable.

Note: If using a HEDIS indicator, you may cite the specifications used (e.g., HEDIS 2000, Volume 2 – Technical Specifications, pp. 24 – 27) to complete the numerator, denominator, and inclusion and exclusion criteria). You **must** describe and justify any variations to HEDIS specifications (e.g., addition or omission of codes, use of different age groups than specified, etc.).

RELEVANT INFORMATION

4. Indicator Denominator Statement

The denominator statement should include a description of the entire population that is eligible for a process of care and/or is at risk for (an) adverse outcome(s).

Denominators include a statement of the disease condition being targeted, the time interval being measured, and/or the demographic or site of care qualifiers. At the very least, the disease condition and time interval are required.

Examples of Acceptable and Unacceptable Denominator Statements

- An acceptable denominator statement would be "All congestive heart patients over the age of 65 seen in the ambulatory care setting during the measurement year." However, not all components are necessary. Therefore, the statement "All patients diagnosed with heart failure during the measurement year" would be acceptable, as well. In this case, the additional criteria should be specified in the inclusion and exclusion criteria.

continued

Review Element 3

- An unacceptable denominator statement would be "All patients diagnosed with heart failure," unless additional adequate time interval information is provided in the inclusion and exclusion criteria.

Demographic qualifiers can include racial/ethnic descriptors, such as "All African-American women over the age of 50 enrolled during the bi-annual measurement period." The justification for using racial/ethnic qualifiers would need to be made in other sections of the QAPI document.

Certain types of restrictive descriptors are suspect and may invalidate a denominator statement. For example, the statement "Those patients with congestive heart failure who are participating in a case management program during the enrollment year" represents a restriction on the denominator defined by a plan-initiated process-of-care/intervention. CMS has clarified that "the organization must clearly specify what data are used to identify the population at risk and show that these data can reliably and validly capture the entire population (i.e., without systematically excluding a subset or subsets of the population)."

Restrictions that obviously correlate with the likelihood of success on the indicator (e.g., patients in the case management program get more intensive interventions and are more likely to show improvement) are unacceptable.

5. Indicator inclusion criteria (Maximum 255 Characters)

6. Indicator exclusion criteria (Maximum 255 Characters)

Instructions: Describe the limiting criteria used to further refine the numerator or denominator, or to define who is eligible or ineligible. The description should be specific as to which criteria relate to the numerator and which criteria relate to the denominator. For all indicator denominator, numerator, and inclusion and exclusion criteria, all numeric codes (e.g., ICD9-CM, CPT, DRG, HCPCS, etc.) should be accompanied by the full narrative description of the diagnosis, procedure, equipment, or service.

Note: If using a HEDIS indicator, you may cite the specifications used (e.g., HEDIS 2000, Volume 2 – Technical Specifications, pp. 24 – 27) to complete the numerator, denominator, and inclusion and exclusion criteria. You **must** describe and justify any variations to HEDIS specifications (e.g., addition or omission of codes, use of different age groups than specified, etc.).

RELEVANT INFORMATION

5. & 6. Inclusion and Exclusion Criteria

Inclusion and exclusion criteria guide the data collection process to determine if the indicator has been met. Inclusion and exclusion criteria may include use of age groups, M+CO enrollment criteria, and clinical information, such as CPT-4 and ICD-9 codes.

M+CO may conduct projects that address members in more than one product line (e.g. Medicare, Medicaid, and Commercial), **as long as they demonstrate** that the Medicare population is included in the measurement and intervention. Rates do NOT have to be reported separately for Medicare unless measures are based on standardized measures, such as HEDIS where product-specific reporting is required.

Inclusion criteria are characteristics that must exist to be classified as a member of a population or sample.

Examples of Inclusion Criteria

For a diabetic study, sample inclusions could be defined as:

Denominator:

- Age 65 years or older
- Diagnosed with diabetes per a list of qualifying ICD9-CM diagnosis codes (e.g., 250, 357.2, 362.0, etc.)
- Enrolled in the M+CO during the measurement year with no more than one gap of 45 days

Numerator:

- Diabetic enrollees with hypertension that were prescribed ACE inhibitors from a list of acceptable drugs

For a mammography study, sample inclusions could be defined as:

Denominator:

- Women age 50 or older enrolled as of December 31 of the reporting year

Numerator:

- Women who had a mammogram in the last two years per a list of qualifying CPT procedure codes (e.g., 76090, 76091, etc.)

continued

Exclusion criteria are characteristics that must **not** exist to be classified as a member of a population or sample.

Examples of Exclusion Criteria

For the diabetic projects above, sample exclusion criteria could be defined as (for the denominator):

- Members found on medical record review to not be true diabetics (coding errors)
- Members who have gestational diabetes

For the mammography project above, sample exclusion criteria could be defined as (for the denominator):

- Male members
- Female members under age 50
- Women who have had a bilateral mastectomy

7. M+CO-selected performance target for this indicator _____

Instructions: *This field must be completed before continuing to the next Review Element.*

RELEVANT INFORMATION

7. Performance Target and Benchmarks

Performance Target

A performance target is the desired level of achievement that the M+CO sets for itself as a standard of care. The M+CO may set its own performance target for the quality indicator. The terms benchmark and performance targets are not necessarily one and the same. CMS is looking for a recognized benchmark as a performance target but realizes that sometimes there is no established or available benchmark for a particular indicator. If this is the case, a M+CO may create an internal performance target based on a clear rationale. The target should be something that a M+CO strives for, but may not necessarily reach, and is preferably a long-range, not merely an interim, goal. If a M+CO does not attain its stated performance target for a given QAPI project, it will not be counted against it in the evaluation of its project, as long as it is moving towards improvement.

continued

Benchmarks

CMS may establish benchmarks for national QAPI projects. When the project is determined by the managed care organization, the benchmarks must reflect performance in other organizations or local, state, or national norms, as established through comparative data or reasonable expectations of optimum performance. The organization must be able to document the basis on which its benchmark was determined.

Some benchmarks for the Medicare population, such as HEDIS results, are appropriate to use and are available as public use files on the cms.hhs.gov web-site. If Medicare-specific data is not available, commercial measures may be appropriate to use.

Note: As of 2002, CMS has not determined benchmarks for national QAPI projects. Refer to the Managed Care Manual (Chapter 5: Quality) for additional information on performance targets and benchmarks.

8. Rationale/justification for performance target chosen (Maximum 4000 Characters)

Instructions: Describe the process by which your organization selected the specified performance target. The rationale/justification for the performance target should address the process used (e.g., a literature review of performance levels). You may also use expert opinion, national benchmark, or external consultation of the performance, which should be explained.

9. Indicator will measure changes in [select all that apply]

- Health status
- Functional status
- Enrollee satisfaction (Improvement in satisfaction must not be the sole demonstrable outcome of a clinical project. Some improvement in health/functional status must also be measured.)
- Aspect of services (access, availability, etc.)
- Process-of-care

Instructions: Select the change(s) the indicator will measure. The QAPI standards require that the quality indicator measures a change in one of the listed options. For this reason, an "Other" option is not provided. After completing item #9, you will be prompted to enter additional indicators, if desired, or continue on to the next Review Element.

Review Element 3

RELEVANT INFORMATION

9. Indicator Will Measure Changes in

For clinical projects, the indicator should measure outcomes of care, which includes health status, functional status, and enrollee satisfaction, or a process-of-care proxy measure for these outcomes.

Measures of processes are used as a proxy for outcomes only when those processes have been established through published studies or a consensus of relevant practitioners to be significantly related to outcomes.

Measurement may be related to structure, process, or outcomes of care. Outcomes indicators measure what does or does not happen to the enrollee after something is or is not done. Outcomes are the result of the process (e.g., complications, infections, mortality, morbidity, and satisfaction).

Examples of Outcome Measures

Health Status Examples:

- A score from a health status assessment tool for overall health (e.g., the SF-12), which will measure health condition of the enrollee
- Mental health composite score from SF-36 will measure the behavioral/mental health status of the enrollee
- A condition-specific tool, such as the one used for asthma or low back pain
- Drug interaction reports and surgical complication reports

Functional Status Examples:

- Assessment of activities of daily living (ADLs)
- CAHPS survey questions related to functional status

Enrollee Satisfaction Examples:

- Satisfaction with health plan from the CAHPS survey
- Telephone response rates (focus on member satisfaction with outcomes)

continued

Examples of Processes-of-Care Measures

Process-of-care indicators measure specific aspects of services that are related to outcomes. They can evaluate services and treatment provided that lead to improved health outcomes. Such measures include activities relating to diagnosis, treatment, prevention, education, and management of care/service.

- Breast cancer screening
- Diabetes management program
- Radiological and/or laboratory procedures
- Surgical procedures
- Ambulatory or outpatient procedures

Examples of Structure-of-Care Measures

Structure of care refers to the rules, regulations, policies, and goals that an organization develops and carries out to govern how the care or service is being provided. Written standards that relate to this category are:

- Utilization of services (e.g., the percent of new M+CO members who saw their PCP within six months of enrollment)
- Adequacy of staffing in a department (e.g. case management)
- Information systems infrastructure and how it relates to quality
- Credentials of specialty providers and their staff
- Availability of services (e.g., number of days between the day an appointment was scheduled and the actual appointment date)
- Access to a provider in an out-of-network area.

[On the Web-based Project Completion Report you will be prompted to]

SAVE AND ENTER ANOTHER INDICATOR OR SAVE AND CONTINUE TO REVIEW ELEMENT 4

Review Element 4: Baseline Study and Analysis

All elements must be completed before the M+CO can submit Demonstrable Improvement. Select a quality indicator from the list, based on the indicators entered in Review Element 3.

1. Baseline data period

1a. Baseline Data Period Start date
MM YYYY

1b. Baseline Data Period End date
MM YYYY

Instructions: Enter the start and end dates (month/year) for the baseline data period.

Note: Data released during one year, such as HEDIS 2001 findings, may be data collected from an earlier time period, such as January through December 2000. For this field, enter the actual time period for which the data were collected. For example, enter 01/2000 and 12/2000 as the start and end dates for annual HEDIS 2001 indicators.

RELEVANT INFORMATION

1. Baseline Data Period

Assessment of the M+CO's performance on the selected indicator is based on systematic, ongoing collection and analysis of reliable and valid data.

The M+CO must:

- Establish a baseline measure of its performance on each indicator (Year 1: Baseline Measurement)
- Re-measure changes in performance (Year 3: Reporting Demonstrable Improvement)
- Continue with re-measurement to document sustained improvement (Year 4: Reporting Sustained Improvement one year after demonstrable improvement)

In this section, the M+CO will document the data collection methodology and efforts used to ensure validity and reliability.

continued

Assessment of compliance with this standard will be coordinated with the review of the organization's information systems.

This section is used to identify the admissible dates for data for the indicator at hand. For example, a full year of data should be used in the creation of annual indicators, such as the proportion of diabetics receiving an annual fundoscopic eye exam. The point of this section is to ensure that the time period for the data matches the time frame for the quality indicator.

2. Baseline data source(s)

[select all that apply and describe]

- HEDIS data: Hybrid (Maximum 4000 characters)
[continue to Review Element 5, unless another baseline data source has been selected as well]
- HEDIS data: Administrative (Maximum 4000 characters)
[continue to Review Element 5, unless another baseline data source has been selected as well]
- Medical records (Maximum 4000 characters)
- Laboratory data (Maximum 4000 characters)
- Pharmacy data (Maximum 4000 characters)
- Administrative claims or encounter data (Maximum 4000 characters)
- Hybrid (combination of administrative claims/encounter data and medical records) (Maximum 4000 characters)
- Survey data: CAHPS (Maximum 4000 characters)
[continue to Review Element 5, unless another baseline data source has been selected as well]
- Survey data: HOS (Maximum 4000 characters)
[continue to Review Element 5, unless another baseline data source has been selected as well]
- Survey data: Provider: Physician (Maximum 4000 characters)
- Survey data: Provider: Other provider (Maximum 4000 characters)
- Survey data: Other (Maximum 4000 characters)
- M+CO program data (tracking logs, grievances/complaint data, etc.) (Maximum 4000 characters)
- Other (Maximum 4000 characters)

Instructions: Identify the data source(s). Describe the data in a sentence or two. If the baseline data source is a reported HEDIS measure, no description is required unless another baseline data source also has been selected (in addition to HEDIS). If CAHPS or HOS survey data are employed, only the survey question numbers are required in the description.

RELEVANT INFORMATION

2. Baseline Data Source(s)

HEDIS Data

Methods of data collection can span several sources and techniques. For example, the HEDIS hybrid methodology may be used to obtain data for quality indicators. The National Committee for Quality Assurance (NCQA) HEDIS 2000 Technical Specifications describe hybrid methodologies for data collection of HEDIS indicators as using membership or claims data to identify an eligible population, determining an appropriate sample size, and conducting medical record reviews, or perhaps other forms of data collection, from a sample of the eligible population.

The M+CO may use membership data to identify an eligible population defined by age and gender (e.g., women between 52-69 years of age for breast cancer screening). The M+CO also may use claims data to identify an eligible population when it is defined by a specific service (e.g., hospitalization for mental illness). Once the target population and the required sample size are determined, sampling techniques are used to identify members who will be included in, for example, a medical record review, using the hybrid methodology. Under the administrative method, sampling is not necessary, as claims data are examined to identify the numerator service for all eligible members in the target population.

Not Reported HEDIS data are acceptable as a baseline data source, if they are evaluated and certified by an audit firm. However, only those measures deemed "reportable" by the audit firm should be used as M+CO developed data source for QAPI projects.

Administrative Claims and Encounter Data:

Administrative data include billing data for medical services, prescription fulfillment, and encounter data for medical services. Laboratory values and actual prescriptions are other potential data sources for quality indicators.

M+CO Program Data

Examples:

- A disease registry (if the encounter data includes only limited clinical information to identify persons with a certain condition)
- A tracking log of member complaints
- Member enrollment logs for educational programs

3. Data collection: Describe method of data collection, including efforts to ensure validity and reliability. (Maximum 4000 characters)

Instructions: Describe the data collection methodology employed. If only a reported HEDIS measure, CAHPS, or HOS was chosen in item #2, skip and continue to #4.

RELEVANT INFORMATION

3. Data Collection

The M+CO **must** clearly demonstrate the efforts used to ensure data reliability and to validly capture the entire population at risk without systematically excluding a subset or subsets of the population (i.e., without introducing a systematic source of bias).

Definition of Validity and Reliability

- Validity is an indication of the relevance of the information obtained.
- Reliability is an indication of the repeatability or reproducibility of a measurement.

Validity and Reliability of Data Source(s)

When deciding on data source(s), a M+CO would want to evaluate the validity and reliability of each one. For example, a M+CO might evaluate use of encounter data or pharmacy data to identify persons with a certain condition before choosing one type of data.

For survey data, the M+CO would need to report the following information to document the validity and reliability of the data:

- Validity of the survey instrument and questions (e.g., document references of previous use of such questions with the coding of responses, or document validation studies, such as those employing factor analysis with the results and survey form/tool)
- Methodology of survey implementation, including use of a pilot test of the survey instrument and process
- Qualifications and training of personnel administering the survey, including testing for reliability

continued

- Methods used to contact enrollees/providers in ensuring that the sample is representative of the target population
- The response rate and description of methods employed to obtain an adequate response rate. In the event of a weak final response rate, an effort, such as descriptive statistics, is needed to show the representativeness of the respondents.
- Issues dealing with missing information

For data obtained through medical record reviews or other primary source documents, the M+CO should document the following information to assure that the data are appropriately and uniformly extracted and recorded:

- Personnel qualifications, required by the professional judgement involved
- Guidelines or protocols for obtaining and entering the data
- The abstraction tool and, if appropriate, its previous use
- Abstraction task-specific personnel training
- Pilot testing of the tool and process, including overall and item-by-item results for:
 - Inter-reviewer reliability results, as measured by repeated reviews of the same data
 - Gold Standard validity results, as measured by the congruence between abstracted and “correct” responses

For administrative medical or pharmacy data, the M+CO should use the following information to document the validity and reliability of the data:

- Time period allowed for claims processing/lag
- Comparison of findings to other M+CO sources for similar time periods
- Results from recent audits of the administrative data systems relative to the reliability and validity of the needed data

For a hybrid method of data collection, the M+CO should document the steps taken to identify the eligible sample using membership or claims files. For example, HEDIS 2001, Volume 2, requires M+COs to identify the denominator and the numerator through both administrative and medical record data. The denominator consists of a systematic sample of members that is found through either administrative or medical record data to have received the service identified in the numerator. The numerator is not solely derived from the administrative data (HEDIS 2001, Vol. 2).

For all sources of data, the M+CO needs to document the methods it used to ensure:

- The data captured the entire population at risk (i.e., without systematically excluding a subset or subsets of the population)
- Completeness of important data fields (i.e., responses to surveys and addresses for mailings)

continued

Review Element 4

- Compliance with any standard data processes established by CMS or a State Medicaid agency, if the M+CO is required to report routinely the quality indicator to the respective agency
- Compliance with confidentiality requirements provided in the QAPI Standard

In general, when the M+CO derives the data from its information system, its reliability and validity will be assessed in a coordinated review of the M+CO's information systems.

4. Data analysis: Describe methods used to analyze data and collect the quality indicator. (Maximum 4000 characters)

Instructions: Describe the methods used to analyze the data and calculate the quality indicators. If only HEDIS, or CAHPS, or HOS were chosen in item #2, skip this element and continue to Review Element 5.

Note: The HEDIS measure must be reported.

RELEVANT INFORMATION

4. Data Analysis

For all data sources, include information on how the:

- Data were processed and checked for reliability and validity
- Outliers were identified and how they were handled
- Missing data were handled
- Quality indicator(s) were computed from the data

For administrative data, note the percentage of records for which there were no membership records. For survey or medical record review data, note the percentage of responses/records with missing data in fields used to calculate the quality indicator(s).

Fully Acceptable and Completely Unacceptable Data Analysis

continued

Example of a Fully Acceptable Data Analysis for Administrative Data:

- Data were extracted from our **D**urable **A**utomated **T**ransfer **A**ssistant (DATA) system using our standard **EXT**ended Research **ACT**ivity (EXTRACT) program. The EXTRACT program has been used for state projects for over five years and has withstood annual audits for accuracy since its creation. The program applies inclusion and exclusion criteria supplied by the Quality Improvement Team against multiple administrative datasets to create a working dataset. The data were checked for sufficient reliability and validity by being compared against audited, reportable, HEDIS data. This comparison yielded favorable results.
- EXTRACT automatically looks for and prints outliers through a +/- 3 SD system. We then checked each outlier by hand to determine if it was an:
 - Input error, in which case it was corrected and remained in the dataset, or a
 - Divergent value that was inside the plausible range, in which case the data were left in the dataset, or an
 - Unexplainable value that was outside the plausible range, in which case the data were removed from the dataset.
- EXTRACT also checks for missing data. When missing data are found, EXTRACT runs standard algorithms to see if the data are missing "at random"—a condition that only exists when the variable is uncorrelated with other variables. For uncorrelated missing data, mean imputation was used to replace the missing values. For correlated missing data, regression imputation was used for constructing the replacement data.

Or

- EXTRACT also checks for missing data. We eliminated records with missing data from the analysis. Before doing so, however, we had EXTRACT check to see if those with missing data were representative of those without the missing data on each variable in the analysis. We used an alpha of 0.10 for the analysis and found that those with missing data had other characteristics, which were very much the same as those without missing data, validating the removal of the records with missing data from the dataset.
- After completing the data extraction, outlier analysis, and missing data handling, we then turned to the actual quality indicator construction. Once we had a clean and defensible numerator and denominator from steps 1, 2, and 3, we simply divided the numerator by the denominator to form the numeric proportion that is the quality indicator.

Examples of Completely Unacceptable Data Analysis for Administrative Data:

- MIS created the indicators using administrative data.

continued

- Missing data were deleted and the quality indicators were created by division.
- We check all inputs for outliers and missing data, so they shouldn't be a problem. Our analyst calculates our quality indicators.
- We used our annually audited data, just like we do for all of our other reporting.
- Spot checks show that our data are reliable and valid, so we used them to form the quality indicators.
- Our system does not accept missing or outlier data, so we calculated the quality indicator from the data.

[On the Web-based Project Completion Report you will be prompted to]

SAVE AND CONTINUE TO REVIEW ELEMENT 5

Review Element 5: Baseline Study Population and Baseline Measurements/Performance

All elements must be completed before the M+CO can submit Demonstrable Improvement. Select a quality indicator from the list, based on indicators entered in Review Element 3.

1. Baseline study population

1.1 Enter the entire eligible population size (number) _____

Instructions: Provide the baseline entire population size.

RELEVANT INFORMATION

1. Entire Population

The entire population is generally the total eligible population identified from administrative data in the formation of quality indicators. The entire population is also the target population to which the intervention is directed and for which results are generalized. The size of the entire population is therefore determined after all inclusion and exclusion criteria have been applied. The number provided in this section is the maximum number possible for the denominator of the associated quality indicator.

1.2 Are you using a sample of the entire eligible population?

- Yes [please provide sample size in 1.2a, and complete 1.3]
- No [continue to 2]

1.2a Sample size (number) _____

Instructions: Indicate if a sample was used in the analysis of the quality indicator. If a sample was used, complete 1.2a.

1.3 If a data sample is used, provide the following information

1.3a Describe justification for sample size (e.g., power analysis) (Maximum 4000 characters)

Instructions: *If a sample was used, provide the justification for the sample chosen.*

1.3b Describe baseline sampling methodology

[select ONE and describe in 1.3c]

- Random
- Stratified random
- Other (e.g., systematic)

1.3c Sampling methodology description (Maximum 4000 characters)

Instructions: *Indicate the type of methodology used in the sampling process in 1.3b, and describe the sampling process in 1.3c.*

Note: *Only text may be copied and pasted from existing documents. Mathematical symbols cannot be copied into the space provided and should be spelled out in the description (e.g., alpha and beta)*

RELEVANT INFORMATION

1.3c Sampling Methodology Description

When a sample is generated from the underlying population (i.e., the entire population), the sampling methodology should ensure that the collected data validly reflect the performance of all practitioners and providers who serve Medicare and other product line enrollees and whose activities are the subject of the quality indicator. In addition, the data should validly reflect the care given to the entire population (including special populations with complex care needs) to which the indicator is relevant.

The M+CO should demonstrate that the sample size is sufficient to distinguish an appropriate level of change in the quality indicator. The use of a power analysis is strongly recommended and information concerning the analysis should be provided.

For example, a justification statement such as “sample size is set to detect difference at $p < 0.05$ level” is insufficient.

continued

Power Analysis

The standards do not require the use of power analysis for the determination of sample size. Power analysis is a statistical technique that estimates the likelihood that the null hypothesis will be rejected if it is false. When a given level of power is desired, power analysis can be used to determine the required sample size, as well as to demonstrate whether a change in a quality indicator is either statistically significant or is at a minimum level.

The QAPI standards require that changes in the quality indicator demonstrates improvement in performance between baseline and re-measurement. If the M+CO uses power analysis to determine the sample size, it should report the following information:

- Statistical package used in the analysis with detailed description of the methodology
- If statistical testing is employed, the type of test used (such as a two-tailed, chi-square test of association between two proportions or a two-tailed t-test)
- Level of acceptable error allowed
 - Probability of a Type I error (rejecting a true null hypothesis) is referred to as alpha (such as $\alpha=0.05$).
 - Probability of a Type II error (failure to reject a false null hypothesis) is referred to as beta (b)
 - Power, which is $1-b$
- Estimated baseline value of quality indicator used in the power calculations
- Size of the change in quality indicator to be detected through samples

The NCQA HEDIS 2000 Technical Specifications provide a recommended sample size of 411 for most HEDIS indicators when a hybrid method is used, and the M+CO does not have baseline values. The sample size of 411 was generated from a power analysis that included the following assumptions:

- Normal approximation of a binomial distribution using a two-tailed test of significance between proportions
- Level of error: $\alpha=0.05$ and $b= 0.20$
- Baseline quality indicator of 50%

continued

- Ability to detect a difference of 10 percentage points in the quality indicator (raw percentage points)

CMS accepts the HEDIS sampling methodology for QAPI projects. If additional cases are drawn (over sampling), the plan should provide reasons and justifications accordingly. The plan should also describe the causes and numbers of samples lost in the data collection process.

The M+CO should document that all members of the target population are equally likely to be selected. For example, when studying well childcare, a M+CO should not exclude children with special care needs whose primary care provider is a specialist, other than a pediatrician or family medicine provider. If the target population is a provider group, each relevant provider should have the same chance of being selected as every other provider serving quality indicator-eligible enrollees. Each member or provider who was not included in the baseline sample should have the same chance of being selected for the follow-up measurements, as those who were included in the baseline sample. These criteria will generally mean random sampling, although stratified random sampling may be appropriate when the intent is to compare care by different practitioners or at different sites.

Many reference manuals (e.g., the NCQA HEDIS 2000 Technical Specifications (See Guidelines for the **Systematic Sampling Methodology**)) document the methods used to identify a sample, such as how to identify a sample for a survey or medical record review.

The description of the sampling method should include information on the use of exclusions in the data collection process, substitution if information for an identified member is not obtained, and, if applicable, the data stratification process. If a random sample is not employed, the M+CO should provide a detailed description of the sampling method and justification used. The only exception is when a plan follows HEDIS systematic sampling methodology.

Specifications recommend that, if a quality indicator applies to fewer than 100 members, the M+CO should use data for all eligible members.

Sampling Information

When using population data (e.g., a census conducted with administrative data), the study results can be as precise as the data that were used in processing them. When that's not possible (e.g., using medical record abstraction data for very large numbers of people), samples are used to estimate what the population results would have been, if population data could have been obtained.

continued

Study samples have three specific advantages over study populations: 1) reduced cost, 2) greater speed, and 3) greater scope for the same study resources than what could be achieved if the study was conducted on population data.

Sampling is comprised of sample size, sampling methodology, sample validation, and sampling time frame. The sampling methodology specifies the ways by which the samples are derived. The sample validation ensures that the sampling methodology was met through how it was put into practice. The sampling time frame specifies when, in time, the data from the samples are valid for inclusion in the research.

Determining Sample Size

Sample size is **critical** to finding statistically significant differences. In general, larger samples are needed to detect small differences, and smaller samples are needed to detect larger differences. For example, the sample size needed to determine if people can be hurt in a high-speed automobile accident (i.e., large change from normal) is quite small. However, a large sample would be needed to see if a given water supply is causing a local increase in the rate of some cancers (i.e., small change from normal).

The sample size also influences the degree of certainty and precision in the results. For many applied statisticians, determining sample size is "where the rubber meets the road." In most situations, determining sample size boils down to a balancing act between precision and cost. The best advice is to consult a statistician.

Sampling Methodology

For most healthcare research, one of three traditional sampling methodologies are usually employed: 1) simple random, 2) stratified, and 3) systematic. For complex healthcare issues, two or more sampling methodologies may be needed. In all cases, specifying the sampling methodology yields a critical perspective for interpreting the study results.

Simple Random Sampling:

Simple random sampling has two properties that make it the standard against which to measure all other sampling methodologies. First, it is unbiased in that each person or unit has the same chance of being chosen as any other person or unit. Second, the selections are independent of one another in that the selection of one person or unit does not alter the chance of being selected for any other person or unit. An example of simple random sampling would be to assign a random number to all members of a population and then choose those members with the lowest random numbers to the extent allowed by the study resources.

continued

Stratified Sampling:

Stratified sampling divides the population or units into homogeneous groups along a characteristic that is relevant to the study question and draws a simple random sample from within each stratum or group.

For example, when examining medical records for the delivery of diabetic services across four physical-health managed care organizations, one might first divide the overall population into individuals within each of the four organizations and then randomly sample within each organization.

Systematic Sampling:

Systematic sampling starts with a randomly chosen person or group and then selecting every *n*th person (e.g., every 10th person for a 10 percent sample) or unit in a previously ordered population. When a population is previously ordered in a manner that is unrelated to whatever is being studied (e.g., alphabetic recipient lists and quality of care issues once someone is seen by a physician), systematic sampling closely resembles the statistical properties of simple random sampling but without some of its cost. As such, systematic sampling is frequently employed as a way to stretch scarce study resources.

Sample Validation

Sample validation ensures that a sample is representative of the targeted population (for a single group study) and that samples are substantively equivalent (for a multiple group or multiple time frame study). Sample validation is necessary to assure that the random samples are truly random and yield targeted, population-equivalent information. Two relatively small and isolated samples being drawn at random from the same population does not automatically guarantee that the samples will be equivalent. More important, reasonable equivalence is a requirement for justifiable comparisons and for meaningful results. Fortunately, such equivalence can be sufficiently verified for most purposes through the use of descriptive statistics (i.e., means and standard deviations).

Sampling Time Frame

Samples can be drawn at various points in time that makes sense for the QAPI project. Three types of sampling time frames are typical in healthcare research: 1) sequential cross-sectional, 2) cross-sectional, and 3) longitudinal. QAPI studies almost exclusively use sequential cross-sectional sampling. Cross-sectional and longitudinal sampling are covered below as background information to help understand sequential cross-sectional sampling.

continued

Sequential Cross-sectional Sampling:

Sequential cross-sectional sampling is currently popular in healthcare research and is the most common sampling methodology for QAPI studies. This technique samples from the target populations two or more times over specified intervals. Healthcare populations are not typically stable, nor are many of their medical conditions. The public health policy perspective is to examine what is happening to a population in terms of the incidence and the prevalence of certain conditions, processes of care, or medical outcomes over time.

A population that is becoming healthier for unknown reasons is still a healthier population. A population that is seeing primary care providers more frequently over time is providing the healthcare system with more cost effective opportunities for preventive care, even if the population is somewhat different because of shifting demographics. Healthcare is a somewhat closed system. Those who no longer receive care from one provider will most likely receive care from another. What is considered important from a sequential cross-sectional sampling perspective are the processes of care and outcomes for the only individuals who are addressed by the system—those serviced by it.

Cross-sectional Sampling:

Cross-sectional sampling is conducted at one point in time. A common metaphor for cross-sectional sampling is "a slice in time." When two differing healthcare systems are being compared and their populations are reasonably equivalent or can be made so, cross-sectional sampling is a cost-effective means of answering questions about differing healthcare processes and outcomes between the two systems. The major limitation to cross-sectional sampling is the lack of a comparison group or comparable context for the results.

Longitudinal Sampling:

Longitudinal sampling is conducted on the same group of individuals at two or more points in time. The technique is frequently used to measure the impact of a new policy on a stable group of individuals. When the sampling is done at appropriate times on both sides of a policy change, this technique has a major advantage over other techniques (i.e., the change from the first time period to the second time period can be attributed to the policy change). The Health Outcomes Study (HOS) uses longitudinal sampling. HOS measures a cohort (sample of enrollees) at two points in time.

continued

The chief disadvantage of longitudinal sampling is sampling mortality—not all subjects from the first time period are still there for the second sampling. Some of the subjects have may moved, died, or are unavailable for re-measurement. The population that is available for re-measurement may not be reasonably equivalent to the starting population. A major disadvantage to longitudinal sampling for healthcare outcome research is that many medical conditions worsen over time and may present an important source of bias when comparing the results of the two time frames.

2. Baseline measurements/performance

2.1 Baseline numerator _____ [must be completed before entering DI in RE7]

Instructions: Enter the baseline numerator for the baseline performance.

2.2 Baseline denominator _____ [must be completed before entering DI in RE7]

Instructions: Enter the baseline denominator. Explain when the baseline denominator and total sample size are different.

2.3 Baseline performance _____

Instructions: Enter the baseline performance by dividing the numerator (2.1) by the denominator (2.2), then multiply by 100 to produce a percentage.

2.4 Performance target _____ [from Review Element [RE] 3, Item 7]

RELEVANT INFORMATION

2.4 Performance Target

This is the value that the M+CO entered in Review Element 3, Item7.

Examples of Completed Baseline Measurement Information

Indicator: ACE inhibitor use:

2.1 Baseline numerator (#)	1,851
2.2 Baseline denominator (#)	3,621
2.3 Baseline performance (%)	51.1% (1,851/3,621x100=51.1%)
2.4 Performance target (%)	75%

Indicator: Call abandonment rate:

2.1 Baseline numerator (#)	400
2.2 Baseline denominator (#)	1,000
2.3 Baseline performance (%)	40.0% (400/1000x100=40.0%)
2.4 Performance target (%)	20%

3. Barrier analysis [optional] (Maximum 4000 characters)

Instructions: You may copy and paste text from existing documents into the text field. You are **encouraged** to enter information concerning a barrier analysis if conducted.

RELEVANT INFORMATION

3. Barrier Analysis

Barrier analysis is the identification of the potential causes, including underlying factors that contribute to the identified performance.

Examples of targeted issues for a barrier analysis:

- Systems level barriers (e.g., data, intake, scheduling, policy issues etc.)
- Unique population characteristics
- Knowledge limitations
- Resource limitations (including time)
- Service delivery issues (including organizational and procedural issues).
- Literature review
- Focus groups to identify barriers

continued

Examples of people targeted for a barrier analysis:

- Physicians
- Beneficiaries
- M+CO staff (e.g., receptionists, schedulers, etc.)
- Auxiliary personnel (e.g., lab personnel)
- Some reasons why members may not get a diabetic retinal eye exam (DRE) include:
 - Knowledge deficit on the part of members and/or providers regarding the importance of DREs for early detection of vascular complications
 - Process barrier, such as the need for referrals
 - Access issue, such as lack of transportation
 - Availability issue, such as the number of ophthalmologists and optometrists in the M+CO's network

The M+CO also may report other findings that might influence the baseline measurements, such as data collection issues or unexpected occurrences.

[On the Web-based Project Completion Report you will be prompted to]
SAVE AND CONTINUE TO REVIEW ELEMENT 6

Review Element 6: Interventions Aimed at Achieving Demonstrable Improvement

All elements must be completed before the M+CO can submit Demonstrable Improvement. Enter information about the interventions. If "Other" is selected in any category, the M+COs are expected to describe "other" in the section called "Intervention description."

1. Intervention type

[select ONE of the following intervention types]

- Education: outreach visits, conferences/meetings, printed/on-line resources/materials, tools, other mass media campaigns and communication venues
- Reminder tracking systems
- Organizational changes: policy changes, quality improvement, structural redesign, or re-engineering
- Provider performance feedback
- Other community-level interventions
- Additional resources
- Other M+CO initiatives to improve performance
[describe in "Intervention description"]

Instructions: For each intervention, select one intervention type, target audience, and any collaborating partners. Provide the date the intervention was initiated and use the text field to describe the intervention and the rationale for the intervention. After entering 1-6 for an intervention, you may enter additional intervention or continue to Review Element 7.

RELEVANT INFORMATION

1. Intervention Type

Similar to quality indicators, interventions are entered one a time. **At least one** intervention is required. Reporting on all related interventions is encouraged and will assist the reviewers in understanding the scope of work and the effort that has been performed by the M+CO to move the indicator. QAPI projects should include specific interventions that are system-wide, self-sustaining, and multi-faceted in their approach.

continued

Examples of Types of Interventions

- **Educational materials and formal CME programs** include printed and on-line resources and materials, such as clinical guidelines and tools, immunization tracking logs, chart reminder stickers, posters, condition-specific articles, and guidelines for members written in easy-to-understand language. Formal CME programs including educational conferences that offer continuing education credits for providers frequently cover topics such as clinical practice guidelines for disease management, as well as quality improvement initiatives.
- **Reminders, tracking systems:** Provider reminder systems (i.e., concurrent feedback) include both manual and computer-assisted medical record or other essentially real-time, patient-related reminders.
- **Organizational change** (i.e., policy changes, quality improvement, structural redesign, or re-engineering) in a managed care environment, eliminating referrals for diabetic eye exams is an example of an organizational policy change. Another would be revising administrative policies and procedures to expedite grievance processing.
- **Provider performance feedback** is similar to a retrospective audit with feedback. Provider performance on a particular indicator (e.g., the proportion of a provider's female patients who received a timely mammogram) is measured, and a report may display the results for each practice and for comparable practices (i.e., peers). Peer results are aggregated or blinded so that provider confidentiality is assured. These audits inform practitioners about their own practice. Feedback can be either retrospective (provided after the service) or concurrent (provided at the time of actual service). For example, physicians could receive reports on the proportion of their female patients who have received PAP smear screening for cervical cancer, when indicated by current clinical recommendations.
- **Other community-level interventions**, such as marketing, mass media campaigns, are similar to product advertisement. The media (e.g., television, radio, and printed material) can be used to promote a service to a wide population.

2. Target audience

[select all that apply; if “Other” selected, describe in “Intervention description”]

- Enrollees/Member
- M+CO staff: Clinical staff
- M+CO staff: Non-clinical staff
- Practitioners: Physician
- Practitioners: Nurse Practitioner
- Practitioners: Physician Assistant
- Practitioners: Pharmacist
- Practitioners: Other Providers
- Facility
- General public/community
- Other [describe in "Intervention description"]

RELEVANT INFORMATION

2. Target Audience

The target audience for an intervention is defined as the group for whom a behavior change is desired.

3. Intervention description

[provide a description of the intervention, including frequency]

Instructions: Provide a description of the intervention. This text box has a 4,000-character limit.

RELEVANT INFORMATION

3. Intervention Description

The intervention description should provide sufficient detail to justify that any observed improvement in the quality indicators could be reasonably attributed to the intervention(s) undertaken by the organization. The M+CO is not required to demonstrate conclusively (for example, through a controlled study) that the interventions caused the change in the quality indicator. Information describing the number of participants who were targeted and number who participated, frequency of interventions, mode of delivery, trainer qualifications, and setting of intervention assists the reviewers in determining if the intervention could reasonably be expected to affect the quality indicator.

continued

Modifications made to the interventions, from the time period between the baseline measurement and the demonstrable improvement, can be provided in this section (e.g. updates to clinical guidelines). The M+CO also may wish to include the rationale (i.e., feasibility, objectivity, and reliability) for the intervention in this section. Alternatively, this information may be supplied in the optional "Barrier Analysis" (Review Element 5, Item #3).

Intervention content can be either provided verbally or in writing. It should be based on health education and/or psychology theories or models (e.g., PRECEDE framework on the predisposing, enabling, and reinforcing factors; Health Belief Model (H.B.M) on the forces which facilitate preventive behavior; and Transtheoretical Model on the five phases of behavior change). The messages need to be appropriate to the audience. Messengers/ Educators/Trainers should be educators, pharmacists, nurses, and physicians with background and/or experiences in public health education.

Settings can be hospitals, schools, physician offices, or homes depending on the number, the background of the audience and trainers, the nature of the contents of messages, and the equipment needed for the interventions

The number of participants and educators need to be specified and, if available, the percentage of participants over the targeted population to be educated

The frequency of interventions also needs to be specified, such as a quarterly report or annual review, rather than entering a separate intervention for each date for the same type of intervention.

4. Intervention initiation date: [MM/YYYY]

4.a Intervention timeframe: [select only one]

Ongoing

End Date

Enter end date [MM/YYYY]

➔ **Instructions:** Enter the date on which the intervention was initiated and check the timeframe. If "End Date" is selected, enter the end date.

RELEVANT INFORMATION

4. Intervention Initiation Date

The M+CO must provide the date from which the intervention actually began (e.g., when the mailing was sent, conference was held, office visits first conducted, etc.)—**not** the date when planning began or when materials were printed—to the date that the intervention ended, unless the intervention is ongoing.

5. Intervention partners

[select all that apply; if "Other" selected, describe in "Intervention description"]

- Enrollees/Members
- Practitioners: Physicians
- Practitioners: Nurse Practitioner
- Practitioners: Physician Assistant
- Practitioners: Pharmacists
- Practitioners: Other Providers
- Facility
- Healthcare agencies
- Hospital associations
- Professional societies
- Consumers
- Community-based organizations
- Other M+COs
- QIO
- Other

Instructions: If you worked with other organizations on the planning and implementation of the intervention, provide the types of partners.

RELEVANT INFORMATION

5. Intervention Partners

Partners are individuals, groups, or organizations that work together to achieve one specific objective of the QAPI project with the help of shared decision-making, (e.g., sharing resources or developing materials or tools for enrollees' education). Partners are not defined the same as collaborators for QAPI projects. Collaborative projects are those in which two or more entities work together on all aspects of the QAPI project, from project design through measurement, interventions, and re-measurement.

Examples of Intervention Partners

- Collaboration from Day One (CFDO) offers providers immediate involvement in the performance of QI studies by encouraging their participation from the start. Providers who commit from the start feel more obligated to follow through with promises of change. In addition, providers who are involved with the study questions and design often respond more openly to study conclusions that are less than favorable. Study groups can also serve as effective means to disseminate study results and assist with interventions.

continued

- Alliances with professional societies/opinion leaders involve the use of respected network providers and/or respected experts as champions to influence and gain provider commitment. Opinion leaders are people who occupy a central position in the communication network. Opinion leaders are able to influence individuals' attitudes and behavior in a desired way.

6. Additional information: Do you plan to mail in additional information on your interventions (i.e., binders, packets, tool kits)?

- Yes
 No

Instructions: *You may send in additional information to the reviewer, such as copies of mailings, surveys, educational material, or other items that may assist the reviewer in understanding the interventions and efforts used to target the desired population. Send the information to your assigned M+CQRO. If "Yes" is selected, the contact name and address for the assigned M+CRO will appear on the screen*

You are not required to send in additional information. However, it can be helpful to the reviewers in evaluating whether the intervention could reasonably be expected to impact the indicator.

OTHER RELEVANT INFORMATION ON INTERVENTIONS

An intervention is defined as an activity or activities designed to change behavior. Effective interventions may be developed as a result of a barrier analysis. Factors can be identified through a cause-and-effect diagram or flow chart of a process.

Key Points

- Interventions should ideally be initiated in the first quarter after baseline measurement.
- Interventions should address system-level problems that have been identified through analysis of plan performance.
- Interventions can be reasonably expected to affect the results.
- The M+CO does not have to identify interventions for each barrier in baseline assessment.

continued

Multiple Intervention Strategies

Research has shown that multiple strategies in trials had greater success. Studies targeted to behavioral change based on explicit need assessment had the highest likelihood of impact (i.e., 90% exhibited change). Interventions should be conducted at a system level to address underlying problems rather than simply to improve the performance of a specific indicator or provider. Interventions that are unlikely to induce permanent change (e.g., a one-time reminder letter to physicians or beneficiaries) are insufficient. Again, multiple interventions aimed at an indicator are usually more effective.

Other effective intervention strategies include financial incentives for elimination of member co-payments for preventive services, positive financial incentives (e.g., bonuses) for providers who achieve higher rates of preventive services within their panel, or negative incentives (e.g., withholds) for those who do not meet an established criterion for preventive services.

Most Effective vs. Least Effective Intervention Strategies

Most Effective Interventions:

Physician reminders
Patient-mediated methods

Academic detailing
Opinion leaders
Audit with feedback
Multi-faceted

Least Effective Interventions:

Educational materials
Traditional CME without enabling or reinforcing strategies
Mailings
Mass media

Examples of Completed Interventions Information

Example A:

1. Intervention Type	Reminder Tracking System
2. Target Audience	Physicians/Other Practitioners
3. Intervention Description	Diabetes Tool Kit, including reminder-tracking system, practice guidelines, reminder postcards and wallet cards, mailed to all providers one time. The tool kit was developed in collaboration with the local chapter of the CDE and the Network provider Quality Committee.
4. Date Initiated	09/2000 – 9/2000
5. Partners	State QIO
6. Additional Information	Yes, will be mailed

continued

Example B:

1. Intervention Type	Organizational Change
2. Target Audience	Physicians/Other Practitioners, Other: Office Staff
3. Intervention Description	Clinical Practice Guidelines were adopted by QI Committee and mailed to all Network provider offices. Additional detailing visits to 460 provider offices were made to institute tracking system, which was accepted by 230 providers.
4. Date Initiated	09/2000-11/2000
5. Partners	State QIO
6. Additional Information	Yes

Example C:

1. Intervention Type	Education
2. Target Audience	Members/Beneficiaries
3. Intervention Description	Education Brochure and patient education materials, outlining needed tests and schedule, mailed to all members with diabetes. Followed up with Diabetes Education speaker program for members of which 500 attended 4 sessions held on 4 consecutive Saturdays in October. Speakers included physician leaders and endocrinologist.
4. Date Initiated	10/1999
5. Partners	Local CDE Chapter
6. Additional Information	No

Example D:

1. Intervention Type	Education
2. Target Audience	Physician, Other Practitioners
3. Intervention Description	PCP education series provided at 4 Provider Group meetings, outlining progress on indicators with guest speaker (network endocrinologist) and covering topics related to diabetes preventive care.
4. Date initiated	11/1999-12/1999
5. Partners	None
6. Additional Information	No

continued

Review Element 6

Example E:

1. Intervention Type	Provider Performance Feedback
2. Target Audience	Physician, Other Practitioners, Other: Office Staff
3. Intervention Description	Distributed annually to all providers of diabetic members a Provider Performance Profile that displays rates for each indicator by practice and shows comparisons against the aggregate and other providers. Additional feedback provided at detailing visits.
4. Date Initiated	01/2001
5. Partners	None
6. Additional Information	No

[On the Web-based Project Completion Report you will be prompted to]

SAVE AND ENTER ANOTHER INTERVENTION

SAVE AND CONTINUE TO REVIEW ELEMENT 7

Review Element 7: Demonstrable Improvement

All elements must be completed before the M+CO can submit Demonstrable Improvement. Select a quality indicator from the list, based on indicators entered in Review Element 3.

1. Demonstrable improvement data period

1a. Demonstrable improvement period start date

MM YYYY

1b. Demonstrable improvement period end date

MM YYYY

Instructions: Enter the start and end dates (month/year) for the demonstrable improvement data period. For example, if the QAPI project was initiated using HEDIS data in 2000, the data period may be Jan-Dec 2001, the intervention period may be Jan-Dec 2002, and the demonstrable improvement period may be Jan-Dec 2003.

2. Were there changes in the study between baseline and demonstrable improvement for the following?

[if so, select all that are applicable and describe each change and reason for it; must be completed before continuing to #3]

- No changes
- Quality indicator definition (Maximum 4000 characters)
- Data source(s) (Maximum 4000 characters)
- Data maturity (Maximum 4000 characters)
- Data collection methods (Maximum 4000 characters)
- Data analysis (Maximum 4000 characters)
- Sample size (Maximum 4000 characters)
- Target Population size (Maximum 4000 characters)
- Sampling methodology (Maximum 4000 characters)

Instructions: If there were changes in the study between the baseline measurement and re-measurement for demonstrable improvement (defined as "significant improvement sustained over time"), indicate the type of change and describe the change and the rationale for the change. If there were no changes, select "No changes" and continue to item #3, "Demonstrable improvement performance."

RELEVANT INFORMATION

2. Changes in the Study

To accurately measure demonstrable improvement (defined as significant improvement achieved over time), the study methodology for demonstrable improvement measurement should be the same as for the baseline measurement. The methods for identifying the eligible population and data samples should be the same for both studies. The M+CO should use the same sampling frame and methodology to obtain baseline and repeat measurements.

It is acceptable to change the numerator requirements for the quality indicator definition based on changes in clinical practice guidelines. However, it would not be acceptable, for example, to begin with a method in which an individual with multiple hospital admissions could be chosen more than once to be in the data sample and then to switch to a method in which the individual could be chosen only once.

If HEDIS measure specifications changed between the measurement years, then the M+CO **must** document the impact of the change on the results. The M+COs will not be held accountable for changes to HEDIS specifications; however, the impact on the study and results should be documented.

Changes other than study method that may impact study results include population/enrollment changes, geographic changes (add/drop counties), mergers and acquisitions, etc. Such changes, as well as the potential impact on the study and results, should be reported in detail.

3. Demonstrable improvement measurements/ performance

3.1 Demonstrable improvement numerator _____

Instructions: Enter the numerator for the quality indicator. Improvement for DI is evaluated against the baseline performance.

3.2 Demonstrable improvement denominator _____

Instructions: Enter the denominator for the quality indicator. This number may be different from the baseline denominator due to shifting demographics, enrollments, or sampling requirements. Improvement for DI is evaluated against the baseline performance

Review Element 7

3.3 Demonstrable (DI) improvement performance _____

Instructions: Enter the demonstrable improvement performance by dividing the numerator (3.1) by the denominator (3.2), then multiply by 100 to produce a percentage.

RELEVANT INFORMATION

3.3 Demonstrable Improvement

Demonstrable improvement is defined as “significant improvement achieved over time”. Significant does not imply statistical significance. The improvement in performance must be significant to the population being addressed.

Examples of Completed Demonstrable Improvement Results

Indicator: ACE Inhibitor Use:

3.1 Demonstrable Improvement numerator	2,278
3.2 Demonstrable Improvement denominator	3,817
3.3 Demonstrable Improvement (DI) performance	59.7%
3.4 Baseline performance	51.1%
3.5 Performance target	75%

Indicator: Call Abandonment Rate:

3.1 Demonstrable Improvement numerator	257
3.2 Demonstrable Improvement denominator	854
3.3 Demonstrable Improvement (DI) performance	30.1%
3.4 Baseline performance	40.0%
3.5 Performance target	20%

continued

Demonstrable Improvement for Multi-year Projects

If a project is a CMS-approved multi-year project, the M+CO must have established intermediate targets (i.e., measurable interim goals) for assessing improvement during the project period. The targets should be specified in a project work plan approved by CMS. The intermediate targets may relate to a process goal, rather than an outcome goal.

Multi-year projects must meet the following criteria:

- There must be a clear and defensible reason for defining a project as a multi-year project.
- The timetable for the project is reasonably related to the complexity of the project or the length of time that must elapse before the outcomes of the project can be assessed.
- There must be significant ongoing activity related to the project during each of the review years for which the project is to be counted. A project involving only a one-time system change that is expected to affect the final outcome goal will not necessarily be considered as an ongoing project during each of the intervening years. The project would be treated as an ongoing project only if the project provided for continuous data collection throughout the project period, and there were efforts to identify and implement system changes aimed at improving the long-term outcome.
- The project must specify some form of interim goals or intermediate outcomes for each project year, so that it is possible to track the continuing progress of the project. For example, an organization conducting a project on breast cancer survival rates may report a process-of-care indicator, such as mammography screening rates, or an intermediate outcome, such as the stage of breast cancer at detection, as in interim goal.

3.4 Baseline performance _____ [from Review Element 5, Item 2.3]

3.5 Performance target _____ [from Review Element 3, Item 7]

Review Element 1S: Subsequent or Modified Interventions Aimed at Achieving Sustained Improvement

All elements must be completed before the M+CO can submit Sustained Improvement.

If you have continued, added, or modified an existing intervention, the following information is REQUIRED FOR EACH INTERVENTION.

Select one of the following options:

- Added a new intervention [go to #1]
- Modified an existing intervention [go to #7]
- No additional interventions or changes to existing interventions [go to Review Element 2S]

→ **Instructions:** *If you are conducting a new intervention, select “Added a new intervention” and enter information into each field. Reporting on all interventions is encouraged and will assist reviewers in evaluating the intervention’s impact on the indicator.*

Additional interventions

1. Intervention type

[select ONE of the following new intervention types]

- Education: outreach visits, conferences/meetings, printed/on-line resources/materials, tools, other mass media campaigns and communication venues
- Reminder tracking systems
- Organizational changes: policy changes, quality improvement, structural redesign, or re-engineering
- Provider performance feedback
- Other community-level interventions
- Additional resources
- Other M+CO initiatives to improve performance [describe in "Intervention description"]

RELEVANT INFORMATION

1. Intervention Type

Examples of Types of Interventions

- **Educational materials and formal CME programs** include printed and on-line resources and materials, such as clinical guidelines and tools, immunization tracking logs, chart reminder stickers, posters, condition-specific articles, and guidelines for members written in easy-to-understand language. Formal CME programs including educational conferences that offer continuing education credits for providers frequently cover topics such as clinical practice guidelines for disease management, as well as quality improvement initiatives.
- **Reminders, tracking systems:** Provider reminder systems (i.e., concurrent feedback) include both manual and computer-assisted medical record or other essentially real-time, patient-related reminders.
- **Organizational change** (i.e., policy changes, quality improvement, structural redesign, or re-engineering) in a managed care environment (e.g., eliminating referrals for diabetic eye exams) is an example of an organizational policy change. Another would be revising administrative policies and procedures to expedite grievance processing.
- **Provider performance feedback** is similar to a retrospective audit with feedback. Provider performance on a particular indicator (e.g., the proportion of a provider's female patients who received a timely mammogram) is measured, and a report may display the results for each practice and for comparable practices (i.e., peers). Peer results are aggregated or blinded so that provider confidentiality is assured. These audits inform practitioners about their own practice. Feedback can be either retrospective (provided after the service) or concurrent (provided at the time of actual service). For example, physicians could receive reports on the proportion of their female patients who have received PAP smear screening for cervical cancer, when indicated by current clinical recommendations.
- **Other community-level interventions**, such as marketing, mass media campaigns, are similar to product advertisement. The media (e.g., television, radio, and printed material) can be used to promote a service to a wide population.

2. Target audience

[select all that apply; if "Other" selected, describe in "Intervention description"]

- Enrollees/Members
- M+CO staff: Clinical staff
- M+CO staff: Non-clinical staff
- Practitioners: Physician
- Practitioners: Nurse Practitioner
- Practitioners: Physician Assistant
- Practitioners: Pharmacist
- Practitioners: Other Providers
- Facility
- General public/community
- Other [describe in "Intervention description"]

RELEVANT INFORMATION

2. Target Audience

The target audience for an intervention is defined as the group for whom a behavior change is desired.

3. Intervention description

[provide a description of the intervention, including frequency]

Instructions: Provide a description of the intervention. This text box has a 4,000-character limit.

RELEVANT INFORMATION

3. Intervention Description

The intervention description should provide sufficient detail to justify that any observed improvement in the quality indicators could be reasonably attributed to the intervention(s) undertaken by the organization. The M+CO is not required to demonstrate conclusively (for example, through a controlled study) that the interventions caused the change in the quality indicator. Information describing the number of participants who were targeted and number who participated, frequency of interventions, mode of delivery, trainer qualifications, and setting of intervention assists the reviewers in determining if the intervention could reasonably be expected to affect the quality indicator.

continued

Modifications made to the interventions from the time period between the baseline measurement and the demonstrable improvement can be provided in this section (e.g., updates to clinical guidelines). The M+CO also may wish to include the rationale (i.e., feasibility, objectivity, and reliability) for the intervention in this section. This information may also be supplied in the optional "Barrier Analysis" (Review Element 5, Item #3).

Intervention content can be either provided verbally or in writing. It should be based on health education and/or psychology theories or models (e.g., PRECEDE framework on the predisposing, enabling, and reinforcing factors; Health Belief Model (H.B.M) on the forces which facilitate preventive behavior; and Transtheoretical Model on the five phases of behavior change). The messages need to be appropriate to the audience. Messengers/ Educators/Trainers should be educators, pharmacists, nurses, and physicians with background and/or experiences in public health education.

Settings can be hospitals, schools, physician offices, or homes depending on the number, the background of the audience and trainers, the nature of the contents of messages, and the equipment needed for the interventions

The number of participants and educators need to be specified and, if available, the percentage of participants over the targeted population to be educated

The frequency of interventions also needs to be specified, such as a quarterly report or annual review, rather than entering a separate intervention for each date for the same type of intervention.

4. Intervention initiation date: [MM/YYYY]

4.a Intervention timeframe: [select only one]

Ongoing

End Date

Enter end date [MM/YYYY]

Instructions: Enter the date on which the intervention was initiated and check the timeframe. If "End Date" is selected, enter the end date.

RELEVANT INFORMATION

4. Intervention Initiation Date

The M+CO must provide the date from which the intervention actually began (e.g., when the mailing was sent, conference was held, office visits first conducted, etc.) — **not** the date when planning began or when materials were printed —to the date that the intervention ended, unless the intervention is ongoing

5. Intervention partners

[select all that apply; if "Other" selected, describe in "Intervention description"]

- Enrollees/Members
- Practitioners: Physicians
- Practitioners: Nurse Practitioner
- Practitioners: Physician Assistant
- Practitioners: Pharmacists
- Practitioners: Other
- Facility
- Healthcare agencies
- Hospital associations
- Professional societies
- Consumers
- Community-based organizations
- Other M+COs
- QIO
- Other

Instructions: *If you worked with other organizations on the planning and implementation of the intervention, provide the types of partners.*

RELEVANT INFORMATION

5. Intervention Partners

Partners are individuals, groups, or organizations that work together to achieve one specific objective of the QAPI project with the help of shared decision-making, (e.g., sharing resources or developing materials or tools for enrollees' education). Partners are not defined the same as collaborators for QAPI projects. Collaborative projects are those in which two or more entities work together on all aspects of the QAPI project, from project design through measurement, interventions and re-measurement.

Examples of Intervention Partners

- Collaboration from Day One (CFDO) offers providers immediate involvement in the performance of QI studies by encouraging their participation from the start. Providers who commit from the start feel more obligated to follow through with promises of change. In addition, providers who are involved with the study questions and design often respond more openly to study conclusions that are less than favorable. Study groups can also serve as effective means to disseminate study results and assist with interventions.

continued

- Alliances with professional societies/opinion leaders involve the use of respected network providers and/or respected experts as champions to influence and gain provider commitment. Opinion leaders are people who occupy a central position in the communication network. Opinion leaders are able to influence individuals' attitudes and behavior in a desired way.

6. Additional information: Do you plan to mail in additional information on your interventions (i.e., binders, packets, tool kits)?

- Yes
 No

Instructions: *You may send in additional information to the reviewer, such as copies of mailings, surveys, educational materials, or other items that may assist the reviewer in understanding the interventions and efforts used to target the desired population. Send the information to your assigned M+CQRO. If "Yes" is selected, the contact name and address for the assigned M+CRO will appear on the screen*

You are not required to send in additional information. However, it can be helpful to the reviewers in evaluating whether the intervention could reasonably be expected to impact the indicator.

OTHER RELEVANT INFORMATION ON INTERVENTIONS

An intervention is defined as an activity or activities designed to change behavior. Effective interventions may be developed as a result of a barrier analysis. Factors can be identified through a cause-and-effect diagram or flow chart of a process.

Key Points

- Interventions should ideally be initiated in the first quarter after demonstrable improvement measurement.
- Interventions should address system-level problems that have been identified through analysis of plan performance.
- Interventions can be reasonably expected to affect the results.
- The M+CO does not have to identify interventions for each barrier in baseline assessment.

continued

Multiple Intervention Strategies

Research has shown that multiple strategies in trials had greater success. Studies targeted to behavioral change based on explicit need assessment had the highest likelihood of impact (i.e., 90% exhibited change).

Interventions should be conducted at a system level to address underlying problems rather than simply to improve the performance of a specific indicator or provider. Interventions that are unlikely to induce permanent change (e.g., a one-time reminder letter to physicians or beneficiaries) are insufficient. Again, multiple interventions aimed at an indicator are usually more effective.

Other effective intervention strategies include financial incentives for elimination of member co-payments for preventive services, positive financial incentives (e.g., bonuses) for providers who achieve higher rates of preventive services within their panel, or negative incentives (e.g., withholds) for those who do not meet an established criterion for preventive services.

Most Effective vs. Least Effective Intervention Strategies

Most Effective Interventions:

Physician reminders
Patient-mediated methods

Academic detailing
Opinion leaders
Audit with feedback
Multi-faceted

Least Effective Interventions:

Educational materials
Traditional CME without enabling or reinforcing strategies
Mailings
Mass media

MODIFIED INTERVENTIONS

For changes to an existing intervention, you will be prompted to select the intervention type. All the information that was entered for Review Element 6 will appear. Make the appropriate changes to the interventions previously entered and then select “MODIFY INTERVENTION”. Provide the date the intervention was initiated and check if ongoing or provide the date of completion. Use the field to describe the intervention and the rationale for the intervention. Reporting on all interventions is encouraged and will assist reviewers in understanding the work that you have done on your QAPI project. If “Other” is selected in any category, M+COs are expected to describe this in the “Intervention description.” Items 7-12 should be completed for each additional intervention.

7. Select the intervention that was modified from the list

[based on what was entered in Review Element 6, Item 1]

8. Target audience

[select all that apply to the modified intervention; if "Other" selected, describe in "Intervention description"]

- Enrollees/Members
- M+CO staff: Clinical staff
- M+CO staff: Non-clinical staff
- Practitioners: Physician
- Practitioners: Nurse Practitioner
- Practitioners: Physician Assistant
- Practitioners: Pharmacist
- Practitioners: Other Providers
- Facility
- General public/community
- Other [describe in "Intervention description"]

9. Intervention description

[provide a description of the modification to the intervention]

10. Intervention initiation date: [MM/YYYY]

10.a Intervention timeframe [select only one]

Ongoing

End Date

Enter end date [MM/YYYY]

Instructions: Enter the date on which the intervention was initiated and check the timeframe. If "End Date" is selected, enter the end date.

11. Intervention partners

[select all that apply to the modified intervention; if "Other" selected, describe in "Intervention description"]

- Enrollees/Members
- Practitioners: Physicians
- Practitioners: Nurse Practitioner
- Practitioners: Physician Assistant
- Practitioners: Pharmacists
- Practitioners: Other
- Facility
- Healthcare agencies
- Hospital associations
- Professional societies
- Consumers
- Community-based organizations
- Other M+COs
- QIO
- Other

12. Additional information: Do you plan to mail in additional information on your modified interventions (i.e., binders, packets, tool kits)?

Yes

No

Instructions: You may send in additional information to the reviewer, such as copies of mailings, surveys, educational materials, or other items that may assist the reviewer in understanding the interventions and efforts used to target the desired population. Send the information to your assigned M+CQRO. If "Yes" is selected, the contact name and address for the assigned M+CRO will appear on the screen

You are not required to send in additional information. However, it can be helpful to the reviewers in evaluating whether the intervention could reasonably be expected to impact the indicator.

Review Element 1S

RELEVANT INFORMATION ON INTERVENTIONS

8. through 11. (Target audience, Intervention description, Intervention initiation date, and Intervention partners)

Refer to Review Element 1S -Relevant Information for 2 through 5 and Other Relevant Information on Interventions.

Review Element 2S: Sustained Improvement

All elements must be completed before the M+CO can submit Sustained Improvement. Select a quality indicator from the list, based on indicators entered in Review Element 3.

1. Sustained Improvement data period

1a. Sustained Improvement Period Start date

MM YYYY

1b. Sustained Improvement Period End date

MM YYYY

Instructions: Enter the start and end dates (month/year) for the sustained improvement data collection period.

2. Were there changes in the study between baseline and sustained improvement for the following?

[if so, select and describe each change and the reason for it; this section must be completed before continuing]

- No changes
- Quality indicator definition (Maximum 4000 characters)
- Data source(s) (Maximum 4000 characters)
- Data maturity (Maximum 4000 characters)
- Data collection methods (Maximum 4000 characters)
- Data analysis (Maximum 4000 characters)
- Sample size (Maximum 4000 characters)
- Target Population Size (Maximum 4000 characters)
- Sampling methodology (Maximum 4000 characters)

Instructions: If there were changes in the reported indicator study between the demonstrable improvement measurement and the re-measurement for sustained improvement, indicate the type of change. Describe and explain the rationale for the change. If there were no changes, select "No changes" and continue to item #3, "Sustained improvement performance."

RELEVANT INFORMATION

2. Changes in the Study

The organization **must repeat** the measurement of the indicators one year after achieving demonstrable improvement to demonstrate that the achieved improvement has been sustained for at least 12 months.

To accurately measure improvement, the study methodology for sustained improvement measurement should be the same as the methodology for demonstrable improvement. The methods for identifying the target population and data samples should be the same for both measurements. The M+CO should use the same sampling frame and methodology to obtain baseline and repeat measurements.

It is acceptable to change the numerator requirements for the quality indicator definition based on changes in clinical practice guidelines. However, it would not be acceptable, for example, to begin with a method in which an individual with multiple hospital admissions could be chosen more than once to be in the data sample and then to switch to a method in which the individual could be chosen only once.

If HEDIS measure specifications changed between the measurement years, the M+CO **must** document the impact of change on the results. The M+CO will not be held accountable for changes in HEDIS specifications; however, the changes and impact on the study must be documented.

Changes other than study method that may impact study results include population/enrollment changes, geographic changes (add/drop counties), mergers and acquisitions, etc. Such changes, as well as the potential impact on the study and results, should be reported in detail.

Example of Reasons for Documented Indicator Study Changes

- Changes to the overall system can affect the re-measurement of an indicator such as an increase or decrease in the population.
- Addition of a new claims database that would improve the reliability and accuracy of data collection and sources of data.

These changes should be identified in this section as they affect the outcome of the project.

Note: If a project is reported as achieving improvement, and the M+CO does not undertake further system interventions under this project cycle, it will not be regarded as ongoing. The organization must carefully distinguish between active projects and concluded projects for which the repeat measurement(s) has not yet been achieved.

3. Sustained improvement measurement / performance

3.1 Sustained improvement numerator _____

3.2 Sustained improvement denominator _____

3.3 Sustained improvement performance _____

Instructions: Enter the sustained improvement numerator and denominator and enter the sustained improvement performance (the percentage derived from the numerator (3.1) divided by the denominator (3.2), then multiplied by 100. These numbers are likely to be different from the baseline and demonstrable improvement denominators due to shifting demographics, enrollments, or sampling requirements. Improvement for sustained improvement is evaluated against the baseline performance.

3.4 Demonstrable (DI) improvement performance _____

[from Review Element 7, Item 3.3]

3.5 Performance target _____ [from Review Element 3, Item 7]

RELEVANT INFORMATION

3. Sustained Improvement Performance Measurement

Examples of Completed Sustained Improvement Information

Indicator: ACE Inhibitor Use

3.1 Sustained Improvement numerator	2,465
3.2 Sustained Improvement denominator	4,254
3.3 Sustained improvement Performance	57.9%
3.5 Performance Target	75%

continued

Indicator: Call Abandonment Proportion

3.1 Sustained Improvement numerator	189
3.2 Sustained Improvement denominator	752
3.3 Sustained improvement Performance	25.1%
3.5 Performance Target	20%

Sustained Improvement for Multi-year Projects

If a project is a CMS-approved multi-year project, the M+CO must have established intermediate targets (i.e., measurable interim goals) for assessing improvement during the project period. The targets should be specified in a project work plan approved by CMS. Sustained improvement will be measured and evaluated one year after demonstrable improvement is achieved.

External Consultation and Lessons Learned

1. Did you seek Consultation and/or Technical Assistance from the Quality Improvement Organization (QIO) in your State?

- Yes
 No

RELEVANT INFORMATION

1. QIO Consultation and/or Technical Assistance

If the M+CO periodically seeks assistance from its QIO regarding a specific component of its QAPI project, this is considered to be consultation and/or technical assistance

Types of consultation and/or technical assistance from the QIO might include any of the following:

- Medical record abstraction
- Abstractor training
- Data collection & analysis
- Data & process validation
- Statewide comparisons/benchmarking
- Design & development of interventions (graphics & printing)
- Dissemination of intervention materials (mailings)
- QAPI Project Completion Report format
- Study development
- CQI training

1a. Indicate QIO involvement on this QAPI Project: [select all that apply]

- Performance Improvement Project Review
- Study Design Development
- Liaison with CMS, specific to QISMC
- Continuous Quality Improvement (CQI) Training
- Data Analysis
- Development, Testing, and Training on Electronic and/or Paper Abstraction Tools
- Design & Development of Intervention Materials (graphic design and printing)
- Dissemination of Intervention Materials
(mailing to all physicians and/or beneficiaries)
- Facilitation of Group Collaborative Projects (focus group, provider meetings)
- Brief Consultation
- Collaborative Project
- Other

Items 2 – 5 are optional.

2. Lessons learned: [maximum 4000 characters]

Instructions: Provide only new information if different from that reported for demonstrable improvement and/or recap pertinent information from the whole project.

RELEVANT INFORMATION

2. Lessons Learned

In addition to providing information relative to the M+CO's experience with the second half of this report (reporting on new or modified interventions and sustained improvement), the M+CO may also want to re-cap or acknowledge pertinent information relative to the first half of its project (up to and including its measurement for demonstrable improvement). This would give the reviewer a more comprehensive understanding of the full scope of the M+CO's experiences on this project.

"Lessons learned" applies to an overall assessment of the project, including strengths and weaknesses, breakthroughs, and room for further improvement.

For example:

- The addresses of the population were not current. Survey methodology will require modification for future surveys to include use of postal address verification/forwarding service.
- Needed to link the disease management program with the physician health service corporate initiative, so that lab data would be collected from consistent documentation tools.

External Consultation and Lessons Learned

3. Barriers encountered/limitations for the project [maximum 4000 characters]

RELEVANT INFORMATION

3. Barriers

Barriers refer to any special challenges or problems that arose. It also applies to obstacles and if they were overcome. This analysis may point to the need for further improvement.

For example:

- New providers added to plan after educational series—need to incorporate guidelines/education into provider training.
- New pharmacy benefit added in the middle of the study.
- Physician offices do not have information systems to track or identify members for educational opportunities.
- Limited staff to analyze surveys.
- Had to run three claims requests to get one accurate claim for each patient.

4. System-Level changes made and/or planned [maximum 4000 characters]

Instructions: *If you initiated or planned any other system-level changes related to the project topic, after those listed in Subsequent or Modified Interventions, use the text field to describe the additional interventions. You may also want to re-cap any earlier changes that are pertinent.*

RELEVANT INFORMATION

4. System-level Changes

Examples of System-Level Changes

- Administrative approval for the hiring and training of support staff to assist in analysis
- Evaluation of physician office information systems to assist in data collection, development of reminder tools to encourage physician to implement ACE Inhibitor use
- Development of new enrollee survey using CAHPS methodology from HEDIS
- Use of administrative and medical record data to analyze performance of specific providers
- Education series on CPT codes for office staff

5. Did you seek consultation and/or technical assistance from another organization, outside of your QIO?

- Yes
 No

5a. Identify the organization

5b. External consultation/technical assistance from another organization

[select all that apply]

- Performance Improvement Project Review
- Study Design Development
- Liaison with CMS, specific to QISMC
- Continuous Quality Improvement (CQI) Training
- Data Analysis
- Development, Testing, and Training on Electronic and/or Paper Abstraction Tools
- Design & Development of Intervention Materials (graphic design and printing)
- Dissemination of Intervention Materials (mailing to all physicians and/or beneficiaries)
- Facilitation of Group Collaborative Projects (focus group, provider meetings)
- Other

→ **Instructions:** Identify and describe external consultation and technical assistance from the other organization. Select all that apply. Be sure to indicate the type of external consultation and/or technical assistance obtained.

External Consultation and Lessons Learned

RELEVANT INFORMATION

5b. External Consultation and/or Technical Assistance from Another Organization

If the M+CO periodically seeks assistance from another organization regarding a specific component of its QAPI project, this is considered to be consultation and/or technical assistance.

Types of consultation and/or technical assistance from another organization might include any of the following:

- Medical record abstraction
- Abstractor training
- Data collection & analysis
- Data & process validation
- Statewide comparisons/benchmarking
- Design & development of interventions (graphics & printing)
- Dissemination of intervention materials (mailings)
- QAPI Project Completion Report format
- Study development
- CQI training.

Glossary of Terms

accuracy: The closeness of a computed, estimated, or measured value to the exact or "true" value. For example, if an individual is weighed three different times, the closeness of the three weights to the individual's real weight is the degree of accuracy in the weight measurements.

barrier analysis: The identification of the underlying factors, issues, conditions, or situations that contribute to a resistance to change for a specified topic.

baseline data measurement: The initial data gathering and assessment process that takes place before interventions are instituted. Results are compared with data collected after full intervention implementation to determine whether the interventions have been effective.

collaboration: The M+CO mutually shares and works together with other plans, physician groups or community organizations to achieve common goals of QAPI. For example: The QIO and the M+CO jointly conduct a comprehensive QAPI project, working together on all of the following:

- Developing quality indicators
- Collecting the baseline data
- Designing and implementing interventions
- Re-measuring for demonstrable improvement
- Implementing subsequent or modified interventions
- Re-measuring 1 year for sustained improvement

consultation/technical assistance: The M+CO periodically seeks assistance from its QIO or another organization regarding a specific component of its QAPI project. This is considered to be consultation and/or technical assistance and not a standard type of comprehensive collaborative project. Technical assistance might include medical record abstraction, abstractor training, data collection and analysis, data and process validation, statewide comparisons/benchmarking, design and development of interventions (graphics and printing), dissemination of intervention materials (mailings), QAPI Project Completion report format, study design development, and CQI training.

continuity and coordination of care: The manner in which care is provided when a patient receives care from multiple providers and across multiple episodes of care.

demonstrable improvement: A significant improvement in a quality indicator over time. Significant in this context does not imply statistical significance. Also, the second data assessment point for a QAPI project.

denominator: Mathematically, the number below the horizontal line in a fraction, denoting into how many equal parts the unit is divided. In a quality improvement activity, the denominator represents the set from which the numerator, a sub-set, is derived.

Glossary of Terms

descriptive statistics: Statistics that are used to describe and summarize numerical data that do not involve generalizations to a larger set of data. Quantitative data assessments generally require descriptive statistics, which include measures of central tendency (i.e., mean, median, or mode) and measures of variability (i.e., range or standard deviation).

initiation of a performance improvement project: For purposes of this report, initiation occurs when a project has progressed to the point of active collection of baseline data.

M+CO-selected performance target: The desired level of achievement that the organization sets for itself as its targeted standard of care.

median: The middle score of a set of scores.

mean: The arithmetic average of a set of scores.

mode: The most frequently occurring score in a set of scores.

numerator: Mathematically, this is the number above the horizontal line in a fraction, denoting the number of fractional parts taken. In a quality improvement activity the numerator represents the subset of the denominator for which results being studied were achieved.

partners: Are individuals groups or organizations that work together to achieve one specific objective of a QAPI project with the help of shared decision-making (e.g., sharing resources or developing materials or tools for enrollee's education).

power analysis: A statistical procedure for:

- 1) Determining the required sample size needed for adequate sensitivity or precision; and
- 2) Estimating the likelihood of committing a Type II error.

One can increase statistical power (precision, sensitivity) by increasing the size of the effect (a stronger treatment), reducing variability (moving from the field to the laboratory or using more reliable tests), or reducing the standard error (increasing sample size).

primary prevention: Preventing a disease, condition or injury by intervening before that disease, condition or injury can occur (e.g., immunizations and the use of seat belts).

project: An initiative by an organization to measure its own performance in one or more focus areas, undertake system interventions to improve its performance, and follow up on the effectiveness of those interventions.

proxy measure: A substitute or surrogate measure for an outcome which may be resistant to direct or timely measure (e.g., immunization rate as a proxy for rate of

disease and ACE inhibitor prescription rate for members with CHF as a proxy for wellness).

p-value: A statistic that expresses the degree to which a finding is probably related to chance. Its calculation is dependent on the number of subjects.

qualitative analysis: The systematic summation and interpretation of non-numeric data to reveal meaning and patterns of relationships.

quality indicator: A clearly defined and objectively measurable aspect of care or service that is expressed as a rate or ratio built from a numerator and denominator. Quality indicator measures compared over time indicate whether changes are leading to improvements (e.g., beta-blocker use following acute myocardial infarction, ACE inhibitor prescription in members with congestive heart failure, and immunizations).

quantitative analysis: The systematic statistical manipulation and analysis of numerical data to describe phenomena or the numerical relationships among them.

random: Unbiased, that is, having no pattern or differing likelihood structure.

random sample: A sample obtained by chance through random assignment procedures. Simple random sampling requires that each unit of the population has an equal chance of being selected.

reliability: The extent of a measure's consistency, repeatability, and reproducibility.

secondary prevention: Interventions used during an illness, condition or disease to prevent complications or recurrence of that illness, condition or disease (e.g., use of peak flow meter to aid in chronic asthma care or mammography to prevent serious complications of breast cancer).

standard deviation: A measure of the variability that indicates, approximately, the average variation from the mean value for all values in the data set; technically, the square root of the variance.

statistical significance: The probabilistic determination that the results obtained in the analysis of the data from the sample are unlikely to be due to chance according to the preset level of risk

stratified random sample: A procedure through which a random sample is selected in proportion to each independent stratum or subgroup in the population. The subgroups represent characteristics important to the study.

sustained improvement: A significant improvement in a quality indicator maintained over time and at least one year after demonstrable improvement is achieved. Significant in this context does not imply statistical significance. Also, the third data assessment point for a QAPI project.

Glossary of Terms

target audience: The group for whom a behavioral change is desired (e.g., a physician or physician group targeted to change the manner of prescribing beta-blockers for Medicare members with myocardial infarction).

target population: The clearly defined and objectively measurable population of the eligible Medicare membership to be affected by the quality indicator. For example, for beta-blocker prescription after myocardial infarction, the target population consists of all eligible Medicare members continuously enrolled and having an acute myocardial infarction during the dates of the study).

tertiary prevention: Processes and procedures employed when an illness has already caused disability, but the disability can be reduced or somewhat prevented from worsening (e.g., early treatment and rehabilitation of stroke victims).

Type I error: The error of indicating that a relationship exists between variables when it does not.

Type II error: The error of indicating that a relationship does not exist between variables when it does.

validity: The extent to which something measures what it is intended to measure. The validity of a study is a composite of:

1. The extent to which the data collected for the study accurately measure the characteristic or property they are intended to measure (internal validity), and
2. How sound and justifiable are the inferences made from study data (external validity).