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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
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Red italicized font identifies new material.

CLARIFICATION - EFFECTIVE DATE: Not Applicable.

Table of Contents - is revised to change the section titles for sections 30, 30.1.2, 30.2, 30.2.1, .30.2.1.1, 30.2.1.2, 30.3, 30.3.1, 30.3.2, 30.3.3, and 35.4.2.

Section 30 - Quality Assessment and Performance Improvement (QAPI) Projects - is revised to include text regarding requirements for M+C organizations to conduct 1 QAPI project per year. Beginning year 2003 M+C organizations are required to initiate 1 QAPI project per year. The sentence allowing M+C organizations discretion to select projects has been eliminated. Also, in this revision, the acronym "QAPI" has been added throughout the chapter to clarify projects discussed that are QAPI projects.

Section 30.1.1 - General is revised to include text regarding CMS's criteria in selecting QAPI projects. Also, the first bulleted paragraph was added regarding an M+C organization's responsibility to initiate QAPI projects in the years 2003 and 2004, and a fifth bulleted paragraph was added regarding an M+C organization's responsibility to consider a local marketplace initiative. A local marketplace initiative is defined as a

project in which any of several specified organizations facilitate, initiate, request, or approve elements of the initiative in a local area.

Section 30.1.2 - Quality Assessment and Performance Improvement Projects - has had its name changed from "Performance Improvement Projects" and to specify projects to be conducted in years 2003 and 2004. The paragraph regarding the requirement for the M+C organization to initiate a national project before the end of the second contract year has been deleted. A chart has been added to this section to show data to be used for measuring improvement and time frames for reporting of M+C organization QAPI Projects. In addition, "Quality Assurance" had been changed to "Quality Assessment" throughout.

Section 30.1.3 - Phase-In Requirements - Several paragraphs are added to clarify the 2-year phase-in period in which QAPI projects are required to show significant and sustained improvement for M+C organizations which contract with Medicare only. For those that contract with Medicare and Medicaid, the organization must initiate the second QAPI project by the end of the second contract year, and also must conduct other projects required by their state. Baseline years for data collection for any QAPI project have been updated in the last paragraph to reflect that a 2002 QAPI project may include baseline data from year 2001 or 2002.

Section 30.1.4 - Ongoing Requirements (QISMC Document Standard 1.3.3) - is revised to clarified requirements regarding QAPI projects for organizations that contract with Medicare only, and for those that contract with Medicare and Medicaid to clarify that at least one of the QAPI projects must have achieved significant and sustained improvement. We have added a fifth requirement to the second paragraph regarding CMS national project requirements to specify that the organization must use CMS specified indicators.

Section 30.1.5 - Focus Areas - Spelling correction.

Section 30.1.5.1 - Clinical Focus Area - Clinical Focus Areas Applicable to All Enrollees (QISMC Document Standard 1.3.4) - Miscellaneous word changes.

Section 30.1.5.2 - Non-Clinical Focus Areas - Non-Clinical Focus Areas Applicable to All Enrollees (QISMC Document Standard 1.3.5) - Miscellaneous word changes.

Section 30.2 - Attributes of Quality Assessment and Performance Improvement (QAPI) Projects) - (QISMC Document Standard 1.4) - Added the acronym "QAPI" in several places.

Section 30.2.1 - Selection of Topics for M+C Selected Projects and Local Marketplace Initiatives - The title was changed to indicate this section covers topics which are chosen by the M+C organization.

Section 30.2.1.1 - Sources of Information - is created as a separate section out of a previously unnumbered subsection. No text was changed.

Section 30.2.1.2 - M+C Organizations Using Physician Incentive Plans - is created as a separate section out of a previously unnumbered subsection. No text was changed. Also M+C was added to the section title.

Section 30.2.2 - Quality Indicators - is revised to delete the last sentence of the first subsection regarding the availability of data external to the M+C organization, and added "M+C" in two places for clarification.

Section 30.2.3 - Significant, Sustained Improvements - is revised to include local marketplace initiatives, and miscellaneous word changes were made.

Section 30.2.4 - Sustained Improvement Over Time - is revised to refer the reader to "Chart: Timeframes for Reporting M+C Organization QAPI Projects" in section 30.1.2, and miscellaneous word changes were made.

Section 30.3 - Types of QAPI Projects - is revised to clarify that an M+C organization is required to initiate a QAPI project, not complete one per year.

Section 30.3.1 - National QAPI Projects - Miscellaneous word changes.

Section 30.3.2 - M+C Organization Selected QAPI projects - is revised to clarify that M+C organizations that contract only with Medicare must conduct only one QAPI project each year, the M+C organization selected project eliminated beginning year 2002. Local collaborative projects are also subject to manual and QISMC document standards.

Section 30.3.3 - Other QAPI Projects - is revised to change the unnumbered subsection "Collaborative Projects" to "Local Marketplace Initiative QAPI Projects" and other wording to reflect this change in the name. A new unnumbered section "Alternative Option" was inserted regarding Year 2004 QAPI project options - an M+C organization may select the National Diabetes QAPI project, or a local marketplace initiative. This new section describes local marketplace initiative requirements. Also miscellaneous spelling changes were made to the entire section.

Section 30.3.4 - **Process for CMS Multi-Year QAPI Project Approvals -** Miscellaneous word changes.

Section 30.4 - Evaluation of QAPI Projects - is revised for miscellaneous word changes, and a reference to the Chart in section 30.1.2 in the unnumbered section "When to Report". Under the unnumbered subsection "Reporting Timelines", corrected the numbering in the explanation of flowcharts and miscellaneous word changes in all sections.

Section 35.1 - Terminology - Miscellaneous word changes.

Section 35.2 - Deeming Requirements - is revised to delete the reference to a web page for deeming requirements.

Section 35.3 - General Rule - Miscellaneous word changes.

Section 35.4 - Obligations of Deemed M+C Organizations - Added a chart demonstrating the process an M+C organization must follow to initiate deemed status, followed by an explanation of the chart, and miscellaneous word changes.

Section 35.4.1 - Deemed Status and CMS Surveys - Miscellaneous word changes.

Section 35.4.2 - Removal of an M+C Organization's Deemed Status - Miscellaneous word changes.

Section 35.5 - CMS's Role - Miscellaneous word changes

Section 35.5.1 - Oversight of Accrediting Organizations - Miscellaneous word changes.

Section 35.6 - Obligations of Accrediting Organizations with Deeming Authority - Miscellaneous punctuation corrections.

Section 35.6.1 - Application Requirements - is revised to delete second sentence regarding CMS requirement for accrediting organization to seek deeming authority in all 6 areas, and miscellaneous word changes.

Section 35.6.4 - Reporting Requirements - Miscellaneous word changes.

Section 35.7 - Reconsideration of Application Denials, Removal of Approval of Deeming Authority, or Non-Renewals of Deeming Authority - Miscellaneous punctuation corrections, and of section number.

Section 35.7.1 - Informal Hearing Procedures - Miscellaneous spelling correction.

Section 35.7.2 - Informal Hearing Findings - Miscellaneous word changes.

Section 35.7.3 - Final Reconsideration Determinations - Miscellaneous punctuation correction.

Section 40.1 - Background - Miscellaneous word changes.

Section 40.2 - **Specifics Applicable to Consumer Assessment of Health Plans Study (CAHPS) ®and Health Plan Employer Data and Information Set (HEDIS)® -** Miscellaneous word changes.

Section 40.3 - **HEDIS Submission Requirements -** Miscellaneous language changes.

Section 40.4 - The Medicare Health Outcomes Survey (HOS) Requirements - Miscellaneous word changes.

Section 40.5 - Medicare CAHPS Requirements for Enrollees and Disenrollees - Miscellaneous word changes.

Medicare Managed Care Manual

Chapter 5 - Quality Assessment

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30 - Quality Assessment and Performance Improvement *(QAPI)* Projects - (Rev. 10, 08-14-02)

These standards direct an M+C organization to operate an internal program of quality assessment and performance improvement that achieves significant improvements sustained over time in enrollee health, functional status and satisfaction across a broad spectrum of care and services. *As a part of the internal program of quality assessment and performance improvement M+C organizations are required to conduct QAPI projects. The Quality Improvement System for Managed Care (QISMC) requirement for an M+C organization selected QAPI project was eliminated effective 2002 and no M+C organization selected QAPI project is required for that year. Effective 2003, M+C organizations are required to initiate one QAPI project per year.*

The M+C organization must collect and report data reflecting performance on standardized measures of health outcomes and enrollee satisfaction as appropriate, and meet such minimum performance levels on these measures as may be established under its contract with CMS or states. The M+C organization must also demonstrate compliance with basic requirements for administrative structures and processes that promote quality of care and beneficiary protection.

30.1 - Basic Requirements - (Rev. 10, 08-14-02)

30.1.1 - General - (Rev. 10, 08-14-02)

CMS will seek to:

- *Select QAPI national project topics based on the following factors to the degree possible:*
    - *Align managed care quality efforts with fee-for-service quality activities in order to improve health care outcomes for beneficiaries and reduce provider burden;*
    - *Select QAPI national projects based on Health Plan Employer Data and Information Set (HEDIS®) measures for consistency with private purchasing efforts;*
    - *Ensure relevance to both the Medicare and Medicaid populations;*
    - *Maximize Quality Improvement Organization (QIO) resources by selecting a QAPI national project consistent with current QIO clinical priority areas, and*

The M+C organization must:

- *Initiate one QAPI Project per year, beginning in 2003. For 2003, M+C organizations will do the national CMS QAPI project, CLAS/CHCD (see the national 2003 CLAS/CHCD QAPI project requirements in the Chapter 5 Exhibits). Beginning in 2004, M+C organizations will have the option of the national CMS Diabetes QAPI project or a local marketplace initiative;*

- Achieve required minimum performance levels, as established by CMS (for Medicare) or, for M+C organization*s* which also hold Medicaid contracts, by the State Medicaid *A*gency (for Medicaid), on standardized quality measures (QISMC document standard 1.1.1);

- Conduct *QAPI projects* that achieve, through ongoing measurement and intervention, demonstrable improvement defined as "significant improvement sustained over time" in aspects of clinical care and non-clinical services that can be expected to have a beneficial effect on health outcomes and enrollee satisfaction (QISMC document standard 1.1.2); and

- Correct significant systemic problems that come to its attention through internal surveillance, complaints, or other mechanisms (QISMC document standard 1.1.3). The basic requirements for this domain establish three distinct, but related, strategies for promoting high quality health care in M+C organizations serving Medicare and Medicaid enrollees. First, each managed care organization must meet certain required levels of performance when providing specific health care and related services to enrollees. These required levels of performance may be established by CMS (for Medicare) or the State Medicaid agency (for Medicaid). The minimum performance level would be established by examining historical performance levels, as well as benchmarks (best practices), of managed care organizations and other delivery systems with respect to the population being measured, but does not include a requirement for statistical significance.

- *Consider the potential for a local marketplace initiative project. A local marketplace initiative project is one in which any of several organizations (QIO, Medicaid Agency, a state government agency or a private purchaser) facilitate, initiate, request or approve in a local area. M+C organizations are not prohibited from the roles of facilitator, initiator or requestor as long as one or more of the other organizations carries out these roles. The QIO 7th Scope of Work focuses on this type of collaboration (see section 30.3.3).*

NOTE: As of 2001, CMS has yet to establish or require minimum performance levels. However, CMS has established Congestive Heart Failure (CHF) indicators for risk adjusted extra payments. Those requirements can be found on the CMS web site, http://www.cms.hhs.gov/, in OPL 2000.129 and in Chapter 7, Payment.

Second, managed care organizations must conduct *QAPI* projects that are outcome-oriented and that achieve significant improvement sustained over time in care and services. The standards expect that an organization will continuously monitor its own performance on a variety of dimensions of care and services for enrollees, identify its own areas for potential improvement, carry out individual projects to undertake system interventions to improve care, and monitor the effectiveness of those interventions.

Third, the organization must take timely action to correct significant systemic problems that come to its attention through internal surveillance, complaints, or other mechanisms. For instance, if an external quality review organization discovers a systemic problem

pertaining to an aspect of care delivery as a result of performing an analysis of quality of care on a different aspect of health care, the organization is expected to address the problem promptly.

30.1.2 - *Quality Assessment and* Performance Improvement Projects - (Rev. 10, 08-14-02)

*Quality assurance and p*erformance improvement *(QAPI)* projects are projects conducted under the organization's QAPI program that achieve demonstrable improvement in major focus areas of clinical care and non-clinical services (QISMC document standard 1.3). Demonstrable improvement is defined for QAPI projects as significant improvement sustained over time. Significant does not mean statistically significant, but rather that improvement is shown.

Definition: A *QAPI* project is an initiative by the organization to measure its own performance in one or more of the focus areas described in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3, undertake system interventions to improve its performance, and follow-up on the effectiveness of those interventions. (QISMC document standard 1.3.1.1)

Assessment of the effectiveness of an organization's QAPI program will include review of individual *QAPI* projects. In the first two years, review will focus on whether an organization has initiated *a QAPI* project. In all subsequent years, reviews will focus on whether or not projects have achieved significant, sustained improvement in quality indicators. For each project, the organization will be required to supply documentation sufficient to assess the extent to which the project has met all relevant standards.

*QAPI p*roject topics and the quality indicators used to assess each project are chosen either by the organization itself *(see section 30.3.3)*, by CMS (for Medicare) or by the State Medicaid *A*gency (for M+C organizations contracting with Medicaid) either for an individual organization or on a national or *s*tatewide basis. (QISMC document standard 1.3.1.2.)

The organization will be required to conduct *the national CMS QAPI* project *or, beginning in 2004, either the national CMS QAPI project or a local collaborative marketplace initiative, and* if the M+C organization has a contract for Medicaid, *any projects which are required* by the State Medicaid *A*gency.

A *QAPI* project will be considered to have achieved significant improvement in a focus area during any project year in which an improvement meeting the minimum thresholds of this manual is attained. The use of the term "significant improvement" does not mean that "statistically significant" improvement is required.

It is not expected that a *QAPI* project initiated in a given year will necessarily achieve improvement in that same year. For example, a project focusing on improving health outcomes for patients with a given condition might continue for several years before it would be possible to measure the effect of the organization's interventions. Such a project

would not be counted as achieving improvement until the year in which the improvement is demonstrated. (An exception for certain multi-year projects is provided under the QISMC document standard 1.3.7.2.)

The first *QAPI* project year begins on a date established by CMS (for Medicare). (QISMC document standard 1.3.1.4)

The following chart illustrates elements of the QAPI reporting cycles for the years 1999 through 2004. The elements include the year for collection of baseline data, the year that interventions would normally be conducted, and the data to be used for measurement of significant improvement and sustained remeasurement.

Timeframes for Reporting M+C Organization QAPI Projects

						2004 National or Local Project	***----------→***
					2003 National Project	***----------→***	
				2002 National Project (baseline limited to 1 year)			
			2001 National and M+CO Initiated Projects	***----------→***			
		2000 National and M+CO-Initiated Projects	***-------→***				
	1999 National and M+CO-Initiated QAPI Projects---→	***----------→***					
Baseline	*1998 data* *HEDIS 1999 Reporting/ CAHPS*	*1999 data* *HEDIS 2000 Reporting /CAHPS*	*2000 data* *HEDIS 2001 Reporting /CAHPS*	*2001 data* *HEDIS 2002 Reporting /CAHPS*	*2002 data* *HEDIS 2003 Reporting /CAHPS*	*2003 data* *HEDIS 2004 Reporting /CAHPS*	*2004 data* *HEDIS 2005 Reporting /CAHPS*
Interventions	*1999*	*2000*	*2001*	*2002*	*2003*	*2004*	*2005*
"Significant Improvement" Measurement	*2000 data* *HEDIS/CAHPS 2001 (10/01/01)**	*2001 data* *HEDIS/CAHPS 2002 (10/01/02)**	*2002 data* *HEDIS/CAHPS 2003 (10/01/03)**	*2003 data* *HEDIS/CAHPS 2004 (10/01/04)**	*2004 data* *HEDIS/CAHPS 2005 (10/01/05)**	*2005 data* *HEDIS/CAHPS 2006 (10/01/06)**	*2006 data* *HEDIS/CAHPS 2007 (10/01/07)**
Sustained Remeasurement	*2001 data* *HEDIS/CAHPS 2002*	*2002 data* *HEDIS/CAHPS 2003*	*2003 data* *HEDIS/CAHPS 2004*	*2004 data* *HEDIS/CAHPS 2005*	*2005 data* *HEDIS/CAHPS 2006*	*2006 data* *HEDIS/CAHPS 2007*	*2007 data* *HEDIS/CAHPS 2008*

	*(10/01/02)**	*(10/01/03)**	*(10/01/04)**	*(10/01/05)**	*(10/01/06)**	*(10/01/07)**	*(10/01/08)**

*This table is used to illustrate a QAPI reporting cycle that is based on timeframes established by CMS for the reporting of HEDIS Measures and CAHPS, as well other standardized measures used by CMS for the National QAPI projects. The * denotes an expected 90-day submission date based on audited HEDIS result notification that occur in July of every year.*

30.1.3 - Phase-in Requirements - (Rev. 10, 08-14-02)

Phase-in requirements for an organization contracting with Medicare *only* (QISMC document standard 1.3.2.1*)*

An organization has a 2-year phase-in period during which QAPI projects are not required to achieve significant and sustained improvement assuming a 3-year project cycle. (QISMC document standard 1.3.2)

This extended time frame allows new M+C organizations to enroll beneficiaries and accumulate data prior to the initiation of a QAPI project. This time frame is also similar to HEDIS requirements.

All subsequent QAPI project years begin on the anniversary of the beginning of the first project year. QAPI project years are independent of the CMS review cycle and there may be instances where an M+C organization completes a QAPI project after the end of a project year, but before the CMS review for that year is conducted. Upon request by the M+C organization, the QAPI project may be included in the review for the preceding year if all necessary documentation is available for the CMS review.

Effective in 2002, each newly contracting M+C organization is expected to initiate the yearly CMS national QAPI projects (see Chapter 5 §30.3.1 and Appendix A) before the end of the second contract year and in each subsequent year. For example, organization A signs a contract with CMS on January 1, 2002, and organization B signs a contract August 1, 2002. For both organizations, the second contract year will be 2003, initiation of a QAPI project is not required in year 2002, the first year of the contract.

Beginning in 2004, M+C organizations may either initiate the CMS national QAPI project each year or elect to participate in a local marketplace initiative (Chapter 5 §30.3.3)

Phase-in requirements for an organization contracting with both Medicare and Medicaid (QISMC document standard 1.3.2.2)

For those M+C organizations that contract with Medicare and Medicaid, by the end of the second contract year and thereafter, the organization must initiate the required CMS national QAPI projects. This does not exempt the organization from conducting other projects as required by their state.

A *QAPI* project is considered to have been initiated when it has proceeded to the point of baseline data collection. That is, the organization has selected a particular aspect of care for study, has identified the statistical indicator or indicators that will be used, and has begun the process of collecting the data needed for an initial assessment of its performance on the indicator(s). Data for the baseline must be either in the first year of the project or from one year before. For example, in implementation of a 200*2* QAPI Project, the baseline data collected may be from either year 200*1* or 200*2*. Review for the

first year will focus on compliance with the QISMC document standards 1.4.1 through 1.4.3.

30.1.4 - Ongoing Requirements (QISMC Document Standard 1.3.3) - (Rev. 10, 08-14-02)

Requirement for an Organization Contracting With Medicare But Not Medicaid (QISMC Document Standard 1.3.3.1)

By the end of the fourth contract year (this *is* the second year after the 2-year phase-in period), and each subsequent year, at least *one* of the *M+C* organization's *CMS national QAPI* projects have achieved significant and sustained improvement in the topic and quality indicators *identified* by CMS. (QISMC document standard 1.3.3.1).

Requirement for an Organization Contracting With Both Medicare and Medicaid (QISMC Document Standard 1.3.3.2)

By the end of the fourth contract year (the second year after the 2-year phase-in period), and each subsequent year, at least *one* of the M+C organization's *CMS national QAPI* projects have achieved significant and sustained improvement in the topic and quality indicators *identified* by CMS. The *M+C organization must meet the requirements for other* projects *required by their S*tate Medicaid *A*gency

The purpose of the CMS national performance improvement projects is to improve the quality of care and services provided to beneficiaries. After the phase-in (start up) period described in the QISMC document standard 1.3.2.2, each plan that contracts with Medicare (but not Medicaid) must demonstrate every 12 months (beginning in the third project year) that it has significantly improved care or beneficiary health outcomes in *the* specified *national QAPI project* area and that it has sustained the improvement over time. For an organization contracting with both Medicare and Medicaid, this requirement is not doubled - such an organization must show that it has achieved significant and sustained improvement in the specified focus areas (again, in any combination of clinical and non-clinical areas) every 12 months.

Requirements for All Organizations (QISMC Document Standard 1.3.3.3)

For Medicare, managed care organizations may use an existing on-going project for its required annual QAPI project if that existing project meets the requirements of this Manual and the QISMC document standards. The MCO must, however, conduct a remeasurement o*f* the relevant quality indicators during this initiation year to establish a new baseline against which significant and sustained improvement may be determined at the end of a 3-year project period.

M+C organizations which have satisfactorily completed a state Medicaid project and met the State's requirement for improvement or have conducted a project that meets the requirements for improvement of a private accreditation organization granted deeming

authority by CMS, may use those projects as *the CMS national* QAPI projects if the following requirements are met:

1. Medicare enrollees are included in the sample;

2. The project is relevant to the Medicare population;

3. The project was completed or reviewed during the project period;

4. The M+C organization provides CMS with a report (analysis) from the State Medicaid agency or accrediting organization that verifies the satisfactory completion of the QAPI project, and

5. *The M+C organization must use CMS specified indicators.*

A M+C organization should contact its CMS RO representative regarding the process for reporting a project so credit may be afforded for monitoring purposes, and for technical assistance regarding the conduct of a QAPI project.

30.1.5 - Focus Areas - (Rev. 10, 08-14-02)

M+C organizations should initiate *QAPI* projects that achieve significant and sustained improvement in all of the focus areas specified in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3.

Although it is not possible for any *M+C* organization to measure all aspects of health care provided to every beneficiary, it is possible for it to measure diverse aspects of care, and care provided to diverse populations of enrollees. By undertaking a variety of quality improvement projects, an organization can improve the quality of care provided to the greatest number of its enrollees and to those enrollees who, while perhaps not great in number, are those in greatest need; e.g., vulnerable populations such as the mentally ill, or beneficiaries with chronic health conditions. For this reason, the managed care organization must ensure that the chosen topic areas for quality improvement projects are not limited to only recurring, easily measured subsets of the health care needs of its enrolled population; e.g., primary preventive care of adults, high cost care of adults.

Quality improvement projects must focus both on mental and physical conditions and on all clinical and non-clinical areas addressed in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3. The M+C organization is not required to complete QAPI projects in all areas before repeating an area. Focus areas may be repeated to address priority areas of clinical concern, health care delivery system issues and issues in member services. However, the M+C organization must address all focus areas over time.

30.1.5.1 - Clinical Focus Area - Clinical Focus Areas Applicable to All Enrollees (QISMC Document Standard 1.3.4) - (Rev. 10, 08-14-02)

The QISMC document standard 1.3.1.2 allows CMS (for Medicare) and State Medicaid *A*gencies (for Medicaid) to specify project topics and quality indicators to be used by a

particular plan, if CMS or a *s*tate determines that the managed care organization has not achieved sufficient diversity in its quality improvement projects, such that important populations or health care services are not receiving sufficient attention within the managed care organization.

- Primary, secondary, and/or tertiary prevention of acute conditions (QISMC document standard 1.3.4.1);
- Primary, secondary, and/or tertiary prevention of chronic conditions (QISMC document standard 1.3.4.2);
- Care of acute conditions (QISMC document standard 1.3.4.3);
- Care of chronic conditions (QISMC document standard 1.3.4.4);
- High-volume services (QISMC document standard 1.3.4.5);
- High-risk services (QISMC document standard1.3.4.6); and
- Continuity and coordination of care (QISMC document standard 1.3.4.7).

Primary prevention consists of preventing a disease from occurring by reducing an individual's susceptibility to an illness; e.g., immunizations are a form of primary prevention. Secondary prevention takes place once an individual is already afflicted with a condition (e.g., hypertension, asthma, uterine cancer) but through secondary prevention (e.g., taking of medications, use of a peak flow meter, early detection), the effects of the condition can be controlled or prevented. Tertiary prevention is applicable when an illness has already caused disability, but the disability can be reduced or prevented from worsening; e.g., early treatment and rehabilitation of stroke victims.

Sometimes, however, quality improvement projects can focus not on a clinical condition, per se, but on a service, particularly a high-volume service, and how it can be improved. A managed care organization may target quality improvement in a frequently performed surgical procedure, or across different surgical or invasive procedures. In such cases, the managed care organization would be targeting the service, as opposed to a clinical condition.

A managed care organization also must target high-risk procedures even if they may sometimes be low in frequency. A managed care organization may assess experiences with care received from specialized centers inside or outside of the organization's network; e.g., burn centers, transplant centers, cardiac surgery centers. It could assess and improve the way in which it detects which of its members have functional disabilities and assess these members' satisfaction with the care received from the organization. It could also analyze high-risk conditions such as invasive procedures in ambulatory settings.

Finally, an organization must also improve continuity and coordination of care. Both of these characteristics of good quality health care address the manner in which care is

provided when a patient receives care from multiple providers and across multiple episodes of care. Such studies may be disease or condition-specific or may target continuity and coordination across multiple conditions. For example, an organization could assess the extent to which care is coordinated across primary care providers and mental health providers subsequent to a discharge from an inpatient psychiatric facility.

30.1.5.2 - Non-Clinical Focus Areas - Non-Clinical Focus Areas Applicable to All Enrollees (QISMC Document Standard 1.3.5) – (Rev. 10, 08-14-02)

Availability, Accessibility and Cultural Competency of Services (QISMC Document Standard 1.3.5.1)

*QAPI p*rojects should focus on assessing and improving the accessibility of specific services or services for specific conditions, including reducing disparities between services to minorities and services to other members (see also QISMC document standard 1.4.4.1.4), as well as addressing barriers due to low health literacy. Projects may also focus on improving the effectiveness of communications with enrollees, and targeting areas of improvement identified as a result of the evaluation conducted under QISMC document standard 2.3.4.

This standard works in conjunction with QISMC document standard 3.1.7.1 which requires the organization to develop and monitor its own standards of timely access to all services and continuously monitor its own compliance with these standards. This standard requires that the *M+C organization* go*es* beyond examining how it evaluates compliance with its own standards, requires the *organization* to identify ways to exceed its own standards, and continues to identify ways to improve the ability of consumers to receive the services that they need in a timely manner. For example, a *QAPI* project might focus on reduction of inpatient admissions for ambulatory sensitive conditions (those for which timely ambulatory care may prevent inpatient admissions). A project might address the promptness with which referral services are furnished in response to a positive result on a given diagnostic test.

For detailed guidance regarding definition and implementation of cultural competency requirements, see QISMC document standard 3.1.5 and Manual Section 2.3.1.5, National Project on Clinical Health Care Disparities or Cultural and Linguistically Appropriate Services .

Appeals, Grievances and Other Complaints (QISMC Document Standard 1.3.5.3)

Projects related to the grievance and coverage determination processes may aim either to improve the processes themselves or to address an underlying issue in care or services identified through analysis of grievances or appeals. For example, an organization with a high rate of grievances not resolved until the third or fourth step in its grievance procedure, might focus on how grievances are addressed in the initial phases of the process. An organization with a high rate of grievances related to one particular type of service might instead focus on improvements in access to or delivery of that service. Similarly, an organization with a high rate of adverse determinations overturned by the

Medicare independent reconsideration contractor might aim to reduce this rate by improving its procedures for initial review of authorization requests. An organization with a high rate of sustained adverse determinations (for example, denials of inappropriate emergency room care) might instead focus on measures to improve provider and enrollee understanding of its procedures for obtaining covered services.

NOTE: In the review of the QAPI requirements, nine of the ten focus areas found in the QISMC document were specifically stated in regulation. The focus area "interpersonal aspects of care" was not. Therefore in early 2001, that focus area was eliminated as a requirement.

If a project for year 1999, 2000, or 2001 has already been implemented using that focus area, CMS will continue to consider that focus area valid. CMS will accept projects done under "interpersonal aspects of care" through 2001. If an M+C organization has implemented a project using the non-clinical focus area "interpersonal aspects of care", for reporting purposes, your project may be placed into the "availability, accessibility and cultural competency of services" focus area category with a note that the project focus is on interpersonal aspects of care in the project completion report.

30.2 - Attributes of *Quality Assessment and* Performance Improvement *(QAPI)* Projects (QISMC Document Standard 1.4) - (Rev. 10, 08-14-02)

An individual *QAPI* project involves:

- Identification of an aspect of clinical care or non-clinical services to be studied;
- Specification of quality indicators to measure performance in the selected area;
- Collection of baseline data;
- Identification and implementation of appropriate system interventions to improve performance;
- Repeated data collection to assess the immediate and continuing effect of the interventions and determine the need for further action;
- Section 30.2.1 (QISMC document standard 1.4.1) addresses the relevance and importance of each project conducted by an organization;
- Section 30.2.2 (QISMC document standard 1.4.2 and 1.4.3) assesses the meaningfulness of the specific performance indicators selected for measurement in an individual project and the validity and reliability of the measurement; and
- Section 30.2.3 and 30.2.4 (QISMC document standard 1.4.4 and 1.4.5) evaluates the extent to which a project resulted in significant improvement sustained over time.

An individual *QAPI* project is regarded as successfully completed only if it meets each of the standards in sections 30.2.1 through 30.2.3. (QISMC document standard 1.4.1 through 1.4.4)

Because the key *QAPI* project components identified in those standards are interdependent, failure on any one of them affects the overall project. For example, if the organization chooses to measure its performance on quality indicators that have no likely relation to outcomes, improvement in the indicators cannot be expected to improve health or functional status. If the organization cannot collect reliable data, it cannot demonstrate improvement, and so on. The organization's documentation of a completed project must provide evidence of compliance with each standard.

30.2.1 - Selection of Topics *for M+C Selected Projects and Local Marketplace Initiatives* - (Rev. 10, 08-14-02)

Within each focus area, the organization selects a specific topic or topics to be addressed by a *QAPI* project. (QISMC document standard 1.4.1)

Topics are identified through continuous data collection and analysis of comprehensive aspects of patient care and member services by the organization. (QISMC document standard 1.4.1.1)

Topics are systematically selected and prioritized to achieve the greatest practical benefit for enrollees. (QISMC document standard 1.4.1.2)

Selection of topics takes into account: The prevalence of a condition among, or need for a specific service by, the organization's enrollees; enrollee demographic characteristics and health risks; and the interest of consumers in the aspect of care or services to be addressed. (QISMC document standard 1.4.1.3)

These standards relate to focus areas for projects selected by the organization itself. Projects conducted at the specific direction of CMS will be deemed to have met this standard.

Documentation of completed projects must show 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.

As §§30.2.1 and 20.1 (QISMC document standards 1.4.1.4 and 1.6.1.3) indicate, the organization's affiliated providers and enrollees must have opportunities to participate in the selection and prioritization of QAPI projects.

30.2.1. 1 - Sources of Information - (Rev. 10, 08-14-02)

The QAPI program must routinely collect and interpret information from all parts of the organization, to identify areas of clinical concern, health delivery system issues, and issues in member services. Types of information to be reviewed include:

- Population Information - Data on enrollee characteristics relevant to health risks or utilization of clinical and non-clinical services, including age, sex, race/ethnicity/language, and disability or functional status.

- Performance Measures - Data on the organization's performance as reflected in standardized measures, including, when possible: Local, State, or national information on performance of comparable organizations.

- Other Utilization, Diagnostic, and Outcome Information - Data on utilization of services, procedures, medications and devices; admitting and encounter diagnoses; adverse incidents (such as deaths, avoidable admissions, or readmissions); and patterns of referrals or authorization requests.

- External Data Sources - Data from outside organizations, including Medicare or Medicaid fee-for-service data, data from other managed care organizations, and local or national public health reports on conditions or risks for specified populations. (In newly formed organizations, or organizations serving a new population, external data may be the major source of potential project topics.

- Enrollee Information on Their Experiences With Care - Data from surveys (such as the Consumer Assessment of Health Plans Study, or CAHPS), information from the grievance and appeals processes, and information on disenrollments and requests to change providers. (Note that general population surveys may under-represent populations who may have special needs, such as linguistic minorities or the disabled. Assessment of satisfaction for these groups may require over sampling or other methods, such as focus groups or enrollee interviews.) The QAPI program should assess, in addition to information generated within the organization, information supplied by purchasers, such as data on complaints.

The QAPI program's project selection process must explicitly take into account quality of care concerns identified by a Quality Improvement Organization, (QIO) formerly known as a Peer Review Organization (PRO) and, for M+C organizations contracting with both Medicare and Medicaid, an external quality review organization (EQRO). While it is not expected that each concern will be addressed through a formal QAPI project meeting the requirements of these standards, the organization should be able to show that issues raised by these organizations were considered in the formulation of its QAPI program agenda, and that alternative remedial action is taken in cases for which a QAPI project is not initiated.

Prioritizing topics

A clinical or non-clinical issue selected for study should affect a significant portion of the organization's Medicare enrollees (or a specified sub-population of enrollees) and have a

potentially significant impact on enrollee health, functional status, or satisfaction. There may be instances in which infrequent conditions or services warrant study, as when data show a pattern of unexpected adverse outcomes; however, the prevalence of a condition or volume of services involved must be sufficient to permit meaningful study.

A project topic may be suggested by patterns of inappropriate utilization, for example, frequent use of the emergency room by enrollees with a specific diagnosis. However, 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. This is not to say that the organization may not make efforts to address over-utilization, but only that such efforts might not be considered QAPI activities for the purpose of assessing compliance with these standards, unless the primary objective is to improve health outcomes. Thus it would be acceptable for a project to focus on patterns of over-utilization that present a clear threat to health or functional status, for example because of a high risk of iatrogenic problems or other adverse outcomes.

Because the achievement of significant and sustained improvement is a central criterion in the evaluation of QAPI projects, projects must necessarily focus on areas in which significant improvement can be effected through system interventions by the organization. Most organizations are likely to give priority to areas in which there is significant variation in practice and resulting outcomes within the organization, or in which the organization's performance as a whole falls below acceptable benchmarks or norms.

It is recognized that the requirement for significant and sustained improvement creates incentives for organizations to focus their QAPI activities on aspects of care in which rapid and measurable improvement is possible through simple interventions. It is not the intention of these standards to discourage organizations from undertaking more complex projects or innovative projects that have a high risk of failure, but that offer some offsetting potential for making a significant difference in the health or functional status of enrollees. Organizations considering such projects should develop long-range goals for projects and establish criteria for evaluation of the organization's progress in implementing its project.

30.2.1.2 - M+C Organizations Using Physician Incentive Plans – (Rev. 10, 08-14-02)

A M+C organization that adopts a physician incentive plan that places physicians at substantial financial risk (as defined at 42 CFR 422.208(d)) for the care of Medicare or Medicaid enrollees, must include in its QAPI program continuous monitoring of the potential effects of the incentive plan on access or quality of care. This monitoring should include assessment of the results of surveys of enrollees and former enrollees required under 42 CFR 422.479(h). In addition, the organization should review utilization data to identify patterns of possible under-utilization of services that may be related to the incentive plan (such as low rates of referral services ordered by physicians at risk for the cost of such services). Concerns identified as a result of this monitoring should be considered in development of the organization's focus areas for QAPI projects.

The QAPI program provides opportunities for enrollees to participate in the selection of project topics and the formulation of project goals. (QISMC document standard 1.4.1.4)

The organization must establish some mechanism for obtaining enrollee input into the priorities for its QAPI program. Possibilities could include enrollee representation on a quality assurance committee or subcommittees or routine inclusion of QAPI issues on the agenda for a general enrollee advisory committee. To the extent feasible, input should be obtained from enrollees who are users of or concerned with specific focus areas. For example, priorities in the area of mental health or substance abuse services should be developed in consultation with users of these services or their families.

30.2.2 - Quality Indicators - (Rev. 10, 08-14-02)

Assessment of the *M+C* organization's performance for each selected topic is measured using one or more quality indicators. (QISMC document standard 1.4.2)

Quality indicators are objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. When indicators exist that are generally used within the public health community or the managed care industry and are applicable to the topic, use of those measures is preferred. (QISMC document standard 1.4.2.1)

Each QAPI project must establish one or more quality indicators that will be used to track performance and improvement over time. An indicator is a variable reflecting either a discrete event (an older adult has/has not received a flu shot in the last 12 months) or a status (an enrollee's hypertension is/is not under control). In either case, an indicator must be clearly defined and subject to objective measurement.

An organization may adopt standard indicators from outside sources, such as the National Committee for Quality Assessment (NCQA)'s Healthplan Employer Data and Information Set (HEDIS) or the Foundation for Accountability's (FACCT) measures, or develop its own indicators on the basis of clinical literature or findings of expert consensus panels. When the organization develops its own indicators, it must be able to document the basis on which it adopted an indicator. It also should be able to show that the process included consultation with affiliated providers and enrollees to assure that measures are meaningful, relevant to the organization's enrolled population, and reflective of accepted standards of practice.

An organization is not required to select specific indicators at the outset of a QAPI project. There may be instances in which a project would begin with more general collection and analysis of baseline data on a topic, and then narrow its focus to more specific indicators for measurement, intervention, and reevaluation. The success of the project will be assessed in terms of the indicators ultimately selected.

All clinical indicators measure changes in health status, functional status, or enrollee satisfaction, or valid proxies of 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. (QISMC document standard 1.4.2.2)

The object 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. Under this definition, measures of costs, or other administrative results do not constitute outcomes. It is recognized, however, that 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 outcomes can be significantly influenced by factors outside the organization's control; e.g., poverty, genetics, environment. In other instances, improvement is possible, but the resources and sophistication needed to analyze the complex factors involved in the outcome and to develop meaningful interventions might be beyond the reach of many organizations.

This standard therefore does not require that quality indicators be outcome measures. Process measures are acceptable so long as the organization can show that there is strong clinical evidence that the process being measured is meaningfully associated with outcomes. To the extent possible, this determination should be based on published guidelines that support the association and that cite evidence from randomized clinical trials, case control studies, or cohort studies. A plan may furnish its own similar evidence of association between a process and an outcome so long as this association is not actually contradicted by a published guideline. Although published evidence is generally required, there may be certain areas of practice for which empirical evidence of process/outcome linkage is limited. At a minimum, the organization must be able to demonstrate that there is a consensus among relevant practitioners with expertise in the defined area as to the importance of a given process. Structural measures are acceptable for non-clinical focus areas such as Culturally and Linguistically Appropriate Services (CLAS.)

Indicators selected for a topic in a clinical focus area (§30.1.5.1, QISMC document standard 1.3.4) include at least some measure of change in health status or functional status or process of care proxies for these outcomes. Indicators may also include measures of the enrollee's experience of and satisfaction with care. (QISMC document standard 1.4.2.3)

While organizations are encouraged to consider enrollee satisfaction as an important aspect of care in any of the clinical areas listed in the QISMC document standard 1.3.4 (§30.1.5.1), improvement in satisfaction must not be the sole demonstrable outcome of a project in any of these areas. Some improvement in health or functional status must also be measured. (Note that this measurement can rely on enrollee surveys that address topics in addition to satisfaction. For example, self-reported health status may be an acceptable indicator). For projects in the non-clinical areas, use of health or functional status indicators is generally preferred, particularly for projects addressing access and availability. However, there may be some non-clinical projects for which enrollee satisfaction or structural indicators alone are sufficient.

The organization selects some indicators for which data are available that allow comparison of the organization's performance to that of similar organizations or to local, state, or national benchmarks. (QISMC document 1.4.2.4)

Significant and sustained improvement may be defined either as reaching a prospectively set benchmark or as improving performance and sustaining that improvement. While the latter form of improvement is acceptable, an organization that works only towards incremental improvements relative to its own past performance can never determine that its performance is optimal or even minimally acceptable relative to prevailing standards in the community. Whenever possible then, an organization should select indicators for which data are available on the performance of other comparable organizations (or other components of the same organization), or for which there exist local or national data for a similar population in the fee-for-service sector. .

Data Collection and Methodology

Assessment of the *M+C* organization's performance on the selected indicators is based on systematic, ongoing collection and analysis of valid and reliable data. (QISMC document standard 1.4.3).

Assessment of compliance with this standard will be coordinated with review of the organization's information systems under §20.2 and the QISMC document standard 1.5.

The organization establishes a baseline measure of its performance on each indicator, measures changes in performance, and continues measurement for at least one year after a desired level of performance is achieved. (QISMC document standard 1.4.3.1)

Documentation of completed QAPI projects must include a detailed account of the data collection methodology used, and the procedures through which the organization has assured that the data are valid and reliable.

Methodology

Most quality indicators are reported in terms of percentages or ratios; for example, the percentage of diabetic members who have a hemoglobin A1C test in the year 2000. An organization adopting this measure must show that it can accurately compute the relevant denominator or population at risk (all diabetic members) and the numerator or indicator (diabetic members who have a hemoglobin A1C test in the specified year).

Identification of the population at risk requires particular scrutiny. For some indicators, the population can be identified in readily available administrative data (all women over 65, or all inpatient discharges with a diagnosis of heart attack). For others, needed data may be more difficult to obtain. For example, even in an organization that collects individual encounter data, this data might not be able to identify all enrollees with diabetes, because physicians may not report ongoing conditions at every encounter. Instead, the organization must identify the population at risk through a valid data source such as a patient disease registry, if present, or through a pharmacy database.

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. The organization may study a sample of the relevant population. If so, it must show that the sample size is sufficient to achieve an appropriate level of confidence in the estimates of the incidence of the indicator under study (see the QISMC document standard 1.4.4.2). The organization also must show that the sampling method is such that all members of the population are equally likely to be selected. (This will generally mean random sampling, although stratified random sampling may be appropriate when the intent is to compare care by different practitioners or at a different site.)

In addition to assuring that data collection is complete and free from bias, the study methodology may need to address other issues in the computation of the indicator. For example, when an indicator relates to receipt of a specific service, the denominator may need to be adjusted to reflect instances in which the patient refuses the service or the service is contraindicated. Similar problems may affect the numerator. For example, in a study of adult immunization rates, the organization would need to establish how it would detect and account for instances in which immunizations were received at a senior center or at a health department, rather than through the primary care practitioner.

Validation

Data will commonly be derived from administrative data generated by the *M+C* organization's health information system or from review of medical records. In assessing non-clinical services, other sources such as enrollee or provider surveys may be appropriate. When data are derived from the health information system, their reliability is obviously a function of the general integrity of the system. In this case, assessment of compliance with this standard will be coordinated with review of compliance with the information system requirements in §20.2 and the QISMC document standard 1.5.

When data are derived from direct review of medical records or other primary source documents, steps must be taken to assure that the data are uniformly extracted and recorded. Appropriately qualified personnel must be used; this will vary with the nature of the data being collected and the degree of professional judgment required. There must be clear guidelines or protocols for obtaining and entering the data; this is especially important if multiple reviewers are used or if data is collected by multiple subcontractors. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

NOTE: If the indicator selected for a QAPI project is a performance measure that the organization is required to report routinely to CMS, review of compliance in this area might be coordinated with whatever validation process CMS establishes for such reporting. CMS may conduct random reviews on a percentage of QAPI projects to assess the integrity of the data.

All data collection for QAPI projects is subject to the confidentiality requirements of the QISMC document standard 2.2.1.

When sampling is used, sampling methodology for assessment of the organization's performance shall be such as to ensure that the data collected validly reflect: (QISMC Document Standard 1.4.3.2)

- The performance of all practitioners and providers who serve Medicare or Medicaid enrollees and whose activities are the subject of the indicator (QISMC document standard 1.4.3.2.1): Once a topic has been selected, the organization must assure that its measurement and improvement efforts are system-wide. Each project must, to the extent feasible, reach all providers in its network who are involved in the aspect of care or services to be studied. This standard does not establish a requirement that an organization review the performance of each and every provider who furnishes the services that are the subject of the project. Sampling is acceptable so long as the organization assures that its samples are genuinely random. The organization must be able to show that:

    - Each relevant provider has a chance of being selected; no provider is systematically excluded from the sampling;

    - Each provider serving a given number of enrollees has the same probability of being selected as any other provider serving the same number of enrollees; and

    - Providers who were not included in the sample for the baseline measurement have the same chance of being selected for the follow-up measurement as providers who were included in the baseline.

    This is, of course, easier to meet if the organization selects for study a condition that affects relatively few of its enrollees or is treated by a limited number of providers. However, the organization might then be unable to show that its selection of topics meets the criteria in §30.2.1 and the QISMC document standard 1.4.1, including the core requirement that topics be selected so as to achieve the greatest practical benefit for enrollees.

    An M+C organization may use a single sample that combines Medicare members with other members. This does not eliminate the requirement for reporting of HEDIS, CAHPS and HOS separately for Medicare. For example, if elements of HEDIS, CAHPS or HOS are used as an indicator for a QAPI project, Medicare must be reported separately. If the QAPI project is non-clinical or does not use HEDIS, HOS or CAHPS elements, it is not necessary to break out the Medicare members as long as the project is relevant to Medicare enrollees and Medicare enrollees are included in the sample.

- The care given to the entire population (including populations with special health care needs and populations with serious and complex health care needs) to which the indicator is relevant. (QISMC Document Standard 4.3.2.2):

- Similar to the equal treatment of all providers and practitioners by the sampling methodology, a sampling methodology should not exclude any population subgroups to which the topic area and indicators are applicable. For example, when studying use of preventive services an organization needs to design its study to include all persons who are in need of the service (e.g., routine health screening) as opposed to including only those individuals who have already made a visit to a managed care organization's providers.

30.2.3 - Significant, Sustained Improvement - (Rev. 10, 08-14-02)

The *M+C* organization's interventions result in significant and sustained improvement in its performance as evidenced in repeat measurements of the quality indicators specified for each performance improvement project undertaken by the organization. (QISMC document standard 1.4.4)

The organization must demonstrate, through repeated measurement of the quality indicators selected for the project, significant change in performance relative to the performance observed during baseline measurement. This significant change does not require statistical significance although statistical significance may be used by the M+C organization to satisfy this standard. In documenting significant improvement, the M+C organization must provide evidence demonstrating that change occurred and that the improvement is meaningful for the organization's Medicare population. In evaluating the projects, CMS will consider such aspects of the project as study design and whether the improvement can be attributed to actions taken by the M+C organization.

The repeat measurement should use the same methodology as the baseline measurement, except that, when baseline data was collected for the entire population at risk, the repeat measurement may use a reliable sample instead. When an organization measures its performance using the identified indicators, it can do so by collecting information on all individuals, encounters or episodes of care to which the indicator is applicable (a census) or by collecting information on a representative subset of individuals, encounters, providers of care, etc.

When a *QAPI* project measures performance on quality indicators by collecting data on all units of analysis in the population to be studied (i.e., a census), significant improvement is demonstrated by achieving (QISMC document standard 1.4.4.1):

- In the case of a *CMS* national *QAPI* project, a benchmark level of performance defined in advance by CMS or significant improvement sustained over time (QISMC document standard 1.4.4.1.1); and

- In the case of a *QAPI* project developed by the organization itself *or a local marketplace initiative*, a local, *s*tate or national benchmark level of performance that is defined in advance by the *M+C* organization or significant improvement sustained over time (QISMC document standard 1.4.4.1.3).

Benchmarks

Benchmarks may be established by CMS for national QAPI projects. When the project is one determined by the managed care organization *or as a local marketplace initiative*, the benchmarks must reflect performance in other organizations, 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 available as public use files on the CMS.gov web-site and are appropriate for use. If Medicare specific data is not available, commercial measures may be appropriate to use.

NOTE: As of 2001, CMS has not determined benchmarks for national QAPI projects.

Performance Target

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 realize*s* that sometimes there is not an established or available benchmark for a particular indicator. If this is the case, an M+C organization may create an internal performance target based on a clear rationale. The target should be something that an M+C organization strives for, but may not necessarily reach. *Failure of* an M+C organization *to* attain *the* stated performance target for a *required* QAPI project, will not *automatically result in a negative score in the final evaluation report as long as there is evidence of continued improvement*.

Sampling

When a *QAPI* project measures performance on quality indicators by collecting data on a subset (sample) of the units of analysis in the population to be studied, significant improvement is demonstrated by achieving the specifications stated under QISMC 1.4.4.1, using a sample that is sufficiently large to detect the targeted amount of improvement. (QISMC document standard. 1.4.4.2) Managed care organizations must provide documentation that the sampling procedure actually implemented was random, valid, and unbiased.

Organizations should be aware that using a sample creates a risk of underestimating actual improvement because of a statistical phenomenon called sampling error. If an organization demonstrates an inadequate amount of improvement based on an estimate that is derived from a sample, CMS will not assume that the inadequate amount of improvement is attributable to sampling error. Organizations therefore face a tradeoff between the cost of using a larger sample to minimize the sampling error and the risk that actual improvement will be underestimated if a smaller sample *is used.* If an organization is experiencing difficulty in determining sample size or methodology, a statistician *should be contacted* about this trade-off before making the decision regarding sample size.

From the perspective of the purchaser, the risk is one of overestimating actual improvement. CMS notes, however, that a chosen sample size that protects organizations against underestimation can be reasonably expected to protect purchasers from overestimation.

The sample or subset of the study population shall be obtained through random sampling. (QISMC document standard 1.4.4.2.1)

The samples used for the baseline and repeat measurements of the performance indicators shall be chosen using the same sampling frame and methodology. (QISMC document standard 1.4.4.2.2)

Interventions

It is essential that the measures of performance before and after the *M+C* organization's interventions be comparable in order to measure improvement accurately. The same methods for identifying the target population and for selecting individual cases for review must be used for both measurements. For example, in a project to improve care of diabetes, it would not be acceptable to draw the baseline sample from a population identified on the basis of diagnoses reported in ambulatory encounter data, and draw the follow-up sample from a population identified on the basis of pharmacy data. In a project to address follow-up after hospitalization for mental illness, it would not be acceptable to shift from a sampling method under which an individual with multiple admissions could be chosen more than once to a method under which the individual could be chosen only once.

The improvement is reasonably attributable to interventions undertaken by the organization (i.e., a project and its results have face validity). (QISMC document standard 1.4.4.3)

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

The organization is not required to demonstrate conclusively (for example, through controlled studies) that a change in an indicator is the effect of its intervention; it is sufficient to show that an intervention occurred that might reasonably be expected to affect the results. Nor is the organization required to undertake data analysis to correct for secular trends (changes that reflect continuing growth or decline in a measure as a result of external forces over an extended period of time). To the extent feasible, however, the organization should be able to demonstrate that its data have been corrected for any major confounding variables with an obvious impact on the outcomes. (For example, an organization should not use a baseline measure of asthma admissions during pollen season and then measure an improvement during another season.)

To the extent feasible, interventions should be designed to address underlying system problems uncovered in the analysis, rather than simply to improve performance on a specific indicator. For example, the organization might determine that one factor in poor outcomes for a given condition was an access problem: too few providers in a given specialty or in a given part of the service area. While the immediate intervention might be to recruit additional providers, the finding should also trigger a review of the organization's policies and procedures for ongoing monitoring of network adequacy.

The expectation of system-level intervention is in contrast to that expressed in some earlier Medicare guidelines on quality assurance activities, that intervention would occur at a provider-specific or patient-specific level. This does not mean that individual instances of substandard care observed in the course of QAPI projects should merely be recorded for statistical purposes and then forgotten. For example, if reviewers identify a specific case in which an enrollee's health is in jeopardy because there has never been follow-up on a given test result, there is clearly an ethical and professional responsibility to assure that the specific needs of that enrollee are promptly addressed. In other instances, findings of QAPI studies may trigger intensive review of the practice patterns of an individual provider, leading to interventions in the form of counseling, possible contract sanctions, or reporting to appropriate professional disciplinary bodies.

30.2.4 - Sustained Improvement Over Time - (Rev. 10, 08-14-02)

The *M+C* organization sustains the improvements in performance described in QISMC document standard 1.4.4 for at least one year after the improvement in performance is first achieved. Sustained improvement is documented through the continued measurement of quality indicators for at least one year after the performance improvement project described in QISMC document standard 1.4.4 is completed. (QISMC document standard 1.4.5)

The organization must repeat measurement of the indicators one year after the initial indicator measurement on the basis of which demonstrable improvement was achieved. This is necessary in order to demonstrate that the improvement that was achieved has been sustained. After an M+C organization has achieved sustained improvement for a project, CMS will not require any further documentation on that project. A M+C organization may then continue or discontinue that project.

A *QAPI* project that has achieved improvement, and under which no further system interventions are undertaken by the organization, will not be regarded as an ongoing project for the purposes of the QISMC document standard 1.3.3 during the period that elapses between the measurement of improvement and the repeat measurement. The organization must carefully distinguish between active *QAPI* projects and *QAPI* projects that have been concluded but for which the repeat measurement has not yet been conducted.

After an M+C organization has met the requirement for both significant and sustained improvement on any given *QAPI* project, no other CMS reporting requirements *are*

required for that project. The M+C organization may choose to continue the project or to go onto another topic.

See the chart Timeframes for Reporting M+C Organization QAPI Projects, in §30.1.2 for sustained improvement remeasurement reporting requirements.

30.3 - Types of *QAPI* Projects - (Rev. 10, 08-14-02)

Effective in 2002, all M+C organizations are required to *initiate one* QAPI project per year. *The* project must be on a topic chosen by CMS, referred to as the national project.

30.3.1 - National *QAPI* Projects - (Rev. 10, 08-14-02)

The national *QAPI* projects address those areas that have been identified as health care priorities for Medicare beneficiaries. These projects will focus on both clinical and non-clinical priorities aimed at reducing morbidity and mortality rates in the Medicare population as well as improving the quality of services provided by the M+C organization. To the degree possible, these national *QAPI* projects will be created and defined with input from beneficiaries, industry representatives, and members of the provider community.

Some *M+C* organizations may have existing projects that could be modified to meet the requirements of the national *QAPI* projects. *An* organization wishing to utilize projects currently underway may do so if *each project:*

- *Follows t*he requirements in this manual chapter;
- Utilize*s* the quality indicators as described for each national *QAPI* project; and
- Conduct*s* a re-measurement in the applicable QAPI initiation year to establish a new baseline against which to assess *its* improvement.

For technical assistance regarding the conduct of a QAPI project, please contact your *s*tate *QIO*

See Appendix A for listing of *CMS* National *QAPI* Projects.

30.3.2 - M+C Organization Selected *QAPI* Projects - (Rev. 10, 08-14-02)

As indicated previously, *M+C organizations* that only contract with Medicare must conduct *one QAPI* project *each* year: *That QAPI project is a* national project defined by CMS. *The requirement for an M+C organization selected QAPI project was eliminated beginning in 2002*.

All the manual and QISMC document standards apply to both national and M+C organization selected projects *such as local marketplace initiatives*, except where an exclusion is specifically indicated.

30.3.3 - Other *QAPI* Projects - (Rev. 10, 08-14-02)

The projects described below are subsets of the national and M+C organization selected *QAPI* projects.

Special Projects

CMS (for Medicare) or the State Medicaid *A*gency for M+C organizations contracting with Medicaid, may require an organization to conduct particular *QAPI* projects that are specific to the organization and that relate to topics and involve quality indicators of CMS or the State Medicaid *A*gency's choosing. (QISMC document 1.3.6.1)

The focus areas specified in §§30.1.5.1 and 30.1.5.2 and in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3, are intended to highlight key components of care and services for organizations serving typical Medicare and Medicaid populations. There may be instances in which CMS or the State Medicaid *A*gency believes that some aspects of care require greater emphasis, either because of the organization's relationship to populations with special health care needs or because the organization's performance is in need of greater improvement in some areas than in others. In such an instance, CMS (for Medicare) or the State Medicaid *A*gency (for Medicaid) may require the organization to conduct a particular project.

An M+C organization will be informed by CMS if it will be required to conduct a special project.

***Local Marketplace Initiative QAPI* Projects**

Organizations may satisfy the requirements of the QISMC document standards 1.3.2 and 1.3.3 by collaborating with one another. (QISMC document 1.3.6.2)

CMS and some State Medicaid *A*gencies have encouraged *local marketplace initiatives*, under which several contracting organizations undertake a joint quality improvement project addressing a common topic. For Medicare, QIOs are not only a convening structure for national performance improvement projects, but are also a regional presence for convening local *marketplace* performance improvement projects. These standards would not preclude such *local initiatives* for M+C organizations contracting with Medicare and Medicaid.

Alternative Option

*M+C organizations have the option to complete either the National Diabetes QAPI Project for 2004 or a local marketplace initiative. Parameters for a*n acceptable local marketplace initiative require that:

- *It must be a community-wide initiative in which most or all M+C organizations 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, remeasurement and interventions as established earlier in Chapter 5.*

Multi-Year *QAPI* Projects

If a *QAPI* project is conducted over a period of more than one review year (QISMC document standard 1.3.7), the project will be considered as achieving significant and sustained improvement in each year for which it achieves an improvement meeting the requirements specified in this manual chapter.

A *M+C* organization may continue a *QAPI* project that has already been determined to have achieved significant and sustained improvement. If further improvement occurs, the project may again be considered to have achieved significant and sustained improvement. However, the improvement will not be measured relative to the original baseline, but relative to the improved performance level previously scored.

A project may be considered as achieving improvement in each year for which it achieves an improvement that constitutes an intermediate target specified in a project work plan developed in consultation with CMS and the State Medicaid *A*gency for M+C organizations contracting with both Medicare and Medicaid. (QISMC document 1.3.7.2)

An organization may undertake a particularly complex or difficult project that is not expected to achieve significant and sustained improvement for several years (i.e., more than three years). This might occur because:

- Improvement in the targeted outcome cannot be measured for a long period; for example, the organization wishes to improve 5-year survival rates for breast cancer;
- Improvement in outcomes can come only after process improvements that are not closely enough related to outcomes to meet the requirement of the QISMC document standard 1.4.3.2; and
- Improvement will require multiple system interventions that cannot be implemented over a short period.

Such a project would not ordinarily be counted as achieving improvement until an improvement meeting the requirement for significant and sustained over time was documented. The *M+C* organization must conduct other projects that achieve improvement more rapidly, because of the requirement that improvement be achieved in *an* area during each 12-month review period after the initial 2-year phase-in period. This standard creates an exception for certain multi-year projects (more than 3 years) with measurable interim goals.

Prior approval by the M+C organization's CMS RO Representative is required prior to the implementation of a multi-year *QAPI* project. If the M+C organization collaborates with a *QIO* in the development and implementation of a QAPI project, then CMS approval is not required. An organization that anticipates that it will meet the minimum requirements of this standard for a review year only if a multi-year project is counted, must request advance review of the project plan at the time the project is initiated. A multi-year project may be approved under the following circumstances:

- 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 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 project is to be counted. For example, while a project that involves a one-time system change that is expected to affect 5-year survival rates cannot measure its success until five years have elapsed, it will not necessarily be considered as an ongoing project during each of the intervening years. It would be treated as ongoing only if it provided for continuous data collection throughout the project period, along with ongoing efforts to identify and implement system changes aimed at improving the long-term outcome.

- The project must specify some form of 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 (such as mammography screening rates) or an intermediate outcome (such as stage of breast cancer at detection) and set goals for each year of the project.

The national projects and M+C organization selected projects are not considered multi-year projects, in this context, even though they are conducted over several years. A "regular" national or M+C organization selected project cannot be converted into a multi-year project without prior approval.

30.3.4 - Process for CMS Multi-Year QAPI Project Approvals – (Rev. 10, 08-14-02)

How to Make a Request for Approval

A standardized request form *is* available on the cms.hhs.gov web site. The M+C organization *must* download this document, fill it out, and send it electronically to the designated address with a copy to their CMS RO representative. An acknowledgement of receipt of the request will be sent to the M+C organization from the recipient of the request.

Who Reviews the Request?

A CMS standing committee will address these requests. This group will consist of representatives from the Medicare+Choice Quality Review Organization *(MCQRO)*, and CMS CO and RO *staff*.

When Should the Request be Submitted?

The M+C organization should identify its intention to do a multi-year project significantly in advance of the proposed implementation date. The committee will address all proposals received subsequent to their last meeting.

An M+C organization may choose to change the topic of its selected project provided that the new project topic meets all of the requirements of this manual. The baseline of the new project topic must also be from the appropriate year. CMS does not require that an M+C organization notify the agency of this type of change. However, an M+C organization may choose to notify *its* CMS RO representative of the change.

30.4 - Evaluation of QAPI projects - (Rev. 10, 08-14-02)

Accrediting Organizations That Are Approved for M+C Organization Deeming Authority

Accrediting organizations that are approved for M+C organization deeming authority will review QAPI projects for those M+C organizations that have selected deemed status via accreditation. If the M+CO would like CMS to review their QAPI project, they must submit the Project Completion Report discussed below before the accrediting organization conducts their deeming site visit. Accrediting organizations are required to assess the M+C organization's QAPI projects and report the results of *the* evaluation to CMS. M+C organizations are encouraged to contact *the relevant* accrediting organization for further instructions.

CMS Regional Office Representatives

The CMS Regional Office staff will continue to be available to M+C organization *staff* when questions arise regarding QAPI projects. M+C organizations may share project information with RO Representative*s* to inform them about the projects and interventions that are being developed and discuss CMS QAPI requirements. However, the responsibility for the final review of the projects is solely that of the M+CQRO teams. CMS regional and central office staff will make the final approval decision.

Although the M+CQROs will be reviewing the QAPI projects, the CMS RO staff will continue to monitor the other aspects of the QAPI Program and Health Information System when they conduct monitoring reviews. It is not expected that the reporting of projects must coincide with CMS monitoring. RO staff will be able to review all previous QAPI project submissions in preparation for monitoring.

Reviewers

The QAPI evaluations are conducted by four contractors, known as the Medicare+Choice Quality Review Organizations (M+CQRO). The M+CQRO are four QIOs - California Medical Review, Inc., Colorado Foundation for Medical Care, Delmarva Foundation for Medical Care and Island Peer Review Organization. The contract period began in February, 2000, and will be completed in February, 2003. The four contractors have developed the training and implementation materials and manuals that are used to provide technical assistance to M+C organizations and CMS in the design, development, implementation and evaluation of their quality assessment and performance improvement programs.

QIOs may provide technical assistance and expertise in the development and implementation of QAPI projects to M+C organizations in their own states. To prevent potential conflict of interest, the M+CQRO's will provide technical assistance to M+C organizations in their own respective states *but* will not review QAPI projects within their own states

Project Completion Report

The Project Completion Report will provide the M+C organization with an effective reporting tool for QAPI projects. The reporting unit will be the H-number (CMS contract identification number) level or less. The M+C organization will be allowed to segment their single contract H-number into smaller units, (subunits) but not to report on a unit larger than the H-number. Each segment will have its own unique password and code for access into the CMS data base. This issue is especially relevant for those large organizations that operate in geographically defined service areas within a larger contract H-number. These organizations will then report on several projects as to ensure that beneficiaries in all service area counties within the H-number are covered by a QAPI project.

M+C organizations which have consolidated contract H numbers over the course of the project will report on the current H-number as recognized by CMS. M+C organizations will report significant improvement on the end of the project contract H numbers, but make note of any change in service areas which might have affected the study outcomes. In some instances units for baseline measurement may not be exactly the same as units used in re-measurement. If unsure of how to proceed, please contact your RO representative.

The Project Completion Report is in a password protected web-based format. The report information will be directly submitted into the CMS Health Plan Management System

(HPMS) database where the web-based project completion report is housed. Each M+C organization has limited access to the HPMS database. This web-based system was available for use in mid-January, 2002.

Each person who is a contact for QAPI reports and is responsible for filling out the report must have their own individual password and access. The user's computer must be able to access the AT&T Global Network. To obtain access to the project completion report (which is also called the QAPI module in HPMS), an individual must apply for HPMS access codes. In order to get access to HPMS, individuals must fill out a form called "APPLICATION FOR ACCESS TO CMS COMPUTER SYSTEMS" which is located at URL http://www.cms.hhs.gov/mdcn/access.pdf. The instructions are also available to complete this form.

Please submit the original completed forms to:

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

Please contact Don Freeburger at DFreeburger@cms.hhs.gov with questions on this process.

The report format is designed to be user-friendly through the inclusion of informational cues and text fields allowing for broad responses. An M+C organization may report any information regarding the project that it feels will describe and support understanding of the project by the reviewer. The M+C organization will be able to determine what information *it* consider*s* proprietary. CMS will not release any proprietary information. Only one indicator and intervention is required in this report. If an M+C organization chooses to report more than one, it will be evaluated only on the indicator(s) for which it achieves significant improvement.

The M+CQROs will evaluate the QAPI projects. This review will include (but not be limited to) analysis of the choice of focus area, patient population and eligibility criteria, selection of intervention and methodological integrity as required in the QISMC document standards. The review will be done solely from the data contained in the QAPI Project Completion Report; no on-site review will be done.

The M+CQROs will provide CMS with a report on each QAPI project via the secure HPMS system. The report will include the final score of the project based on CMS scoring methodology, recommendations as to whether the project met the required goals and recommendations for improvement. The report will also recommend a corrective action plan in the event that the M+C organization did not satisfy all of the requirements.

When to Report ***(See the chart in §30.1.2 for year-by-year detail)***

The M+C organization will have 90 days from the completion of their project to submit its Project Completion Report electronically, via the HPMS system, to the M+CQRO.

The completion date of a project is usually close to the end of the 3-year project cycle, and is the date on which the last data run of the project was completed. This data run demonstrates the required significant and sustained improvement.

The M+C organization determines the actual date of project completion. CMS has not set any specific deadlines for the submission of the project completion reports. CMS considers the type of data the M+C organizations are using (i.e., HEDIS, CAHPS, etc) and any additional factors that may affect when the M+C organization can complete and report their projects. If an M+C organization knows that there will be a significant delay in the reporting of their project beyond the 3-year cycle, they should notify their CMS Regional Office representative.

For example, if a project was initiated in 1999, one could report "significant improvement" in 2001/2002 (depending upon the type of data or indicators used, such as HEDIS.) "Sustained improvement" would then be reported one year later in 2002/2003. Although a 3-year cycle is assumed, an M+C organization may report on demonstrable improvement prior to the end of 3 years, if it has met the QAPI project requirements. The reporting date is also affected by the time period of the baseline data. For example, a 1999 project may use data from either 1998 or 1999.

For those 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 their 2000 project, CMS will expect that the project is completed by the end of 2003. However, because of the HEDIS predetemined reporting timeframes, CMS will accept the Project Completion Report after the audited HEDIS results were announced in June of 2004. It will be assumed that during year 2004, the M+C organization is working on sustaining its improvement for reporting in 2005. If this is the case for your organization, notify your CMS RO Representative.

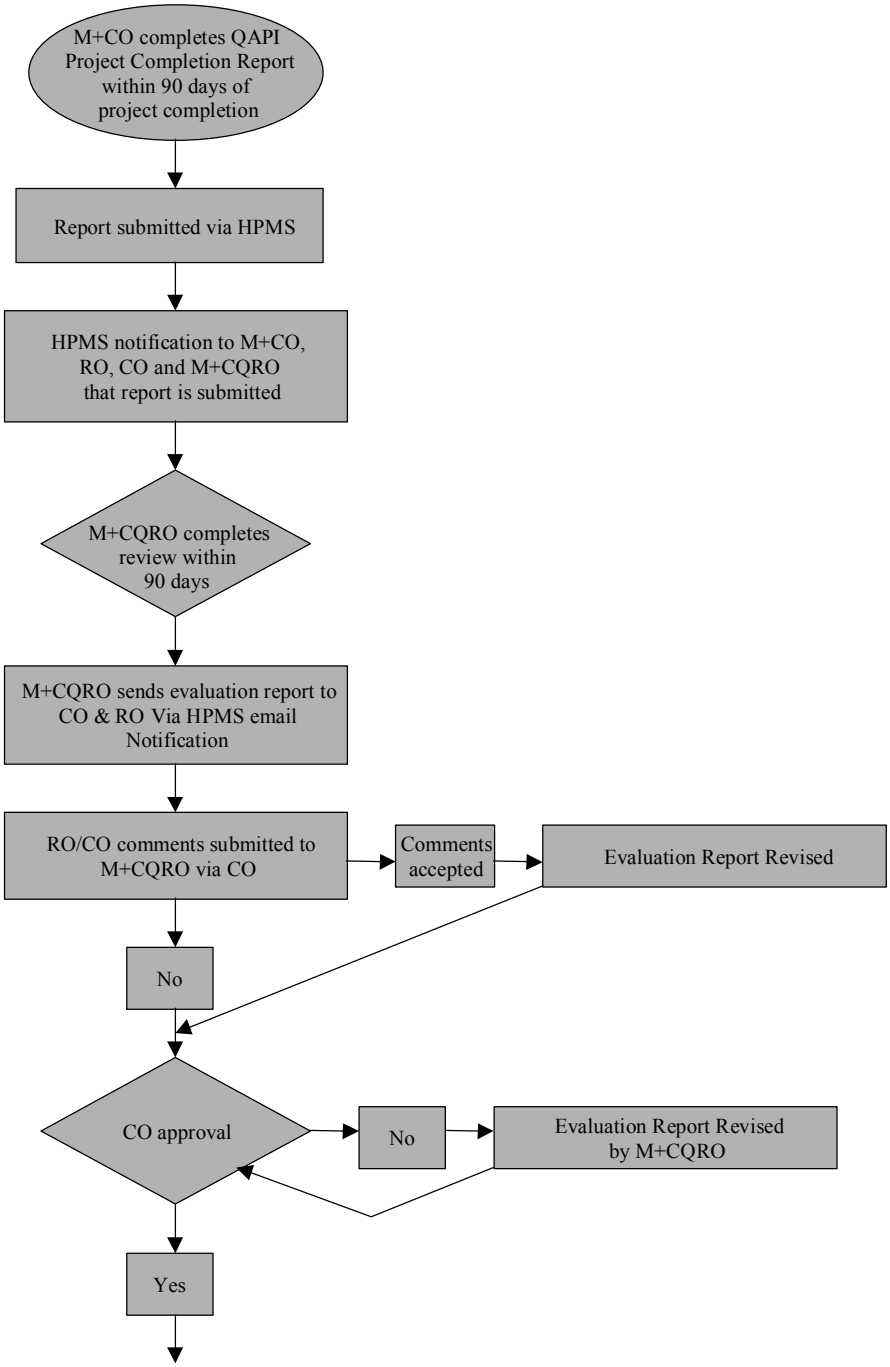
Project Review Report

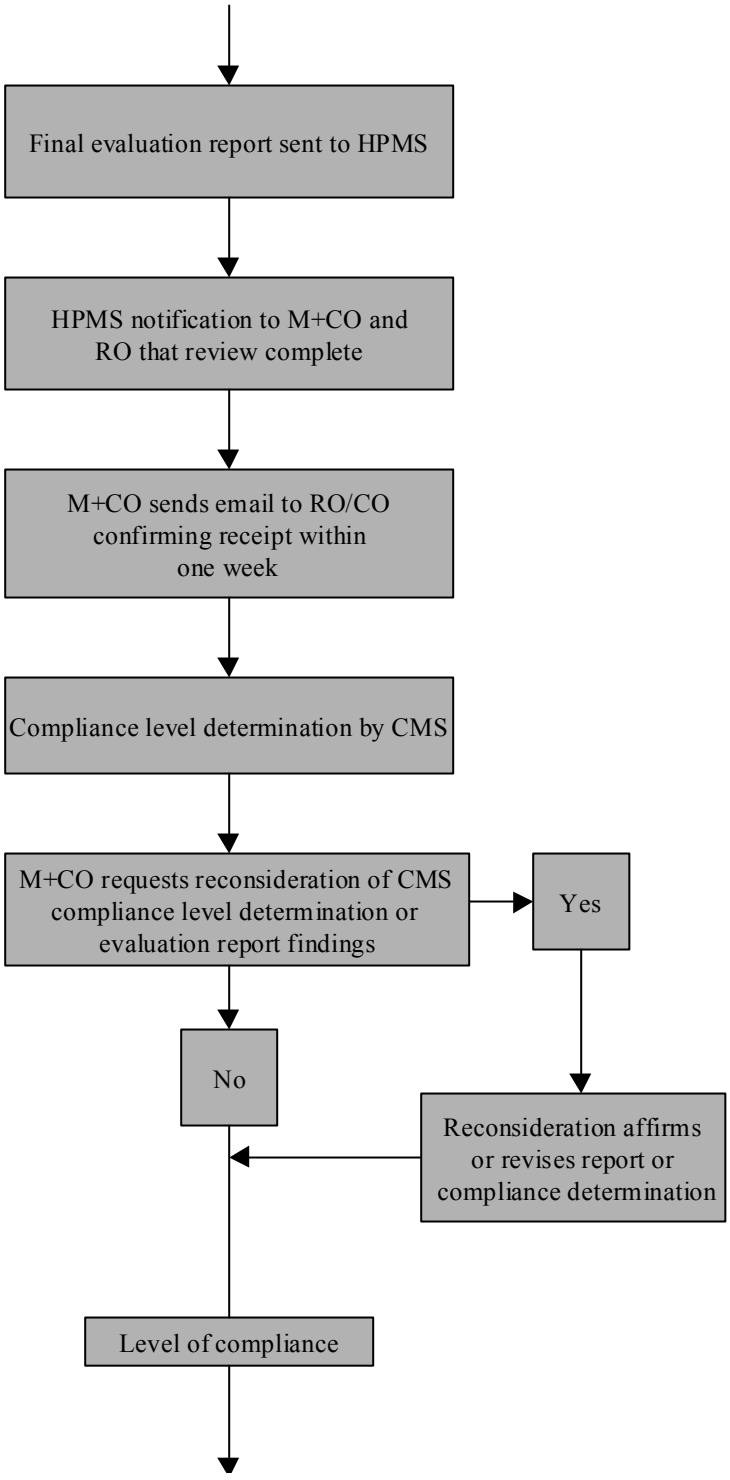
The Project Review Report will be sent to CMS via the HPMS system from the M+CQRO reviewers. This report will highlight the strengths and weaknesses of each project. The M+CQROs will list general recommendations for consideration in the development and execution of future QAPI projects. The report will include the final score of the project based on the scoring methodology. For significant improvement, if a project scores 50 or higher, a corrective action will not be required. If the project scores a 49 or less, CMS will require a corrective action plan.

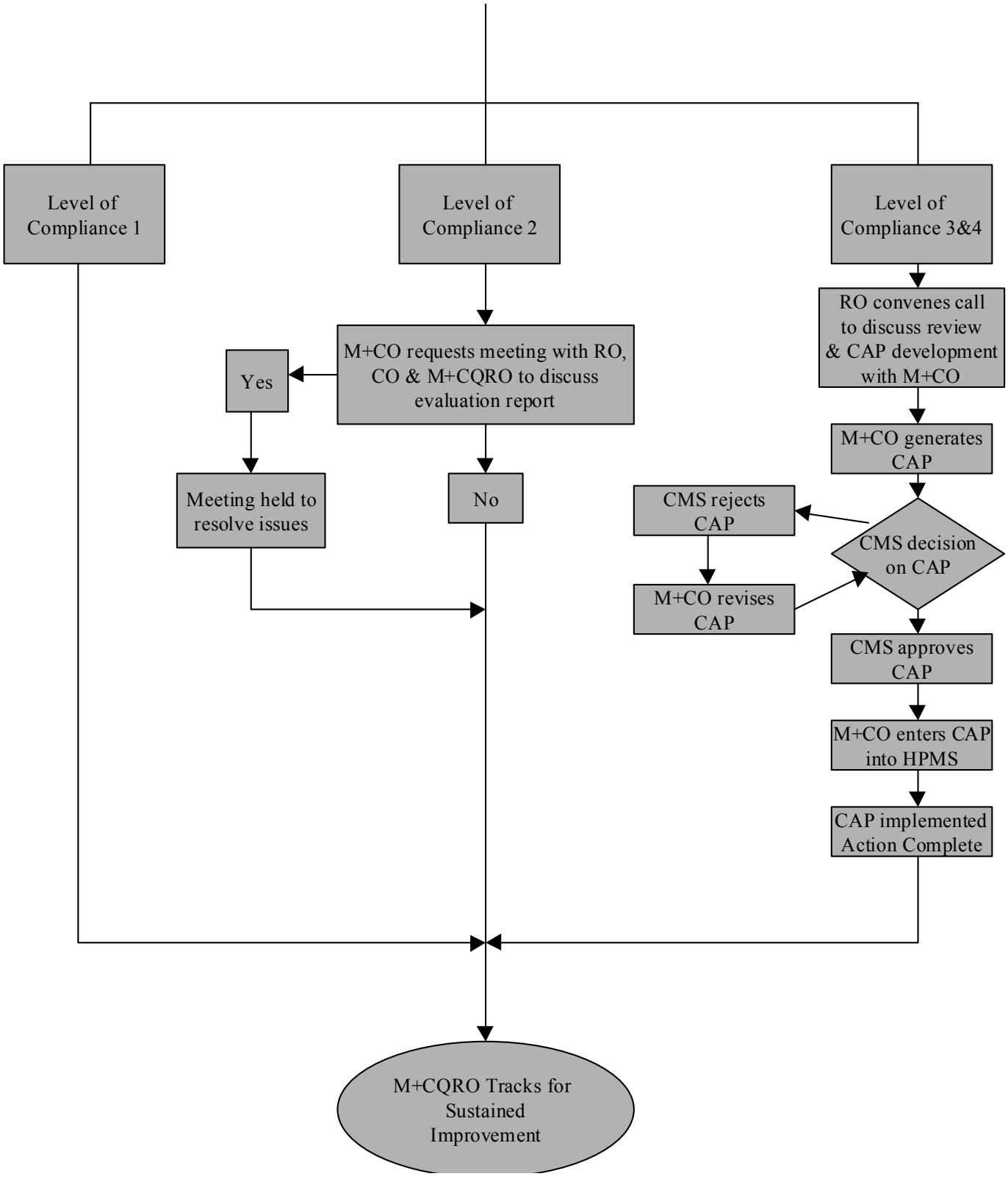
In cases where a CAP has been required, the process described in the above sections will be followed. If the M+C organization wishes to discuss the findings from the project or the CAP, it must contact the CMS RO representative, not the M+CQRO reviewer. All interactions with the M+CQROs will be through the CMS RO. They will facilitate all communication between M+C organization and M+CQRO either via e-mail, telephonically, or through conference calls. If an immediate resolution cannot be achieved, the issue will be reviewed further and a final decision reached.

Reporting Timelines

This process will take place via the HPMS system and e-mail. It is essential that each M+C organization provides accurate, up to date contact information to ensure timely communication in this process. The following flowcharts (numbered 1 through 5) depict the exchange of information and communication processes. A brief narrative explaining the flowcharts is at the end of this section.




Final evaluation report sent to HPMS
HPMS notification to M+CO and RO that review complete
M+CO sends email to RO/CO confirming receipt within one week
Compliance level determination by CMS
M+CO requests reconsideration of CMS compliance level determination or evaluation report findings
Yes
No
Reconsideration affirms or revises report or compliance determination
Level of compliance


Level of Compliance 1
Level of Compliance 2
Level of Compliance 3&4
M+CO requests meeting with RO, CO & M+CQRO to discuss evaluation report
Yes
Meeting held to resolve issues
No
RO convenes call to discuss review & CAP development with M+CO
M+CO generates CAP
CMS decision on CAP
CMS rejects CAP
M+CO revises CAP
CMS approves CAP
M+CO enters CAP into HPMS
CAP implemented Action Complete
M+CQRO Tracks for Sustained Improvement

M+C organization submits project for evaluation within 90 days of project completion.

1. M+CQROs will have 90-days to review and evaluate projects. M+CQRO may contact the M+C organization once for clarification/additional information. The M+C organization is not required to provide any additional information.

2. M+CQRO submits final report to CMS RO and CO for approval.

3. CMS considers any comments from the CMS RO and approves or disapproves the report. If approved, it will then be sent to the M+C organization. If CMS does not approve, the report will be returned to the M+CQRO for revisions.

4. Within one week of receipt of the final evaluation, the M+C organization will confirm to CMS RO and CO staff that *it has* received their evaluation via HPMS.

5. Reconsideration: If the M+C organization does not agree with *it's* evaluation, *staff* may contact *the* CMS RO representative for a reconsideration of the project evaluation. CMS CO and the MCQRO will participate in the reconsideration.

6. Level of Compliance

> *6a.* Level of compliance 1: (Compliant) M+C organization continues with *its* project and goal of attaining sustained improvement.
>
> 6b. Level of compliance 2: (Compliant with minor deficiencies) M+C organization may request a conference call with CMS RO, CO, and M+CQRO to clarify and discuss project results or any issues with the evaluation. The M+C organization should contact their CMS RO representative to facilitate this call. This session is informational and serves as a learning discussion for future projects. The M+C organization then continues with its project and goal of attaining sustained improvement.
>
> *6c*. Compliance levels 3 and 4: *M+C organizations at these c*ompliance *levels must prepare* a corrective action plan

Step 1 - After the M+C organization has confirmed receipt of *it's* evaluation, *it* must then contact *it's* CMS RO representative to convene a conference call with CMS CO and M+CQRO *staffs* to discuss the completed project review. Typically, dates and times are based upon when the M+C organization will be ready to discuss *it's* project. CMS expects that this call will occur within a few weeks of the M+C organizations' receipt of *the* project review.

Step 2 - M+C organization generates the corrective action plan (CAP) within 45 days from receipt of final evaluation report and sends it to CMS. CMS approves an acceptable corrective action plan. This will typically be the CAP that is suggested in the project review report but may be a plan that the M+C organization negotiates with CMS. The M+C organization has 45-days from initial receipt of the project review to submit a CAP for CMS approval.

Step 3 - CMS will either accept or reject the CAP proposal. If rejected, the M+C organization will be required to resubmit another CAP proposal for consideration. However, CMS does not expect CAP proposals to be rejected if they have been previously agreed upon.

Step 4 - Once accepted, the M+C organization will enter the CAP information into the designated location within the QAPI/ HPMS database. Once the CAP has been entered into the database, it cannot be altered. CMS and the M+CQROs will monitor the CAP based on the information in the database.

Step 5 - The M+C organization implements the CAP in the specified timeframes. CMS and the M+CQRO will re-evaluate the CAP for compliance. Once the CAP has been resolved, the M+C organization will then continue with the project for sustained improvement.

Other *T*ools

In addition to the Project Completion Report and Project Review Report, other tools have been developed to assist M+C organizations in the implementation of the QAPI projects. An instructional guide and a reviewer guide provides clarification of the elements requested in the report. The guides include definitions as well as examples of appropriate answers to ensure that both the M+C organization staff and reviewer have the same understanding of the requirements.

The scoring methodology was created using the framework of the QISMC document standards. All aspects of the QISMC standards are important, however, some areas such as significant (demonstrable) and sustained improvement were determined to be the most significant. The scoring is weighted based on the significance placed on particular elements. Scoring is divided into a section for significant improvement, which has a maximum of 80 points, and sustained improvement, which has a maximum of 20 points. The maximum point value assigned to a completed project is 100 points.

All tools are available on cms.hhs.gov, the CMS web site.

Validation

CMS will determine the frequency and type of independent validation and in-depth reviews. These will be done either on site or by having all materials sent to the reviewer. Either the M+CQRO or another CMS contractor may perform these reviews. It is expected that selection for independent validation will be done in a random manner.

The CMS ROs will not be evaluating QAPI projects during their monitoring site visits to an M+C organization. They will continue to review and evaluate the administration of the M+C organization QAPI program and the health information system.

Of the independent validations and audits performed, the evaluation may include but not be limited to:

- Validation/reliability edits/measures for individual records;
- Cross tabulations among comparable data in different files or databases;
- Conducting validity and accuracy checks on data samples;
- Patient selection criteria and applying statistical algorithms that relate sample error rates to population error rates;
- Development and/or implementation of comparability measures using either similar data for other sources or demonstrably valid surrogates;
- Development of data reliability measures and statistical quality controls; and
- Conversion of these statistics into program management report and evaluation analyses.

Corrective Action Process

In the event that an M+C organization does not meet the set requirements in the standards and guidelines determined by CMS, a Corrective Action Plan (CAP) will be required. The CAP is meant to bring the M+C organization into compliance with the QAPI requirements. Once all CAPs have been resolved, CMS will automatically increase the M+C organization's significant improvement score to a total value of 50 points out of a possible 80 points. This increase brings the M+C organization into a compliance level of 2, which does not requires corrective action. This increase will positively affect the total project score after sustained improvement is evaluated in the following year.

Possible Examples of CAP Elements

- Sampling methodology is inappropriate - The M+C organization *must* re-sample and re-calculate final figures for the project under review. The M+C organization may be required to collaborate with the *QIO* for future sampling efforts.
- Methodology is appropriate and study is sound, but did not achieve significant and sustained improvement - The M+C organization may be required to add or strengthen interventions. If appropriate, it may also be allowed to have a specific extension of time if the reviewers believe that more time would show the improvement.
- Interventions do not support indicators - The M+C organization may be required to implement new interventions or collaborate with its *QIO* on future projects.
- Conducts a project, but has poor planning, methodology, indicators, interventions, etc - The M+C organization may be instructed to collaborate with its *QIO* in future projects.

- Failure to conduct a QAPI project - The M+C organization may be required to conduct a CMS-directed special project with significant increased oversight.

The examples of CAPs listed above are not exhaustive. The type of CAP imposed will depend on the quality of the QAPI project and the M+C organization's performance in conducting its QAPI projects.

The requirement for conducting a special project may be imposed for a variety of reasons besides total non-compliance (see §30.3.2). CMS has not yet required any M+C organizations to do a CMS-directed special project.

It is unlikely that an M+C organization's contract will be terminated solely based on poor performance in a QAPI project. However, if an M+C organization was consistently a poor performer on QAPI projects, it would raise questions about its other QAPI projects as well as its performance in other required areas as laid out in this Manual Chapter and the QISMC document standards.

35.1 - Terminology - (Rev. 10, 08-14-02)

Deeming Authority

The authority granted by CMS to private, national accrediting organizations to determine, on CMS's behalf, whether an M+C organization evaluated by the accrediting organization is in compliance with corresponding Medicare regulations.

Deemed Status

Designation that an M+C organization has been reviewed and determined "fully accredited" by a CMS-approved private, national accrediting organization for those standards within the deeming categories that the accrediting organization has the authority to deem.

Accreditation

An evaluative process in which a healthcare organization undergoes an examination of its policies, procedures and performance by an external organization ("accrediting body") to ensure that it is meeting predetermined criteria. It usually involves both on- and off-site surveys.

Fully Accredited

Designation that all the elements within all the accreditation standards for which the accreditation organization has been approved by CMS have been surveyed and determined to be fully met or otherwise acceptable without significant findings, recommendations, or corrective actions.

Private, National Accrediting Organization

Organizations that seek deeming authority must be private, national accrediting organizations. To meet CMS's definition of a private, national accrediting organization, the entity must demonstrate the following:

- It has accredited and re-accredited managed care organizations in multiple States;
- It is recognized as an accrediting body by the managed care industry and relevant national associations;
- It contracts with or employs staff that are appropriately trained and have experience with monitoring managed care plans for compliance with their own accrediting standards; and
- It contracts with or employs sufficient staff to provide accreditation services nationwide.

Accreditation Cycle for M+C Deeming

The duration of CMS's recognition of the validity of an accrediting organization's determination that an M+C organization is "fully accredited." CMS will continue to monitor M+C organizations every two years. In the M+C deeming program, an accrediting organization may use its usual cycle, as long as re-accreditation occurs at least every three years.

Unit of Analysis for Deeming

For deeming, M+C organizations may be accredited at the unit negotiated with the accrediting organization, as long as the unit does not exceed the CMS contract (H-number) level.

Accrediting Organizations' Enforcement of Compliance with Standards that Relate to M+C organization Requirements

Accrediting organizations with deeming authority will be responsible for enforcing compliance *in accredited M+C organizations* by initiating a corrective action process with respect to deficiencies found in those areas where deemed status applies. In their application for deeming authority, an accrediting organization must be able to demonstrate that when they find areas of noncompliance, they (the accrediting organization) will implement a process that is at least as stringent as the process CMS uses to correct areas of noncompliance with similar Medicare requirements.

35.2 - Deeming Requirements - (Rev. 10, 08-14-02)

Congress gave CMS the authority to deem Medicare requirements in the following six areas:

1. Quality assessment and improvement (§1852(e) of the Social Security Act);

2. Confidentiality and accuracy of enrollee records (§1852 (h) of the Social Security Act);

3. Antidiscrimination (§1852 (b) of the Social Security Act);

4. Access to services (§1852 (d) of the Social Security Act);

5. Information on advance directives (§1852 (i) of the Social Security Act); and

6. Provider participation rules (§1852 (j) of the Social Security Act).

35.3 - General Rule - (Rev. 10, 08-14-02)

An M+C organization may be deemed to be in compliance with certain Medicare requirements, if the M+C organization has been accredited and periodically reaccredited by a private, national accrediting organization that has been approved by CMS. To deem an M+C organization, the accrediting organization must use the standards (and the process for monitoring compliance with the standards) that CMS determined, as a condition of deeming authority, are no less stringent than the applicable Medicare requirements.

An M+C organization's deemed status is effective on the later of the following dates:

1. The date on which the accreditation organization is approved by CMS, or

2. The date the M+C organization is accredited by the accreditation organization.

An M+C organization's deemed status will be effective on the date the accrediting organization is approved if the accrediting organization used the same standards and methods of evaluation approved by CMS at the time of the survey. For example, if the M+C organization is accredited on January 5th by an organization that is approved by CMS on March 1st of the same year, on January 5th the accrediting organization must have used the same standards and review processes on January 5th that CMS determined on March 1st were at least as stringent as the applicable Medicare requirements. Thus, in this example if the standards were the same, the M+C organization's deemed status effective date would be March 1st.

35.4 - Obligations of Deemed M+C Organizations - (Rev. 10, 08-14-02)

As noted above, to be granted deemed status an M+C organization must be fully accredited and periodically re-accredited by a CMS-approved accrediting organization. In addition, an M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accrediting organization's accreditation process. There are two types of validation surveys:

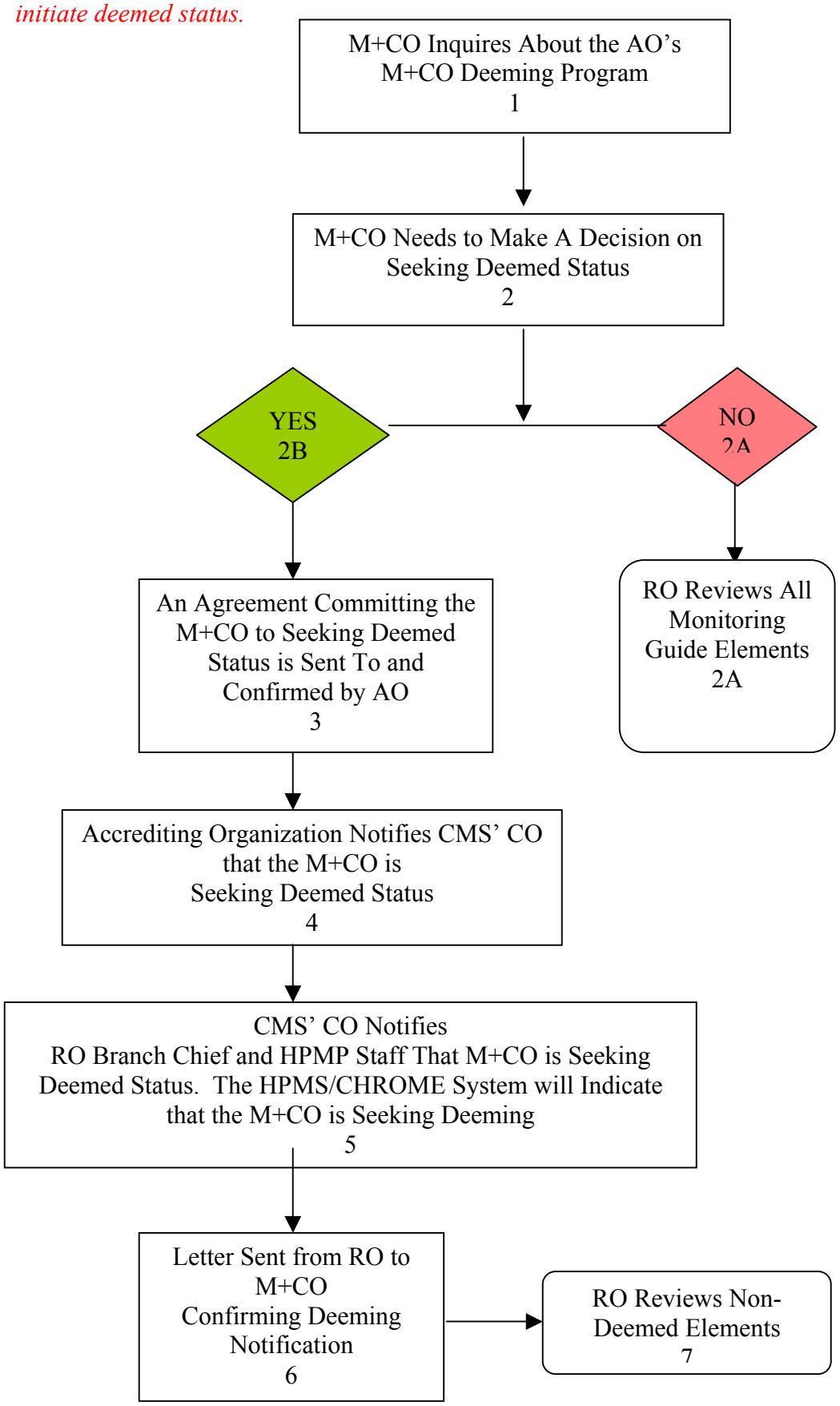
1. Observational (commonly referred to as concurrent); and

2. Retrospective (or look behind) surveys.

An M+C organization that seeks deemed status must also agree to authorize its accreditation organization to release to CMS a copy of its most current accreditation survey, as well as any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

M+C organizations who seek deemed status via accreditation by a CMS-approved accrediting organization can submit the cost of accreditation as an administrative cost in their Adjusted Community Rate (ACR) submission. Administrative costs that bear a significant relationship to the M+C plan being priced are allowed to be included in the ACR. However, the cost for the accreditation should be equally allocated between the M+C organizations Medicare and non-Medicare line of business.

The following chart demonstrates the process that an M+C organization must follow to initiate deemed status.



1. The M+C organization Inquires About the Accreditation Organizations (AO's) M+C Deeming Program:

- *The Medicare + Choice organization (M+C organization) contacts the AO to inquire about the AO's M+C deeming program. This is the opportunity for the M+C organization to learn more about AO's deeming program.*

- *The AO sends informational materials pertaining to its M+C deeming program to the M+C organization. The material will include (1) General information about the deeming program, (2) The standards/elements that the organization will be measured against, and (3) All associated fees and review cycle information.*

- *The M+C organization reviews the information and contacts the AO with any questions or additional information that it may require.*

- *Regional office (RO) staff should continue to work with the M+C organization's to coordinate the CMS performance assessment review because (1) Many of the CMS requirements are not deemable, and (2) The M+C organization may decide that it does not want to pursue deeming.*

2. The M+C Organization Needs to Make a Decision on Seeking Deemed Status Via Accreditation:

2A The Decision is No: The RO Reviews All Monitoring Guide Elements. The M+C organization decides not to seek deemed status, the RO will schedule and conduct a performance assessment visit using the Final Rule Monitoring Guide until the 2002 M+ C Monitoring Review Guide, Version 1, has been approved for use.

- *The RO will schedule and conduct a performance assessment review by using the normal CMS review monitoring review cycle schedule (every two years) and the current version of the M+C monitoring review guide.*

2B. The Decision is Yes: If the M+C organization decides to seek deemed status, the M+C organization will need to contact the AO to request a legal agreement for seeking deemed status via accreditation. The legal agreement may be a contract, an application (with associated fees for withdrawing the application), or another document that commits the M+C organization to seeking deemed status.

3. An Agreement Committing the M+C Organization Seeking Deemed Status is Sent To and Confirmed by the AO:

- *If the M+C organization has an accreditation decision that included its Medicare line of business (or the Medicare population was part of the overall accreditation review) and the AO used the standards that it submitted in their application for M+C deeming authority, an agreement that relates specifically for M+C organization deemed status is signed. The AO will only review for the*

supplemental M+C standards that were added to the AO's accreditation program in order for the AO to be granted M+C deeming authority.

- *If this is a first time accreditation review or the organization is seeking reaccredidation with deemed status, an agreement is signed. The AO will review the M+C organization by using the AO's entire accreditation program for managed care plans (their regular accreditation program plus the M+C organization supplement).*

- *The M+C organization sends the agreement to the AO with all the applicable processing fees.*

- *At this point it is determined that the M+C organization is seeking deemed status via accreditation.*

- *The RO continues to work with M+C organization's to coordinate the performance assessment review for all the requirements that are not deemed. If the accrediting organization site visit is longer than 9 months from the date of the next RO monitoring site visit, the RO will review for compliance with all the monitoring guide elements. If the AO site visit is before the RO review or within the 9-month time frame, the ROs will only review for compliance of those elements that are not part of the deeming program (the non-deemed elements).*

4. Accrediting Organization Notifies CMS that the M+C Organization is Seeking Deemed Status:

Once the agreement has been signed, the AO will notify CMS' central office (CO) contact via e-mail (and voice mail during the transition to deeming) that the M+C organization is seeking deemed status. The AO will provide the date of the deemed status accreditation onsite visit, the M+C organization's H number, and any additional information that CMS may require.

5. CMS' Central Office Notifies the Appropriate Regional Office Branch Chief and the Health Plan Management System (HPMS):

- *Once the AO notifies CMS that it has a signed agreement that the M+C organization is seeking deemed status via accreditation, CO staff will notify the RO Branch Chief and the HPMS staff person responsible for the deeming program.*

    - *Before any pre-visit information request is sent to an M+C organization by RO staff, the HPMS system must be checked for deemed status*

    - *HPMS staff will initiate the indicator in HPMS/CHROME system, which will alert RO staff that the M+C organization is seeking deemed status via accreditation.*

- *If the Final Rule Guide is in use:*

- *The deemed elements will be flagged. While input can still occur, RO staff should not review for deemed elements or submit a finding for any element that has been deemed.*

- *When the 2002 M+C Monitoring Review Guide, Version 1, has been cleared:*

- *The deemed elements will be flagged and the RO will not be able to input findings. In essence, a switch will be turned when an M+C organization signs an agreement with an AO for a deeming review. Once the switch is turned, RO staff will not be able to input information into HPMS for the elements that have been identified as deemable.*

6. Letter Sent From the Regional Office to the M+C organization Confirming Deeming Notification:

After receiving notification from the central office that the M+C organization is seeking deemed status, the RO will then send the M+C organization a letter that notifies the M+C organization that the AAO has informed CMS that it (the M+C organization) is seeking deemed status. This letter will also be a vehicle to confirm that the M+C organization does indeed intend to seek deemed status via accreditation from the AO.

7. Regional Office Staff Review all of the Non-Deemed Elements:

Once it has been established that the M+C organization will have a review by the AO and the AO's site visit is before the RO monitoring visit or within a 9-month timeframe set by CMS, the RO staff will only review non-deemed elements.

35.4.1 - Deemed Status and CMS Surveys - (Rev. 10, 08-14-02)

An M+C organization that is accredited by a CMS-approved accrediting organization is still subject to CMS surveys. As noted above, an approved accrediting organization may only deem an M+C organization for one or more of six areas:

- Quality assessment and improvement;
- Confidentiality and accuracy of enrollee records;
- Antidiscrimination;
- Access to services;
- Information on advance directives; and
- Provider participation rules.

Thus, CMS's regional and central offices will still need to conduct surveys to assess compliance with those requirements that are not deemable, such as grievances and appeals, beneficiary disclosure, marketing, enrollment, and organization determinations.

In addition, if the accrediting organization only has deeming authority in one of the six deemable areas, such as access to services, then CMS will conduct a survey to assess the other five areas, as well as non-deemable requirements. CMS will also retain the authority to investigate "serious" complaints about an M+C organization.

35.4.2 - Removal of an M+C organization's Deemed Status – (Rev. 10, 08-14-02)

CMS will remove part or all of an M+C organization's deemed status if:

1. We determine, based on our own survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted;

2. We withdraw our approval of the accreditation organization that accredited the M+C organization; or

3. The M+C organization fails to meet the obligations of a deemed M+C organization, which are addressed in §35.4.

CMS does not intend to overrule an accreditation organization's survey decision without doing our own investigation. However, if our investigation reveals that a condition is not met, we reserve the right to remove deemed status even though the accrediting organization has not removed accreditation with respect to that condition.

In addition, when CMS withdraws our approval of deeming authority from an accrediting organization, the M+C organization*'*s deemed status will also be withdrawn. M+C organizations will be notified of the withdrawal of deemed status via a public notice. The accrediting organization must notify all their accredited M+C organizations within 10 days. Upon removal of an M+C organization's deemed status, CMS immediately assumes responsibility for ensuring that the organization meets M+C standards.

35.5 - CMS's Role - (Rev. 10, 08-14-02)

CMS has been directed to establish and oversee the M+C organization deeming program. Developing a process for reviewing and approving applications from accrediting organizations seeking deeming authority was the first step in establishing the program. CMS may approve an organization for deeming authority, if *it* can demonstrate, through the application process, that *its* accreditation program is at least as stringent as CMS's, and *it* meet*s* the application requirements addressed in §35.6.1 of this section. The BBRA specified that CMS must approve an accrediting organization by deeming subset (area), rather than by individual requirement. However, an accrediting organization must have a comparable standard for every one of the M+C organization requirements within a deeming subset (area).

If, during the course of monitoring for non-deemable requirements, CMS's RO staff identifies that an M+C organization is not in compliance with a deemable requirement, RO staff must notify CMS CO deeming staff who will ensure that the accrediting organization initiates a corrective action process, when and if appropriate. Although

beneficiary-specific complaints will continue to be handled by RO staff, the RO will not issue the corrective action requirement for deficiencies found in deemed areas.

35.5.1 - Oversight of Accrediting Organizations - (Rev. 10, 08-14-02)

After approving an accrediting organization for deeming authority, CMS has a critical role in providing oversight of accrediting organizations' performance. CMS has a number of mechanisms available to fulfill our oversight responsibilities, including:

1. Conducting another equivalency review if CMS or the accrediting organization adds or changes requirements;

2. Conducting validation surveys to examine the results of the accrediting organization's survey;

3. Conducting an onsite observation of the accreditation organization's operations and offices to verify the organization's representation and assess the organization's compliance with its own policies and procedures;"1 and

4. Investigating accredited M+C organizations in response to serious complaints.

If regional office staff detect a trend (or pattern) of complaints in deemed areas, they will refer the matter to central office deeming staff who will, in turn, contact the appropriate accrediting organization.

Equivalency Review

CMS will compare the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when:

1. CMS imposes new requirements or changes its survey process;

2. An accreditation organization proposes to adopt new standards or changes in its survey process; or

3. The term of an accreditation organization's approval expires.

Validation Review

CMS or its agent may:

1. Conduct a survey of an accredited organization (retrospective or look behind survey),

2. Examine the results of the accreditation organization's own survey; or

3. Attend the accreditation organization's survey (observational survey), in order to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results:

    - Indicate a 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

    - Indicate any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

    - Indicate that, irrespective of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

During the first year of deeming, CMS will conduct only concurrent/observational reviews of accrediting organization performance. Then, CMS will phase-in a combination of both concurrent and retrospective reviews. The phase-in will depend on a number of factors, including the number of M+C organizations that select the Accreditation Organization (AO) for deeming.

Onsite Observation of an Accreditation Organization

CMS may conduct an onsite survey of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite survey may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision-making process, and interviewing the organization's staff. In the M+C organization deeming program, CMS will conduct the accreditation organization survey during the application and reapplication process.

35.6 - Obligations of Accrediting Organizations with Deeming Authority - (Rev. 10, 08-14-02)

Accrediting organizations must apply and enforce the standards that CMS determined as a condition of approval, are at least as stringent as Medicare requirements with respect to the standard or standards in question. To be approved, an accrediting organization must comply with the application and reapplication procedures that are addressed in §35.4 of this section and §422.158 of the Code of Federal Regulations.

Accrediting organizations must also ensure the following:

- Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

- The majority of the membership of its governing body is not comprised of managed care organizations or their representatives; and

- Its governing body has a broad and balanced representation of interests and acts without bias.

- In addition, if CMS takes an adverse action based on accreditation findings, approved accrediting organizations must permit their surveyors to serve as witnesses.

35.6.1 - Application Requirements - (Rev. 10, 08-14-02)

A private, national accrediting organization may seek deeming authority for any or all of the six categories listed in §35.2 of this section and §422.156(b) of the Code of Federal Regulations. For each deeming category for which the accrediting organization is applying for deeming authority, it must, demonstrate that its standards and processes meet or exceed Medicare requirements within that particular category.

A "Federal Register" notice inviting accrediting organizations to send a letter of interest to apply for deeming authority for HMOs and PPOs was issued on June 29, 2000. We will develop application materials that address other types of M+C plans at a later date, if applicable. *Application m*aterials for HMO and PPO deeming authority were sent to interested *accrediting* organizations on July 29, 2000.

A private, national accreditation organization applying for approval must furnish to CMS all of the following materials. (When reapplying for approval, the organization need furnish only the particular information and materials requested by CMS.)

1. The type(s) of M+C coordinated care plans that they seek authority to deem (PPO and/or HMO).

2. A crosswalk that provides a detailed comparison of the organization's accreditation requirements and standards with the corresponding Medicare requirements.

3. A detailed description of the organization's survey process for each type of M+C they are seeking authority to deem, including:

    - Frequency of surveys performed and whether the surveys are announced or unannounced;

    - Copies of survey forms and guidelines and instructions to surveyors;

    - A description of the organizations survey review and accreditation status decision making process;

- The procedures used to notify accredited M+C organizations of deficiencies and the procedures to monitor the correction of those deficiencies;

- Procedures the organization uses to enforce compliance with their accreditation requirements;

4. Detailed information about the individuals who perform surveys for each type of M+C organization that the organization seeks authority to deem, including:

    - The size and composition of and the methods of compensation for *its* accreditation survey teams;

    - The education and experience requirements surveyors must meet to participate in *its* accreditation program;

    - The content and frequency of the in-service training provided to survey personnel;

    - The evaluation system used to monitor the performance of individual surveyors and survey teams;

    - The policies and practices with respect to participation in surveys or in the accreditation decision process by an individual who is professionally or financially affiliated with the entity being surveyed.

5. Description of the data management and analysis system with respect to surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by their data system.

6. The procedures *it* will use to respond to and investigate complaints or identify other problems with accredited organizations, including coordination of these activities with licensing bodies and ombudsmen programs.

7. The policies and procedures regarding withholding, denying and removal of accreditation for failure to meet the organization's standards and requirements, and other actions the organization will take in response to non-compliance with their standards and requirements.

8. The policies and procedures regarding how the organization deals with accreditation of organizations that are acquired by another organization, have merged with another organization, or that undergo a change of ownership or management.

9. Description of all the types (full, partial, or denial) and categories (provisional, conditional, temporary) of accreditation offered by the organization, the duration of each category of accreditation, and a statement identifying the types and categories that would serve as a basis for accreditation if CMS grants the organization M+C deeming authority.

10. A list of all the M+C organizations that the organization has currently accredited, by *s*tate and the type, category of accreditation and the expiration date of the accreditation held by each organization.

11. A list of all the managed care organizations that the organization has surveyed in the past three years, the date *each was* accredited (if denied, the date *it was* denied), and the level (category) of accreditation it received.

12. A list of all managed care surveys scheduled to be performed by the organization within the next three months by organization, date and *s*tate. (The *list* must indicate if *each* managed care organization is an M+C organization.)

13. The name and address of each person with an ownership or controlling interest in the accreditation organization.

14. A written presentation that demonstrates that *it* will be able to furnish data electronically, via telecommunications.

15. A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities. The resource analysis should include financial statements for the past three years (audited if possible) and the projected number of deemed status surveys for the upcoming year.

16. A statement acknowledging that, as a condition of approval, the organization agrees to comply with the ongoing responsibility requirements that are addressed in §35 and §422.157(c) of the Code of Federal Regulations.

If CMS determines that it needs additional information for a determination to grant or deny the accreditation organization's request for approval, we will notify the accrediting organization and allow *it* time to provide the additional information.

As part of the application process, CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents, and interviews with the organization's staff.

35.6.4 - Reporting Requirements - (Rev. 10, 08-14-02)

1. Accrediting organizations that have been approved for deeming authority must provide to CMS in written form and on a monthly basis all of the following:

    a. Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements);

    b. Notice of all accreditation decisions;

c. Notice of all complaints related to deemed M+C organizations;

d. Information about any M+C organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the M+C organization's accreditation within 30 days of taking the action;

e. Notice of any proposed changes to *its* accreditation standards or requirements or survey process. If an accrediting organization implements any changes before or without CMS approval, we may withdraw our approval.

2. If an accrediting organization finds a deficiency in an M+C organization that poses an immediate jeopardy to the organization's enrollees or to the general public, *it* must give CMS written notice of the deficiency within three days of identifying the deficiency.

3. When CMS gives notice that we are withdrawing our approval for deeming authority, the accrediting organization must notify all *its* accredited M+C organizations within 10 days.

4. Accrediting organizations must provide on an annual basis, summary data *to be* specified by CMS, that relate to the past year's accreditation activities and trends.

5. Within 30 days after CMS changes a Medicare M+C organization requirement, the accrediting organization must:

   a. Send a written acknowledgement of CMS's notice of the change,

   b. Submit a new cross-walk reflecting the new requirement; and

   c. Send a written explanation how *it* plan*s* to alter, within a timeframe that CMS will specify in the notice of change, *its* standards and review process to conform to CMS's new requirement.

6. Accrediting organizations must have a mechanism for publicly disclosing the results of an M+C organizations accreditation survey.

7. Accrediting organizations must report *its* assessment of *accredited* M+C organization QAPI projects to CMS via HPMS

35.7 - Reconsideration of Application Denials, Removal of Approval of Deeming Authority, or Non-Renewals of Deeming Authority – (Rev. 10, 08-14-02)

An accreditation organization that has received notice of denial of its request for deeming authority (or specific deeming categories) may request reconsideration. CMS will reconsider any determination to deny, remove, or not renew the approval of deeming authority to private accreditation organizations, if the accreditation organization files a

written request for reconsideration. The request must be filed within 60 days of the receipt of notice of an adverse determination. The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees, and the reasons for the disagreement.

In response to a request for reconsideration, CMS will provide the accreditation organization the opportunity for an informal hearing that will be conducted by a hearing officer appointed by the Administrator of CMS. The informal hearing will also provide the accreditation organization the opportunity to present in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority.

35.7.1 - Informal Hearing Procedures - (Rev. 10, 08-14-02)

CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date. The hearing will be conducted in accordance with the following procedures:

1. The hearing is open to CMS and the organization requesting the re-consideration, including:

    - Authorized representatives;

    - Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

    - Legal counsel.

2. The hearing officer who receives testimony conducts the hearing and documents related to the proposed action.

3. The hearing officer may accept testimony and other evidence even though it would be inadmissible under the usual rules of court procedures.

4. Either party may call witnesses from among those individuals specified above in number 1.

5. The hearing officer doe*s* not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

35.7.2 - Informal Hearing Findings - (Rev. 10, 08-14-02)

Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization that requested the reconsideration. The written report of the hearing officer will include:

- Separate*ly* numbered findings of fact; and

- The legal conclusions of the hearing officer.

35.7.3 - Final Reconsideration Determinations - (Rev. 10, 08-14-02)

The hearing officer's decision is final unless the CMS Administrator, within 30 days of the hearing officer's decision, chooses to review that decision. The CMS Administrator may accept, reject or modify the hearing officer's findings. Should the CMS Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the accreditation organization on the basis of the hearing officer's findings and recommendations and other relevant information. The reconsideration determination of the CMS Administrator is final. The final reconsideration determination against an accreditation organization will be published by CMS in the "Federal Register".

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40 - Standard Reporting Requirements for Medicare Managed Care Organizations: Health Plan Employer Data and Information Set (HEDIS®) Measures that Include the Medicare Health Outcomes Survey (HOS) and the Medicare Consumer Assessment of Health Plans Study (CAHPS® 2.0H) - (Rev. 10, 08-14-02)

40.1 - Background - (Rev. 10, 08-14-02)

This section provides information regarding the annual Medicare HEDIS submission and provides clarification for Medicare contracting organizations under applicable law, regulations and contract requirements governing Medicare+Choice (M+C) organizations, the §1876 of the Act cost contracting organizations, and demonstration projects. This section also explains reporting requirements for HOS, and CAHPS and addresses specific CMS implementation requirements. Throughout this *section of Chapter 5,* the general term, Managed Care Organization (MCO), will be used to refer to all contracting organizations, unless otherwise specified. Effective January 1, 1997, CMS began requiring MCOs to report on performance measures from the HEDIS® reporting set relevant to the Medicare managed care population, and to participate both in CAHPS® and the Health Outcomes Survey (HOS). These requirements are consistent with the law and with the requirements of other large purchasers. It is critical to CMS's mission that it collect and disseminate information that will help beneficiaries choose among MCOs and contribute to better health care through identification of quality improvement opportunities. For M+C organizations, HEDIS represents a performance measurement system that is acceptable to CMS since it uses standard measures adopted by CMS and it meets the provision at 42 CFR 422.152(c)(1).

CMS makes summary, plan-level performance measures available to the public through media that are beneficiary-oriented, such as the Medicare Health Plan Compare Internet site (www.medicare.gov). A subset of HEDIS and CAHPS data is also available in printed form through a toll free line (1-800-MEDICARE). Disenrollment rates are also

available in printed form through the same toll free line. HEDIS summary-level data files are available through CMS's Internet web site as a Public Use File (http://www.cms.hhs.gov/stats/pufiles). The HEDIS and CAHPS (including the annual current enrollment assessment survey, the annual disenrollment assessment survey and the quarterly disenrollment reasons surveys) patient-level files are available at cost to requesters authorized to receive such information. Requesters, for confidentiality reasons, must sign a Data Use Agreement with CMS and must meet CMS's data policies and procedures that include, but are not limited to, submitting a research protocol and study purpose. For information about Data Use Agreements, contact the Division of Data Liaison and Distribution, Enterprise Database Group, within CMS's Office of Information Services.

View table of HEDIS and CAHPS reporting requirements

40.2 - Specifics Applicable to CAHPS and HEDIS - (Rev. 10, 08-14-02)

A - Effects of the Balanced Budget Act of 1997

The Balanced Budget Act of 1997 established Part C of Medicare, known as the M+C program which replaced the §1876 program of risk and cost contracting starting with contracts effective January 1, 2000. The reporting requirements contained in this *section of C*hapter *5* apply to organizations that hold an M+C contract, a §1876 cost contract, or a demonstration contract, in accordance with applicable law, regulations, and contract requirements. HEDIS submission requirements also apply to deemed M+C organizations. Please see section C below for exceptions to this requirement, such as organizations that have terminated their M+C contract or §1876 contract with CMS.

B - Requirements for MCOs

1. Reporting Requirements

    a. HEDIS - A MCO must report HEDIS measures for *its* Medicare managed care contract(s), as detailed in the "HEDIS Volume 2: Technical Specifications" if all of the following criteria are met:

    - The contract was in effect on 1/1 of the measurement (previous) year or earlier;
    - The contract had initial enrollment on 1/1 of the measurement year or earlier;
    - Contract had an enrollment of 1,000 or more on 7/1 of the measurement year;
    - The contract has not been terminated on or before 1/1 of the reporting (current) year.

The HEDIS technical specifications are updated annually. For example, MCOs preparing HEDIS 2002 data submissions must follow instructions in HEDIS 2002, Volume 2, and the HEDIS 2002, Volume 2 Update (to be released in October 2001). Please note that where there are differences between this manual chapter and HEDIS Volume 2, this chapter takes precedence for reporting data. The final HEDIS Volume 2: Technical Specifications is available from NCQA. Please call NCQA Customer Support at 1-888-275-7585 to obtain a copy. When the HEDIS 2001 Volume 2 Update is released HEDIS specifications are frozen. MCOs are required to take into account the update. You may wish to check periodically the HEDIS Data Submission section of NCQA's web site to review Frequently Asked Questions (FAQs).

The Medicare relevant HEDIS measures that M+C MCOs must report are listed in Exhibit I, and the Medicare relevant measures that continuing cost contractors must report are listed in Exhibit IA.

Note that two measures in the Health Plan Descriptive Information Domain (that are listed as Medicare) are not required to be submitted to CMS - Practitioner Compensation and Arrangements with Public Health, Educational and Social Service Organizations.

b. Health Outcomes Survey (HOS) - All MCOs that had a Medicare contract in effect on or before January 1st, of the previous year must comply with the HOS requirements for current year reporting. See the chart at C.10. for specific requirements for demonstration projects.

c. Medicare CAHPS - All MCOs that had a Medicare contract in effect on or before. July 1, of the previous year, must comply with both the current enrollee and disenrollment assessment surveys and disenrollment reasons survey requirements for current year reporting. Medicare CAHPS does not apply to MCOs that received a contract effective after July 1st of the previous year. However, such MCOs may be required to undertake an enrollee satisfaction survey to comply with the CMS regulations on physician incentive plans (Vol. 61, "Federal Register", 13430, March 27, 1996). MCOs may wish to use Medicare CAHPS for this purpose.

2. Minimum Size Requirements - There is a minimum size requirement for MCOs to report HEDIS measures; MCO enrollment must be 1,000 or more on July 1st of the measurement year. In reviewing previous HEDIS submissions, CMS noted that this is the enrollment level at which most MCOs could submit valid data on the Effectiveness of Care measures. There is no minimum size requirement to participate in the HOS and Medicare CAHPS surveys. When an MCO has fewer beneficiaries enrolled than the CAHPS sample size requirements (see table above for specific program requirements) or the HOS sample size of 1,000, at the time the sample is drawn, the entire membership must be surveyed.

An MCO must report all the CMS-required Medicare HEDIS measures, even if the MCO has small numbers for the denominator of a measure. For specific instructions on how to handle small numbers, review the Specific Guidelines in the "HEDIS Volume 2, Technical Specifications." For information regarding the audit designation for these measures review "Volume 5: HEDIS Compliance Audit (Standards, Policies and Procedures."

3. Sampling and Reporting Unit - In all but five states, MCOs will have one reporting unit for HEDIS and HOS. In these five States, MCOs will have no more than two reporting units for HEDIS and HOS. In the states of Florida, Ohio, New York, California, and Texas the collected data will be aggregated into two display units for each State, generally labeled North & South or East & West.

   Medicare CAHPS instituted a sampling unit for the Enrollee Survey and the Assessment Disenrollment Survey that accommodates comparison with Medicare CAHPS fee-for-service (FFS) and retains the collection of satisfaction data at a local level. For the first time, Medicare Managed Care (MMC) CAHPS data will be compared to FFS CAHPS data; first at the State level and eventually at the local level. The comparisons between MMC and FFS will be displayed where there is overlap in the market service areas. If you have any questions about the sampling units, please send questions to CAHPS@cms.hhs.gov

   On the Medicare Health Plan Compare web site, the user will see the same display unit, either local or market area, for CAHPS. However, one can "drill down" to the level of the CAHPS sampling unit for more localized information. The sampling unit is a collection of counties combined into a Health Service Area (HSA) which is a standard unit of measure of health services utilization as determined by the Department of Health and Human Services.

   We recognize that in some cases MCOs have reasons for reporting HEDIS data in other configurations, for example those MCOs who seek NCQA accreditation for their Medicare product line. On a case-by-case basis, CMS will evaluate the accreditable entities for the MCOs to see if we can accommodate MCOs to submit one HEDIS Data Submission Tool (DST) and, if they are accredited in a *s*tate in more than one unit, to use the accreditation units, if feasible. We will need to ensure that a sub-*s*tate segment has sufficient enrollment to produce HEDIS and HOS. Therefore, we will use a threshold of 5,000 enrollees as part of the determination to sub-divide a contract area. While this collection and reporting at a higher level may mask some performance variation at a lower level, we believe that it is not feasible to collect at a lower level due to small numbers, especially for the HEDIS Effectiveness of Care measures. Furthermore, using the HEDIS patient-level detail files, we can do an analysis of performance by re-constructing rates extrapolated from the summary data for other geographic areas within a *s*tate.

   To identify what geographic area should be contained in the MCO's HEDIS reporting unit, the MCO must review the annual HEDIS Reporting Requirements

site on the Medicare Managed Care Home Page on www.cms.hhs.gov. Note that the reporting will be based on the membership in the service area in place during the measurement (previous) year while the reporting entity will reflect the contract or entity structure under the reporting (current) year configuration. If you have a concern or question regarding the area specified for HEDIS contact: Richard Malsbary, Center for Health Plans and Providers, at (410) 786-1132. We will address each request on a case-by-case basis.

The steps CMS will employ to delineate the HEDIS and HOS reporting units are:

a. Identify MCOs that will be continuing to hold contracts in the reporting year;

b. Identify the total Medicare contract service area associated with the post-consolidation H-number of the MCO;

c. Identify the Medicare contract service area associated with the business area for the measurement year; and

d. Specify a reporting unit, by county names, that is either one area in a *s*tate or, in the case of MCOs in Florida, Ohio, New York, California, and Texas may be either one or two reporting units.

Post the reporting units on http://www.cms.hhs.gov/

C - MCOs With Special Circumstances

1. MCOs with Multiple Contract Types - A MCO cannot combine small contracts of different types, e.g., risk and cost, into a larger reporting unit. MCOs can check their reporting units on the hcfa.gov web site.

2. MCOs Carrying Cost or former HCPP Members - HEDIS performance measures will be calculated using only the Medicare enrollment in the M+C contract or the §1876 of the Act contract in effect at the end of the measurement year. Therefore, any residual cost based enrollees within an M+C contract should not be included in HEDIS calculations.

3. For HEDIS measures with a continuous enrollment requirement and for enrollees who converted from one type of contract to another (with the same organization), enrollment time under the prior contract will not be counted.

4. MCOs with New Members "Aging-in" from their Commercial Product Line - These MCOs must consider "aging in" members eligible for performance measure calculations assuming that they meet any continuous enrollment requirements. That is, plan members who switch from a MCO's commercial product line to the MCO's Medicare product line are considered continuously enrolled. Please read the General Guidelines of HEDIS Volume 2: Technical Specifications for a discussion of "age-ins" and continuous enrollment requirements.

5. MCOs with Changes in Service Areas - MCOs that received approval for a service area expansion during the previous year and those that will be reducing their service area effective January 1st of the next contract and reporting year must include information regarding those beneficiaries in the expanding or reducing areas based on the continuous enrollment requirement and use of service provisions of the particular measure being reported.

6. HMOs with Home and Host Plans - The home plan must report the data related to services received by its members when out of the plan's service area. As part of the Visitor Program/Affiliate Option (portability), the host plan is treated as another health care provider under the home plan's contract with CMS. The home plan is responsible for assuring that the host plan fulfills the home plan's obligations. Plan members that alternate between an MCO's visitor plan and the home plan are considered continuously enrolled in the plan.

7. New Contractors and Contractors Below the Minimum Enrollment Threshold - MCOs with initial enrollment on February 1st of the measurement year or later will not report HEDIS performance measures for that calendar year. In addition, MCOs with enrollment below 1,000 on July 1st of the measurement year will not be required to submit a HEDIS report and they will not need to request a DST from NCQA. However, these plans must have systems in place to collect performance measurement information so that they can provide reliable and valid HEDIS data in the next reporting year.

8. Non-renewing/Terminating MCOs - Entities that meet the HEDIS reporting requirements stated above but which have terminated contracts effective January 1st of the reporting year will not be required to submit a HEDIS report or participate in the HOS survey. These contracts are required to participate in the CAHPS surveys in the Fall prior to their contract termination date.

9. MCOs with Continuing §1876 of the Act Cost Contracts - For cost contracts, CMS has modified the HEDIS measures to be reported. Cost contractors will not report the Use of Services inpatient measures. The measures to be reported are listed on Exhibit I.A. CMS does not require cost contractors to report inpatient (e.g., hospitals, SNFs) measures because MCOs with cost-based contracts are not always responsible for coverage of the inpatient stays of their members. Cost members can choose to obtain care outside of the plan without authorization from the MCO. Thus, CMS and the public would not know to what degree the data for these measures are complete.

10. Cost contracts will provide patient-level data for all the HEDIS Effectiveness of Care and the Use of Services measures for which they submit summary level data. (See Exhibit I.A.)

11. Mergers and Acquisitions - The entity surviving a merger or acquisition shall report both summary and patient-level HEDIS data only for the enrollment of the surviving company.

12. CMS recognizes that a separate set of beneficiaries and affiliated providers may be associated with the surviving entity's contract. However, HEDIS measures based on the combined membership and providers of both contracts could be misleading since the management, systems, and quality improvement interventions related to the non-surviving contract are no longer in place. Reported results based on combined contracts may not reflect the quality of care or medical management available under the surviving contract. The surviving contract(s) must comply with all aspects of this section for all members it had in the measurement year.

13. Demonstration Projects - CMS also requires demonstration projects to meet the HEDIS, CAHPS, and HOS reporting requirements, in accordance with applicable law, regulations, and contract requirements. All types of demonstration projects will be expected to comply with all the HEDIS reporting and audit requirements in this section. Specific waivers contained in the demonstration contracts may have been negotiated with CMS and take precedence over any requirements specified in this section. For further information on the requirements for specific demonstrations, contact the CMS project officer.

Demonstration	**HEDIS**	**HEDIS Audit**	**CAHPS**	**HOS**
Social HMOs	Yes	Yes	Yes	Yes
Medicare Choices	Yes	Yes	Yes	Yes
Minnesota Senior Health Options	Yes	Yes	No	No
Wisconsin Partnership Program	Yes	Yes	No	No
Evercare	No	No	No	No
PACE	No	No	No	Yes

D - Implications for Failure to Comply

CMS expects full compliance with the requirements of this section. MCOs must meet the time lines, provide the required data, and give assurances that the data are accurate and audited. In addition, many of the HEDIS requirements described herein will be reviewed as part of CMS's Contractor Performance Monitoring System.

E - Use of Data

Data reported to CMS under this requirement will be used in a variety of ways. The primary audience for the HEDIS, CAHPS, HOS, and Disenrollment summary data is the Medicare beneficiary. These data will provide comparative information on contracts to beneficiaries to assist them in choosing among contracts. In addition, CMS expects

MCOs to use the data for internal quality improvement. The data should help MCOs identify some of the areas where their quality improvement efforts need to be targeted and may be used as the baseline data for Quality Assessment and Performance Improvement (QAPI) projects. Further, the data will provide CMS with information useful for monitoring the quality of, and access to, care provided by MCOs. CMS may target areas that warrant further review based on the data.

40.3 - HEDIS Submission Requirements - (Rev. 10, 08-14-02)

A - Summary and Patient-Level Data

CMS is committed to assuring the validity of the summary data collected before it is released to the public, and to mak*ing* the data available in a timely manner for beneficiary information. MCOs must submit summary measures, after completing the NCQA HEDIS Compliance AuditTM required by Medicare, by the end of June of each reporting year. MCOs must submit HEDIS patient-level data at the same time. CMS requir*es* the submission of patient-level data on the same date as summary data to ensure that the patient-level data matches the summary data. Please note that auditors will review patient-level data for the numerator and denominator of audited measures when checking for algorithmic compliance during the HEDIS audit. Both data files are to be submitted directly to NCQA.

1. Summary Data

    a. Required Measures - MCOs that held Medicare contracts in the measurement year and meet the criteria in §30.2, item B.1 of this chapter must report summary data for all required HEDIS measures identified in Exhibit I, except for the Health Outcomes Survey measure which is not a DST item (See discussion at §40.4). M+C organizations that were §1876 of the Act cost contractors in the measurement year and continuing open enrollment cost contracts must report summary data for all measures identified in Exhibit IA. The HEDIS measures Flu Shots for Older Adults, Pneumonia Vaccination Status for Older Adults, and Advising Smokers to Quit are collected through the CAHPS survey instrument. MCOs must attempt to produce every Medicare required measure, and report a numerator and denominator even if the numbers are small, i.e., the denominator is less than 30.

    b. Data Submission - NCQA will post Healthcare Organization Questionnaires (HOQ) on the NCQA web site in late February. MCOs must accurately complete the HOQ in order to have an appropriate HEDIS Data Submission Tool© (DST) posted on the NCQA web site in April. MCOs must submit HEDIS results for the measurement year using this tool and should make sure that they have sufficient computing capability to run the DST. The tool is a Microsoft Excel®-based application, modified to reflect annual changes in the HEDIS specifications. NCQA can provide more information to MCOs regarding the tool and the submission process.

MCOs will not be allowed to change data after submission to NCQA. A hard copy of the DST can be printed so MCOs can review all rates with their auditor prior to submission.

2. Patient-Level Data Analysis of data with patient-level identifiers for the numerator and denominator of each measure allows CMS to match HEDIS data to other patient-level data for special projects of national interest and research, such as an assessment of whether certain groups (e.g., ethnic, racial, gender, geographic) are receiving fewer or more services than others. These analyses will not be used for public plan-to-plan comparisons.

    a. Required Measures - MCOs must provide patient-level data identifying the contribution of each beneficiary to the denominator and numerator of every required summary measure on beneficiaries and each beneficiary's months of enrollment. Exhibit II lists the clinical Effectiveness of Care process measures (excluding the Health Outcomes Survey measure) and the Use of Services measures for which patient identifiers and member month contributions must be provided. Beneficiaries shall be identified by their individual health insurance claim (HIC) number. The HIC number is the number assigned by CMS to the beneficiary when he/she signs up for Medicare. MCOs use this number for enrollment accretions/deletions.

    b. Data Submission - NCQA expects to continue collecting patient-level data as a flat text file and will provide MCOs with the record layout and detailed examples in the spring of each year. Plans must retain data used for reporting for six years. All patient-level data are protected from public dissemination in accordance with the Privacy Act of 1974, as amended. There have been questions and concerns expressed about the provision of patient-level data, particularly with regard to behavioral health measures. Plans are accountable for providing patient-level data, unless prohibited by State law. In such cases, plans must provide CMS with appropriate documentation of the legal prohibition for CMS's consideration.

B - HEDIS Compliance Audit Requirements

Because of the critical importance of ensuring accurate data, CMS continues to require an external audit of the HEDIS measures before public reporting. MCOs are responsible for submitting audited data, according to the "Full Audit" methodology outlined in Volume 5: HEDIS Compliance Audit: Standards, Policies and Procedures.

CMS requires each MCO to contract with an NCQA Licensed Organization for a NCQA HEDIS Compliance Audit and should do so in a way that will coordinate the audit process for all sources. The licensed audit firms are listed on NCQA's web site at www.ncqa.org. CMS will require that the Licensed Organizations follow the established standards, policies and procedures in NCQA's HEDIS, Volume 5. The Full Audit is described within this reference document. The MCO must ensure that the site visit audit

team is led by a NCQA Certified HEDIS Compliance Auditor and that the auditor is present during the site visit.

In addition, the plan's chief executive officer, president, or other authorized person, such as the medical director, will be required to provide written attestation to the validity of the plan-generated data.

C - Final Audit Reports, Use and Release

Following the receipt by the MCO of the Final Audit Report from the NCQA-licensed audit firm, the MCO must make available a copy of the complete final report to the CMS ROs as needed. CMS ROs may request the report upon completion or as part of the pre-site *monitoring* visit package. In addition, the report*s* should be available for review onsite during *monitoring* visit*s*.

CMS will use the Final Audit Reports to support contract monitoring and quality improvement activities. CMS may use the assessment of the MCO's administrative and information systems capabilities that are contained in the audit report and may use the data to conduct post-submission validation. Final Audit Reports are subject to the Freedom of Information Act (FOIA). CMS will follow the FOIA regarding any release of such report and will make a determination about the release of information in each audit report on a case by case basis. Information that both the MCO and CMS deem proprietary will not be released, unless otherwise required by applicable law.

40.4 - The Medicare Health Outcomes Survey (HOS) Requirements - (Rev. 10, 08-14-02)

The Short Form (SF) 36 supplemented with additional case-mix adjustment variables will be used to solicit self-reported information from a sample of Medicare beneficiaries for the HEDIS functional status measure, Medicare Health Outcomes Survey (HOS). This measure is the first "outcomes" measure for the Medicare population. Because it measures outcomes rather than the process of care, it is primarily intended for population-based comparison purposes, by reporting unit. The HOS measure is not a substitute for assessment tools that MCOs are currently using for clinical quality improvement. Each year a baseline cohort will be drawn and 1,000 beneficiaries per reporting unit will be surveyed. The target response rate is at least 70 percent. If the contract-market has fewer than 1,000 eligible members, all will be surveyed.

Additionally, each year a cohort drawn two years *previously* will be resurveyed. The results of this re-measurement will be used to calculate a change score for the physical health and emotional well being of each respondent. Depending on the amount of expected change the respondent will be categorized as having improved, declined, or as having undergone no change in health status over the two-year period. Percentages of respondents whose health status improved, declined, and remained the same by plan will be released publicly in the year following re-measurement.

All M+C organizations and continuing cost contracts that held §1876 risk and cost contracts, as well as Social HMOs (SHMOs), PACE, and Medicare Choices demonstrations, with Medicare contracts in effect on or before January 1st of the measurement year must comply with this survey requirement.

MCOs, at their expense, are expected to contract with any of the NCQA certified vendors for administration of the survey to both the new baseline cohort and the re-measurement cohort (if the MCO participated when an earlier cohort was drawn for baseline measurement).

Contracts with vendors are expected to be in place by February 1st to ensure survey implementation by mid-March of the reporting year. Further details will be provided by NCQA, CMS's contractor, regarding organizing the survey.

To expedite the survey process, MCOs may be asked to provide telephone numbers or verify telephone numbers for the respondents unable to be identified using other means. MCOs must ensure the integrity of the data files they provide to the vendors by checking for, among other things, shifted data fields or out of range values. MCOs will be financially liable for the cost of any re-work (including but not limited to re-administration of the survey) and subsequent delay by the vendor resulting from corrupt data files transmitted to the vendor by the MCO.

Since the Health Outcomes Survey measure looks at health status over a two-year period, results from the baseline survey will not be publicly released until the year following the re-measurement. See Exhibit III for additional information.

40.5 - Medicare CAHPS Requirements for Enrollees and Disenrollees - (Rev. 10, 08-14-02)

A. Information Regarding the CAHPS Enrollee Survey

In the *f*all of each year, CMS administers the Medicare Managed Care CAHPS survey. MCOs and continuing cost contracts with contracts in effect on or before July 1st of the previous year are included. MCOs that will terminate their contracts on January 1st of the next contract year are included in this administration since they are still participating in the *f*all before their contact ends.

CMS selects the sample for each contract-market. For the Annual CAHPS Assessment Survey of Current Enrollees the sample includes a random sample of 600 members who were continuously enrolled in the contract for six months and were not institutionalized. For MCOs with fewer than 600 eligible members, all eligible members are surveyed. The survey administration mode includes two mailings with telephone follow-up of non-respondents. To conduct telephone follow-up of non-respondents, CMS requests telephone numbers from MCOs for the CAHPS sample embedded within a larger list of beneficiaries enrolled in the MCO. CMS pay*s* for the administration of the survey.

Selected results from each survey will be released to the public to facilitate plan-to-plan comparisons. Only data gathered through CMS's administration will be publicly released. These data will be disseminated to the public via Medicare Health Plan Compare (www.medicare.gov) and 1-800-MEDICARE. In the summer of each year CMS will provide the MCOs participating in the CMS administration of the CAHPS survey with detailed reports for internal quality improvement efforts, consistent with the Privacy Act (Title 5, USC, §552a).

B. Information Regarding CAHPS Disenrollment Survey

The Medicare CAHPS Disenrollment Survey process has two distinct components. The first asks beneficiaries about their reasons for leaving an M+C organization and is called the Reasons Disenrollment Survey. CMS will combine reasons for disenrolling with the annual disenrollment rates for reporting to beneficiaries. CMS is administering this component of the survey on a quarterly basis. The second component called the Assessment Disenrollment Survey includes almost all of the same questions as those in the Annual Medicare Managed Care CAHPS Assessment Survey of enrollees. The information from the Annual Disenrollment Assessment survey is combined with the results of the current enrollee survey to create a more complete picture of beneficiary experiences with Medicare managed care.

For the Annual CAHPS Assessment Survey of Disenrollees the sample rate fluctuates. The sample size will be determined by the application of the proportion of the CAHPS Enrollee Survey sample (600) to total contract enrollment, to the population of disenrollees. CMS will consider "total enrollment" to be the total enrolled population at the time that CMS pulls the sample for the CAHPS Enrollee Survey. The survey administration mode includes two mailings with telephone follow-up of non-respondents. To conduct telephone follow-up of non-respondents, CMS requests telephone numbers from MCOs for the CAHPS sample embedded within a larger list of beneficiaries enrolled in the MCO. CMS pay*s* for the administration of the survey.

The sampling size for the Quarterly Disenrollment Reasons Survey is approximately 385, or if less than 385 all disenrolled members will be surveyed. The survey administration mode includes two mailings with telephone follow-up of non-respondents. To conduct telephone follow-up of non-respondents, CMS requests telephone numbers from MCOs for the CAHPS sample embedded within a larger list of beneficiaries enrolled in the MCO. CMS is paying for the administration of the survey.

CMS provides *each* managed care organization with the information of *its* combined survey results in the late summer of the year following the survey administration. Information from the Quarterly Disenrollment Survey is provided to the managed care organizations in a preview report after the first two quarters of the survey and a final report following the annual survey completion.
