Medicare

Managed Care Manual

Department of Health and Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
5	---	10 - 40.6	---
5	---	Exhibits	---
5	---	Appendix A	---
5	---	Appendix B	---

NEW/REVISED MATERIAL --EFFECTIVE DATE: Not Applicable
IMPLEMENTATION DATE: Not Applicable

Chapter 5, Quality Assurance, this chapter describes requirements for an organization's operations and performance relating to quality measurement and improvement. It includes provisions in the Quality Assurance Performance Improvement (QAPI) and the Quality Improvement Systems for Managed Care (QISMC) documents that have been published previously on CMS' web page.

Managed Care Manual

Chapter 5 - Quality Assurance

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10 - Introduction

(Rev. 3, 10-01-01)

In June, 1998, The Centers for Medicare & Medicaid Services (CMS) now the Centers for Medicare and Medicaid Services (CMS) issued an interim final rule implementing the Medicare+Choice program (Part C of Title XVIII of the Social Security Act) as established by the Balanced Budget Act (BBA) of 1997 (P.L. 105-33). The final rule was published June 29, 2000. These regulations, contained in Part 422 of Chapter 42 of the Code of Federal Regulations, build upon requirements in the Section 1876 risk-contracting program by clarifying previous requirements and introducing certain new provisions required by law.

Subpart D 42 CFR Part 422 establishes the quality assurance and performance improvement (QAPI) requirements that Medicare+Choice Organizations (M+C Organizations) must meet under the BBA. These requirements do not apply to §1876 cost plans or §1833 Health Care Prepayment Plans. M+C network MSA plans and coordinated care plans other than Preferred Provider Organizations (PPO) plans are required to achieve compliance with these requirements through the use of CMS's Quality Improvement System for Managed Care, documented in the Interim QISMC Standards and Guidelines hereafter referred to as the "QISMC document" in this Manual. However, the requirements of §30.1.1 regarding minimum performance levels (QISMC document standard 1.1.1) do not apply to Network Medical Savings Accounts (MSA) plans.

The QISMC document is equivalent to an interim program manual and is integrated into this Chapter and several other Chapters of the Medicare Managed Care Program Manual. It represents CMS's implementation of the Medicare+Choice requirements for an organization's operation and performance in the areas of quality measurement and improvement. As the QISMC document is incorporated into the Medicare Managed Care Program Manual, at least initially, the QISMC numbering system will be retained to assist users in adapting to the new format. The various standards will be placed into the appropriate chapters of the manual and will not continue to be classified by domain.

20 - Quality Assessment and Performance Improvement Program (QAPI)

(Rev. 3, 10-01-01)

Consistent with the BBA, all M+C organizations must give priority to quality assurance and engage in activities and efforts which demonstrably improve their performance. CMS recognizes that organizations' capabilities vary in terms of sophistication, information systems and staff resources. Likewise, their capacities may differ relative to outcome and case mix measures necessary to directly compare quality efforts on a national scale. Nevertheless, the agency is committed to working together with M+C organizations toward our common goal of assuring a consistently high-quality and cost-effective standard of care through the development of mechanisms for measuring improved outcomes of health care and services.

The Medicare, Medicaid and SCHIP Benefit Improvement Protection Act (BIPA) of 2000 amended §1852 (e) (2), subsections (A) and (B) of the Social Security Act (the Act) by requiring M+C Organizations to include a separate focus (with respect to all the elements presented in

subsections A and B) on racial and ethnic minorities in the quality assurance program. Subsection A addresses requirements for M+C plans (other than a private fee-for-service plan (PFFS), a non-network Medical Savings Account (MSA) plan or a preferred provider organization (PPO)). Subsection B addresses requirements for private fee-for-service plans, non-network MSA plans and preferred provider organizations.

The quality assurance program elements presented in subsections A and/or B are as follows. The quality assurance program shall:

- Stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that the Secretary recognizes) that will permit measurement of outcomes and other indices of the quality of Medicare+Choice plans and organizations (subparagraphs A and B);
- Monitor and evaluate high volume and high risk services and the care of acute and chronic conditions (subparagraphs A and B);
- Evaluate the continuity and coordination of care that enrollees receive (subparagraphs A and B);
- Be evaluated on an ongoing basis as to its effectiveness (subparagraphs A and B);
- Include measures of consumer satisfaction (subparagraphs A and B);
- Provide the Secretary with access to information collected as may be appropriate to monitor and ensure the quality of care provided (subparagraphs A and B);
- Provide review by physicians and other health care professionals of the process followed in the provision of such health care services (subparagraph A only);
- Provide for the establishment of written protocols for utilization review, based on current standards of medical practice (subparagraph A only);
- Have mechanisms to detect both underutilization and overutilization of services (subparagraph A only);
- After identifying areas for improvement, establish or alter practice parameters (subparagraph A only);
- Take action to improve quality and assess the effectiveness of such action through systematic follow-up (subparagraph A only);
- Make available information on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options (in such form and on such quality and outcomes measures as the Secretary determines to be appropriate) (subparagraph A only);
- Insofar as it provides for the establishment of written protocols for utilization review, base such protocols on current standards of medical practice (subparagraph B only); and

- Have mechanisms to evaluate utilization of services and inform providers and enrollees of the results of such evaluation (subparagraph B only).

20.1 - Administration of the QAPI Program (QISMC Document Standard 1.6)

(Rev. 3, 10-01-01)

The organization's Quality Assurance Performance Improvement (QAPI) program is administered through clear and appropriate administrative arrangements (QISMC document standard 1.6.1)

In most organizations, the QAPI program is administered by a multi-disciplinary committee that includes both clinical and administrative personnel. Other arrangements are permissible, so long as the organization can demonstrate that clearly identified individuals or organizational components are responsible for each aspect of QAPI activity and that effective organizational structures are in place to assure communication and coordination. In either case, the organization's QAPI program description must show the role, structure, staffing, and function of each participating component and the interrelations among components. There must be evidence that the M+C Organization has an on-going quality assessment improvement program. Administrative meetings must be held at regularly scheduled intervals and adequately attended. Appropriate intervals for meetings must be stated in the organization's policy and procedures. There should be evidence that issues raised are appropriately followed up in subsequent meetings or through other means, and that deliberations lead to actual directions to committee staff, other organization personnel, and/or affiliated providers.

The policy making body oversees and is accountable for the QAPI program (QISMC document standard 1.6.1.1)

The policy making body is defined as the governing body of the organization or a committee of senior executives that exercises general oversight over the organization's management, policies, and personnel. The policy making body as a whole may oversee the QAPI program, or it may designate a committee to perform this function. There must be evidence that the policy making body approves changes in the QAPI program description and approves the annual workplan. It must receive and review periodic reports on QAPI activities. The policy making body must review the annual evaluation required under the QISMC document standard 1.6.2 and take action on any resulting recommendations.

A designated senior official is responsible for QAPI program administration. (QISMC document standard 1.6.1.2)

There must be a single official responsible for the overall functioning of the QAPI program. This may be the organization's chief executive officer, chief medical officer or director, or another senior official who has direct authority to commit organizational resources to the QAPI effort. If the responsible official is not the chief medical officer, the organization must show, through the QAPI program description or other documentation, that the chief medical officer has substantial involvement in QAPI activities, including participation in meetings of the committee or other coordinating structure. Some organizations have a separate official who performs the functions of a medical director for mental health and substance abuse services; it is acceptable for this officer to oversee QAPI activities in these areas.

Employed or affiliated providers and enrollees actively participate in the QAPI program. (QISMC document standard 1.6.1.3)

Providers must participate in QAPI activities, including provision of access to medical records and cooperation with data collection activities. If affiliated providers are not represented on the organization's QAPI committee or other core coordinating structure, the organization must form a clinical subcommittee or other advisory group to assure that clinicians actively participate in key activities, including: selecting and prioritizing QAPI projects, developing indicators, analyzing study results, identifying and proposing solutions to problems, and aiding in communication of QAPI activities and results to other providers.

There is formal and ongoing communication and collaboration among the policy making body that oversees the QAPI program and the other functional areas of the organization, e.g., health services management and member services. (QISMC document standard 1.6.1.4)

Interaction with the QAPI program is specifically referred to in the following standards or related guidelines:

- QISMC document standard 2.4, Resolution of Enrollee Issues,
- QISMC document standard 3.3.2, Service Authorization Process,
- QISMC document standard 3.4.1, Development of Practice Guidelines,
- QISMC document standard 3.5.1.2, Recredentialing of Practitioners.

The organization formally evaluates, at least annually, the effectiveness of the QAPI program strategy, and makes necessary changes. (QISMC document standard 1.6.2).

The evaluation should assess both progress in implementing the QAPI strategy and the extent to which the strategy is in fact promoting the development of an effective QAPI program. It should consider whether activities in the organization's work plan are being completed on a timely basis or whether commitment of additional resources is necessary. The evaluation should include recommendations for needed changes in program strategy or administration. These recommendations must be forwarded to and considered by the policy making body of the organization (see QISMC document standard 1.6.1.1).

Note that this standard does not require that an organization make major revisions in its QAPI strategy each year.

20.1.1 - Evaluation of the QAPI Administration Program

(Rev. 3, 10-01-01)

Evaluation of the QAPI administration program will be based on compliance with the standards as specified in this section. The standards are also contained in the Monitoring Guide. The Monitoring Guide provides the reviewer with examples of specific operational areas to be reviewed and how to review those areas frequently referred to as the methods of evaluation (MOE).

20.2 - Health Information System

(Rev. 3, 10-01-01)

The organization maintains a health information system that collects, integrates, analyzes, and reports data necessary to implement its QAPI program. (QISMC document standard 1.5)

The organization's health information system is central to its efforts to manage patient care and to assess and improve health care quality and outcomes. Every organization should be able to collect and integrate data from all components of its network in order to develop a comprehensive picture of enrollee needs and utilization, including changes in these over time. It should be able to use these data in its quality assessment and performance improvement program, as well as in other management activities.

While there are numerous reasons for organizations to improve their information system capacities, the overarching goal for both CMS and State Medicaid agencies is to improve patient care. For this reason, the QISMC document standard 1.5 focuses on the system's capacity to provide the information required to conduct an effective QAPI program of performance improvement projects and reporting on standard measures that meets the requirements of other standards in this domain.

Although an encounter data system may often be the most efficient means of meeting the requirements of this standard, the organization may use any methods or procedures for data collection, so long as it can demonstrate that its system achieves the objectives of this standard. The organization must be able to document that each of its QAPI activities is based on complete and valid information, however this information is compiled.

The system collects data on enrollee and provider characteristics, and on services furnished to enrollees, as needed to guide the selection of performance improvement project topics (QISMC document standard 1.4.1), and to meet the data collection requirements for performance improvement projects. (QISMC document standards 1.4.3 and 1.5.1).

Measurement of compliance with this standard will be an integral part of assessment of compliance with the QISMC document standards 1.4.1 and 1.4.3.

Topic Selection

The system must provide information needed to identify priority areas for quality improvement. An organization's system should be able to generate such information as:

- Longitudinal profiles of treatment or services furnished to enrollees with a specific diagnosis;
- Profiles of referral services ordered by each primary care practitioner;
- Statistical reports on the prevalence of different conditions or diagnoses among a specific group of enrollees, such as Medicare beneficiaries; and
- Prescription medication usage by type of enrollee, by diagnosis, or by prescribing practitioner.

However, review will focus not on these general system capacities, but on the specific methods adopted for prioritizing topics and on the extent to which the method was applied using valid data.

For example, an organization may indicate that it selected a given condition for a QAPI project because the condition affected 30 percent of its Medicare enrollees. If so, it must be able to show how it knows the prevalence of different conditions among its Medicare enrollees. If its administrative data set has incomplete data from half its providers, the organization cannot make this assertion, unless the information has been obtained through sampling or other means. Again, the standard does not impose a general requirement that organizations be able to report the prevalence of all conditions or diagnoses for all enrollees. It requires that the organization have the specific information it needs to carry out its own particular approach to quality measurement and improvement.

Data Collection for QAPI projects

The organization must be able to collect valid baseline and follow-up measurements for quality indicators selected for QAPI projects. The standard does not require that any of these processes be carried out through any specific type of information system. However, the organization must be able to show how each process was performed and be able to show that all reasonable steps have been taken to assure that the data are complete, accurate and reliable. Any project for which an organization cannot demonstrate compliance with this standard cannot be counted towards the requirements of QISMC standards 1.3.2 or 1.3.3 for completed projects in identified focus areas.

The organization ensures that information and data received from providers are accurate, timely and complete. (QISMC document standard 1.5.2.1)

This standard does not require that organizations receive encounter reporting. However, if the organization relies on encounter reporting or aggregate data reporting for any QAPI activity (e.g., counting enrollees who had breast cancer screenings), then it must have an ongoing process for assuring the accuracy and completeness of the data, whether compiled in its own facilities or reported by outside contractors.

The organization reviews reported data for accuracy, completeness, logic, and consistency. (QISMC document standard 1.5.2.1)

If the organization receives individual encounter data directly from providers, it must have a system for comparing reported data to a sample of medical records, to verify the accuracy of reporting or transmission. The objective is to assure that, to the extent feasible, there is a one-to-one correspondence between items included in an organization’s summary data and specific services entered in medical records or equivalent source documents. (That is, all performed services were reported, and no service not performed was reported.)

If the organization receives aggregate information, instead of individual patient encounter reporting, from any provider, the organization must approve the provider's own system for collecting, recording, aggregating, and reporting the data, and must assure that the provider has its own mechanisms for validation.

Identified deficiencies in reported data must be addressed through provider education or other corrective action. The organization's process for recredentialing or recontracting with practitioners and providers, under the QISMC document standard 3.5, must specify the actions to be taken in the event of ongoing failure by a contractor to meet the organization's health information standards.

The organization, or any contractor developing aggregate data from individual encounter reporting, must have mechanisms to assure that reported data contain all data elements required by the organization. Data must be subject to logic edits to assure, for example, that reported services are consistent with the place of service or type of provider; that the number of services performed is consistent with the span of time (e.g., 20 physician hospital visits in a 2-day span of time is a potential inconsistency); or that procedures or diagnoses applicable only to enrollees of a particular age or sex are not reported for other enrollees. Finally, the integrity of data entry must be assured.

Service data are collected in standardized formats to the extent feasible and appropriate. (QISMC document standard 1.5.2.2)

Standard formats are needed to assure that data elements are reported uniformly by all providers, and that reports from multiple sources are comparable and can be reliably merged into more comprehensive reports. Verification of conformity to the organization should be included in the validation required under the QISMC document standard 1.5.2.1.

The Health Insurance Portability and Accountability Act of 1996 includes privacy and data utilization provisions that will apply to managed care organizations and providers. Until these requirements take effect, each organization remains free to specify its own formats. However, because national standardization is forthcoming, an organization should have a plan for progressing toward commonly accepted data formats as rapidly as possible. In the interim, the use of organization-specific formats has a bearing on evaluation of the organization's compliance with other standards in this section. For example, an organization may need to validate data from contractors more carefully than it would if contractors could use the coding they routinely use in reporting to other payers. In addition, the organization may have difficulty calculating and reporting standardized performance measures that are keyed to non-standard coding.

20.3 - Evaluation of Health Information System

(Rev. 3, 10-01-01)

Evaluation of the health information system will be based on compliance with the standards as specified in the CMS M+C Monitoring Guide. The quality review section of the CMS M+C Monitoring Guide is based on the requirements in this Manual section and provides the reviewer with examples of specific operational areas to be reviewed and how to review those areas, frequently referred to as the methods of evaluation (MOE).

30 - Quality Assessment and Performance Improvement Projects

(Rev. 3, 10-01-01)

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. M+C Organizations will have considerable discretion to select focus areas addressing specific health care and service needs of their populations. 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. 3, 10-01-01)

30.1.1 - General

(Rev. 3, 10-01-01)

The organization must:

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

- Conduct performance improvement 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.

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 performance improvement 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 - Performance Improvement Projects

(Rev. 3, 10-01-01)

Performance improvement projects are projects conducted under the organization's QAPI program address 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 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 performance improvement projects. In the first two years, review will focus on whether an organization has initiated performance improvement projects. 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.

Project topics and the quality indicators used to assess each project are chosen either by the organization itself, by CMS (for Medicare) or by the State Medicaid agency (for M+C Organizations contracting with Medicaid) either for an individual organization or on a national or Statewide basis. (QISMC document standard 1.3.1.2.)

The organization will be required to conduct projects relating to certain topics selected by CMS or, if the M+C Organization has a contract for Medicaid, by the State Medicaid agency, as well as projects relating to topics of its own choosing, as outlined in the QISMC document standards 1.3.2 and 1.3.3.

A 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 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 project year begins on a date established by CMS (for Medicare). (QISMC document standard 1.3.1.4)

Each newly contracting M+C Organization is expected to have initiated a national and M+C Organization selected project before the end of their second contract year. For example, organization A signs a contract with CMS on January 1, 2000, and organization B signs a contract August 1, 2000. For both organizations, the second contract year will be 2001, initiation of a project is not required in year 2002, the first year of the contract. This extended time frame allows new M+C Organizations to enroll beneficiaries, and accumulate data prior to the initiation of a project, and is similar to HEDIS requirements.

All subsequent project years begin on the anniversary of the beginning of the first project year. Note that project years are independent of the CMS review cycle and there may be instances where a M+C Organization completes a 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 project may be included in the review for the preceding year if all necessary documentation is available for the CMS review.

30.1.3 - Phase-in Requirements

(Rev. 3, 10-01-01)

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

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

By the end of the M+C Organization's second contract year, the organization has initiated at least two projects addressing the focus areas specified under the QISMC document standards 1.3.4, 1.3.5.1 and/or 1.3.5.3. For an organization contracting with Medicare, one of those projects relates to a topic and involves quality indicators chosen by CMS. (QISMC document standard 1.3.2.1.1)

By the end of the third contract year, the M+C Organization has initiated at least two additional projects addressing focus areas specified by the QISMC document standards 1.3.4, 1.3.5.1 and/or 1.3.5.3. For an organization contracting with Medicare, one of those projects relates to a topic and involves quality indicators chosen by CMS. (QISMC document standard 1.3.2.1.2)

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

By the end of the second contract year, the new M+C Organization has initiated at least three projects addressing the focus areas specified under the QISMC document standards 1.3.4, 1.3.5.1 and/or 1.3.5.3. One of those projects relates to a topic and involves quality indicators chosen by CMS. The second project relates to a topic and involves quality indicators chosen by the organization itself. The third project relates to a topic and involves quality indicators chosen either by the State Medicaid agency or the organization. (QISMC document standard 1.3.2.2.1)

By the end of the third contract year, the new M+C Organization has initiated at least three additional projects addressing the focus areas specified under the QISMC document standards 1.3.4, 1.3.5.1 and/or 1.3.5.3. One of those projects relates to a topic and involves quality indicators chosen by CMS. The second project relates to a topic and involves quality indicators chosen by the organization itself. The third project relates to a topic and involves quality indicators chosen either by the State Medicaid agency or the organization. (QISMC document 1.3.2.2.2)

A 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 2001 QAPI Project, the baseline data collected may be from either year 2000 or 2001. Review for the first year will therefore focus on compliance with the QISMC document standards 1.4.1 through 1.4.3.

For those organizations that contract with Medicare and Medicaid, if the State Medicaid Agency has not adopted the QISMC document standards, then the organization must initiate the two required Medicare projects (national and M+C Organization selected). This does not exempt the organization from conducting other projects as required by their State.

30.1.4 - Ongoing Requirements (QISMC Document Standard 1.3.3)

(Rev. 3, 10-01-01)

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 would be the second year after the 2-year phase-in period), and each subsequent year, at least two of the organization's projects have achieved significant and sustained improvement in the focus areas specified in the QISMC document standards 1.3.4, 1.3.5.1 and/or 1.3.5.3. One of those projects is related to a topic and quality indicators chosen 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 three of the organization's projects have achieved significant and sustained improvement in the focus areas specified in the QISMC document standards 1.3.4, 1.3.5.1 and/or 1.3.5.3. One of those projects has related to a topic and involved quality indicators chosen by CMS. The second project has related to a topic and involved quality indicators chosen by the organization itself. The third project has related to a topic and involved quality indicators chosen either by the State Medicaid agency or the M+C Organization.

The purpose of 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 a specified area and that it has sustained the improvement over time. These focus areas may be in either clinical or non-clinical areas, as specified in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3. 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 either of its required annual QAPI projects if that existing project meets the requirements of this Manual and the QISMC document standards. They must, however, conduct a remeasurement on 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 Medicare Optional 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, and
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.

In order for the Medicare National QAPI Projects to be accepted the M+C Organization must also use the CMS specified indicators.

M+C Organization should contact their CMS RO (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. 3, 10-01-01)

M+C Organizations should initiate 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 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. 3, 10-01-01)

The QISMC document standard 1.3.1.2 allows CMS (for Medicare) and State Medicaid agencies (for Medicaid) to specify project topics and quality indicators to be used by a particular plan, if CMS or a State 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. 3, 10-01-01)

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

Projects in this area 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 plan go beyond examining how it evaluates compliance with its own standards, but requires the plan to identify ways to exceed its own standards and continue to identify ways to improve the ability of consumers to receive the services that they need in a timely manner. For example, a 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.

30.2 - Attributes of Performance Improvement Projects (QISMC Document Standard 1.4)

(Rev. 3, 10-01-01)

An individual 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 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 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

(Rev. 3, 10-01-01)

Within each focus area, the organization selects a specific topic or topics to be addressed by a 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.

Sources of Information

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 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.

Organizations Using Physician Incentive Plans

An organization that adopts a physician incentive plan that places physicians at substantial financial risk (as defined in 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. 3, 10-01-01)

Assessment of the 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 Assurance (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. Because the availability of such data will vary by topic and by population, this standard does not set a fixed number of focus areas for which benchmarks must be adopted.

However, every organization should be able to establish benchmarks for at least some project topics (e.g., immunizations or diabetic care).

Data Collection and Methodology

Assessment of the 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 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. 3, 10-01-01)

The 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 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 national Medicare 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 project developed by the organization itself, a local, State or national benchmark level of performance that is defined in advance by the 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, 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.

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

When a 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 QISMC1.4.4.1, 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.[1] 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 their actual improvement will be underestimated if they use a smaller sample. If an organization is experiencing difficulty in determining sample size or methodology, they should contact a statistician 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)

It is essential that the measures of performance before and after the 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. 3, 10-01-01)

The 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 a 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 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 projects and projects that have been concluded but for which the repeat measurement has not yet been conducted.

30.3 - Types of Projects

(Rev. 3, 10-01-01)

M+C Organizations are required by contract to complete two QAPI projects per year. One project must be on a topic chosen by CMS, referred to as the national project, while the other project may be one of each organization's own choosing, referred to as the M+C Organization selected project.

30.3.1 - National Projects

(Rev. 3, 10-01-01)

The national projects are intended to 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 projects will be created and defined with input from beneficiaries, industry representatives, and members of the provider community.

Some organizations may have existing projects that could be modified to meet the requirements of the national projects. Those organizations wishing to utilize projects currently underway may do so if:

1. They follow the requirements in this manual chapter;
2. Utilize the quality indicators as described for each national project; and
3. Conduct a re-measurement in the applicable QAPI initiation year to establish a new baseline against which to assess their improvement.

For technical assistance regarding the conduct of a QAPI project, please contact your State PRO.

See Appendix A for listing of National Projects.

30.3.2 - M+C Organization Selected Projects

(Rev. 3, 10-01-01)

As indicated previously, plans that only contract with Medicare must conduct two projects a year:

- A national project defined by CMS, and
- A second project selected by the M+C Organization.

All the manual and QISMC document standards apply to both the national and M+C Organization selected projects, except where an exclusion is specifically indicated.

30.3.3 - Other Projects

(Rev. 3, 10-01-01)

The projects described below are subsets of the national and M+C Organization selected projects.

Special Projects

CMS (for Medicare) or the State Medicaid agency for M+C Organizations contracting with Medicaid, may require an organization to conduct particular projects that are specific to the organization and that relate to topics and involve quality indicators of CMS or the State Medicaid agency'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 agency 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 agency (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.

Collaborative 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 agencies have encouraged collaborative efforts, under which several contracting organizations undertake a joint quality improvement project addressing a common topic. For Medicare, PROs are not only a convening structure for national performance improvement projects, but they are also a regional presence for convening local collaborative performance improvement projects. These standards would not preclude such collaborative efforts for M+C Organizations contracting with Medicare and Medicaid .

Multi-Year Projects

If a 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.

An organization may continue a 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 agency 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 organization must conduct other projects that achieve improvement more rapidly, because of the requirement that improvement be achieved in two areas 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 three 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 project. If the M+C Organization collaborates with a PRO 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. 3, 10-01-01)

How to Make a Request for Approval

A standardized request form will be available on the CMS.hhs.gov web site. The M+C Organization will 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, and CMS CO and RO.

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.

CMS may send out surveys regarding QAPI topics and completion dates. Such surveys are for informational purposes only. Supplying this information to CMS does not constitute an approval for a project. A 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 a M+C Organization notify the agency of this type of change. However, a M+C Organization may choose to notify their CMS RO representative of the change.

30.4 - Evaluation of QAPI projects

(Rev. 3, 10-01-01)

Reviewers

The QAPI evaluations will be completed by four contractors, known as the Medicare+Choice Quality Review Organizations (M+CQRO). The M+CQRO are four PROs - 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 ROs in the design, development, implementation and evaluation of their quality assessment and performance improvement programs.

PROs may provide technical assistance to M+C Organizations in their State in the development and implementation of QAPI projects. To prevent potential conflict of interest, the M+CQRO's will not review QAPI projects within their own states. Thus, the four contractors listed above will provide technical assistance to M+C Organizations in their own respective 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 level or less. The M+C Organization will be allowed to segment their single H-number into smaller units, but not to report on a unit larger than the H-number. Each segment will then have its own unique password and code for access into the CMS data base. The report will be in a web-based format, which will be password protected. The information will be directly submitted into the CMS Health Plan Management System (HPMS) database. The M+C Organization will be able to determine what information they consider proprietary and CMS will not release any proprietary information.

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. However, only one indicator and intervention is required in this report. If a 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 their CMS RO representative with a report on each QAPI project. 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

The M+C Organization will have 90 days from the completion of their project to submit its Project Completion Report electronically 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.

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.

Even if the organization has not achieved significant and sustained improvement, it must report by the end of the 3-year cycle. The M+CQROs will evaluate the project and make recommendations as to how the M+C Organization can best achieve the required significant improvement (see CAP example #2).

Other tools

In addition to the Project Completion 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 demonstrable and sustained improvement were determined to be the most significant. The scoring is weighted based on the significance placed on particular elements.

All tools will be 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 a 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 a 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.

Review of QAPI project

After the M+CQRO reviewers evaluate a completed QAPI project, they will list the strengths and weaknesses of the project as well as any recommendations or suggested corrective actions in a Project Review Report.

Project Review Report

The Project Review Report will be sent to the CMS RO representative. The report will include the final score of the project based on our scoring methodology. If there are any deficiencies, the M+CQRO will recommend that the CAP elements be completed to meet CMS QAPI requirements. The CAP elements will be correlated to the scores on the project.

The RO representative will review the report and add any regional comments or additions. They will then forward the final report to the M+C Organization in the same manner that they communicate the results of a site visit report.

In cases where a CAP has been required, if the M+C Organization concurs with the CAP elements, it will develop a response to each CAP element and forward the response to the RO staff. If the M+C Organization does not concur with the CAP, it must respond in writing to the CMS RO representative, identifying and explaining the issues.

If the M+C Organization wishes to discuss the findings from the project or the CAP, it must contact their 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 a resolution cannot be achieved, the issue will then be forwarded to CMS CO by the RO representative. The issue will then be reviewed and a final decision reached.

Possible Examples of CAP Elements

- Sampling methodology is inappropriate - The M+C Organization will have to re-sample and re-calculate final figures for the project under review. The M+C Organization may be required to collaborate with the PRO 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 PRO 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 PRO in future projects and repeat the project as its next M+C Organization selected study.

- 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 - The Medicare + Choice Deeming Program

This section discusses the Medicare + Choice Deeming Program. Regulations that govern the program are set forth in Part 42, Sections 422.156, 422.157, and 422.158 of the Code of Federal Regulations. The regulations are based on §1852 (e) (4) of the Social Security Act (the Act), which was amended by the Balanced Budget Act of 1997 (BBA) and the Balance Budget Refinement Act of 1999 (BBRA). The BBA directed HCFA, now CMS to establish and oversee a program that allows private, national accreditation organizations to "deem" that a Medicare + Choice organization (M+C Organization) is in compliance with certain Medicare requirements. The BBRA expanded the scope of deeming from two to six areas and specified that the applicant could seek approval for any or all of the six areas.

35.1 - Terminology

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 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

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].

To review the deeming requirements per deeming area, please see http://www.cms.gov/medicare/deeming.htm.

35.3 - General Rule

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

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).

35.4.1 - Deemed Status and CMS Surveys

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

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 Organizations 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

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 they can demonstrate, through the application process, that their accreditation program is at least as stringent as CMS's, and they meet 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

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 need to refer the matter to central office deeming staff who will, in turn, contact the appropriate accrediting organization.

Equivalency Review

CMS will need to 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.

35.5.2 - Enforcement Authority

CMS retains the authority to initiate enforcement action (including intermediate sanctions that are listed in subpart O, §422, Part 42 of the Code of Federal Regulations) against any M+C Organization that we determine, on the basis of our own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

35.5.3 - Notice of Intent to Withdraw Approval

If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that the accreditation organization is not meeting the requirements specified in subpart D of §422, Part 42 of the Code of Federal Regulations, CMS will give the accrediting organization written notice of our intent to withdraw approval.

CMS may withdraw an accreditation organization's approval for deeming authority at any time, if we determine that:

- Deeming based on accreditation no longer guarantees that the M+C Organization meets the M+C requirements and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees and constitutes a significant hazard to the public health; or
- The accreditation organization has failed to meet the obligations specified in §35.6.1of this section, which are based on §§422.156 and 422.158 of the Code of Federal Regulations.

35.6 - Obligations of Accrediting Organizations with Deeming Authority

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

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. The BBRA prohibited CMS from requiring an accrediting organization to seek deeming authority for all six of the deeming areas. An accrediting organization can apply for deeming authority for any or all of the deeming categories. 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. Materials to apply for HMO and PPO deeming authority were sent to interested 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 your accreditation survey teams;

- The education and experience requirements surveyors must meet to participate in your 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 they 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 State 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 they were accredited (if denied, the date they were denied), and the level (category) of accreditation they 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 State. (They must indicate if the 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 they 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 them 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.

35.6.2 - Application Notices

Proposed Notice

Each application will be reviewed for completeness. Approximately 60 days after an application has been determined to be complete, CMS will publish a proposed notice in the "Federal Register" . This notice will announce that CMS has received an application from the accreditation organization and is considering granting the organization's application for M+C Organization deeming authority. The proposed notice will also describe the criteria that CMS will use in evaluating the applications. CMS will provide a 30-day period for the public to comment on the proposed notice.

Final Notice

The BBRA specified that after an application is determined to be complete, CMS has a 210-day period to review the application and the comments from the proposed notice. At the end of the 210 days, CMS will publish a final notice in the "Federal Register" indicating whether we have granted the accreditation organization's request for approval. If CMS has granted the request, the final notice will specify the effective date of the deeming authority and the term of approval for deeming authority, which may not exceed six years.

Notice of Determination

CMS must also give the accreditation organization, within 210 days of receipt of its completed application, a formal notice that:

1. States whether the request for approval has been granted or denied;

2. Provides the rationale for any denial; and

3. Describes the reconsideration and reapplication procedures.

(Please see §35.7 information on a reconsideration of adverse determinations.)

35.6.3 - Withdrawing an Application

An accreditation organization may withdraw its application for approval at any time before it receives the formal notice of determination specified above.

35.6.4 - Reporting Requirements

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 their 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, they 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 their accredited M+C Organizations within 10 days.

4. Accrediting organizations must provide, on an annual basis, summary data that will 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 they plan to alter, within a timeframe that CMS will specify in the notice of change, their 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.

35.7.0 - Reconsideration of Application Denials, Removal of Approval of Deeming Authority, or Non-Renewals of Deeming Authority

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

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 not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

35.7.2 - Informal Hearing Findings

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 numbered findings of fact; and
- The legal conclusions of the hearing officer.

35.7.3 - Final Reconsideration Determinations

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" .

35.7.4 - Request for Approval of Deeming Authority Following a Denial

An accreditation organization that has requested reconsideration of CMS's denial of its request for approval may not submit a new request until the reconsideration is administratively final. An accreditation organization that has received notice of denial of its request for approval may submit a new request, if it:

1. Has revised its accreditation program to correct the deficiencies on which the denial was based;
2. Can demonstrate that the M+C Organizations that it has accredited meet or exceed applicable Medicare requirements; and
3. Resubmits the application in its entirety.

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. 3, 10-01-01)

40.1 - Background

(Rev. 3, 10-01-01)

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 document, 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.

Table - Program Requirements

Contract Year	Sampling Frame / Period	Dates for Participation Eligibility	Minimum Sample Size	Market Area Reporting	Financial Responsibility	Demon-strations	Mergers and Acquisitions	Cost Contract Reporting	Due Dates
HEDIS and HEDIS audit	Services delivered in measurement (previous) year (and earlier for some measures)	First Medicare Enrollment on Jan. 1 of prev. year or earlier. Minimum Medicare enrollment of 1,000 as of July 1 in previous year	Measure specific (MCOs must report all CMS-required Medicare measures according to instructions)	Yes	MCO pays for external HEDIS Audit	Yes, as specified here-in	Reporting by surviving MCO only	Report Cost Contract Measures Only	MCO must submit Audited Summary and Patient-Level Data by June 28.
Health Outcomes Survey	Members continuously enrolled 6 months prior to adminis-tration of survey	Medicare contract in place no later than Jan. 1 of previous year	1000 (If less than 1000 enrollees, all members must be surveyed.)	Yes	MCO pays for NCQA-certified vendor to administer survey	Yes (See section on demonstra-tions)	Reporting of surviving MCO's membership only	Yes	MCO must contract with NCQA certified vendor before Feb. 1 of reporting (current) year
Annual CAHPS: Assessment Survey Current Enrollees	Members continuously enrolled 6 mo. prior to July 1 of measurement year	Medicare contract in place no later than July 1 of previous year	600 (If less than 600, all members will be surveyed.)	Yes	CMS pays for survey administration	Yes (See section on demonstra-tions)	Reporting of surviving MCO's membership only	Yes	CMS will conduct survey in the Fall.

Contract Year	Sampling Frame / Period	Dates for Participation Eligibility	Minimum Sample Size	Market Area Reporting	Financial Responsibility	Demon-strations	Mergers and Acquisitions	Cost Contract Reporting	Due Dates
Annual CAHPS: Assessment Survey Disenrollees	From May - July of the measurement year members enrolled for 6 months prior to disenrolling	Medicare contract in place no later than July 1 of previous year	Varies, see page for specifics	Yes	CMS pays for survey administration	Yes (See section on demonstra-tions)	Reporting of surviving MCO's membership only	Yes	CMS will conduct survey in the Fall.
Quarterly CAHPS Disenroll - ment Reasons Survey	Members who have disenrolled during previous quarter	Medicare contract in place no later than Jan. 1 of previous year	Approxima tely 385, (If less than 385, all disenrolled members will be surveyed)	No	CMS pays for survey administration	Yes (See section on demonstra-tions)	Reporting of surviving MCO's membership only	Yes	CMS will conduct survey quarterly.

40.2 - Specifics Applicable to CAHPS and HEDIS

(Rev. 3, 10-01-01)

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 chapter 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. (1). Reporting Requirements

    a. HEDIS - A MCO must report HEDIS measures for their 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 in §40.2(C)(13) 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 State in more than one unit, to use the accreditation units, if feasible. We will need to ensure that a sub-State 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 State.

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 State 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 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 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	Yes	Yes	No	No

Program				
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. 3, 10-01-01)

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 make the data available in a timely manner for beneficiary information. MCOs must submit summary measures, after completing the NCQA HEDIS Compliance Audit™ required by Medicare, by the end of June of each reporting year. MCOs must submit HEDIS patient-level data at the same time. CMS is requiring 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 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 Questionaires (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 their 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 they may request it as part of the pre-site visit package. In addition, the report should be available for review onsite during the visit.

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. 3, 10-01-01)

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 ago 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. 3, 10-01-01)

A. Information Regarding the CAHPS Enrollee Survey

In the Fall of each year, CMS administers the Medicare Managed Care CAHPS survey. M+C 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 Fall 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 is paying 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 their own 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 is paying 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 the managed care organizations with the information of their 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.

40.6 - Minimum Performance Levels and Performance Goals

While provisions at 42 CFR 422.152(c) permit CMS to establish minimum performance levels which must be met by contracting organizations, CMS has not yet established these levels. To establish minimum performance levels CMS must assure that organizations have had sufficient experience reporting specific measures on which levels would be set. When the accuracy and

validity of submissions over time can be determined, CMS will be able to establish not only minimum performance levels but also set benchmarks for MCOs to achieve as specific goals.

Contacts:

1	HEDIS Technical Specifications and Reporting and HEDIS Compliance Audit	MCOs should address all questions or requests for clarifications about the HEDIS Technical Specifications and audit to NCQA's technical information line (202) 955-5697 or E-mail hedis@ncqa.org.
		Questions about Medicare HEDIS not resolved through NCQA can be directed to Richard Malsbary at (410) 786-1132 in CMS's Center for Beneficiary Choices. When contacting CMS, MCOs should be prepared to tell CMS both the advice that they received from NCQA and the individual at NCQA with whom they spoke.
2	HOS	For technical questions regarding the Medicare Health Outcomes Survey, please contact Chris Haffer in CMS's Center for Beneficiary Choices at (410) 786-8764. Questions relating to the vendors or survey protocol should be addressed to Oanh Vuong at NCQA at (202) 955-1777 or vuong@ncqa.org.
3	CAHPS	For technical questions regarding the Annual Current Enrollee Assessment Medicare CAHPS, please contact Amy Heller at (410) 786-9234 or Lori Teichman at (410) 786-6684 of CMS’s Center for Beneficiary Choices or email CAHPS@cms.hhs.gov. For the Annual Disenrollee Assessment and the Quarterly Reasons Medicare CAHPS, please contact Chris Smith-Ritter at (410) 786-4636 or email CAHPS@cms.hhs.gov.
4	Demonstrations	For questions regarding policy and technical questions on the demonstration projects contact the assigned CMS project officer.

Exhibits

(Rev. 3, 10-01-01)

Exhibit I - Required HEDIS Measures For Medicare Reporting For Summary Data

Effectiveness of Care

Anti-depressant Medication Management

Cholesterol Management After Acute Cardiovascular Events

Breast Cancer Screening

Beta Blocker Treatment After A Heart Attack

Comprehensive Diabetes Care

Follow-up After Hospitalization for Mental Illness

Controlling High Blood Pressure

Medicare Health Outcomes Survey

Access to/Availability of Care

Adults' Access to Preventive/Ambulatory Health Services

Availability of Language Interpretation Services, Parts I & II

Health Plan Stability

Years in Business/Total Membership

Practitioner Turnover

Use of Services

Frequency of Selected Procedures

Inpatient Utilization - General Hospital/Acute Care

Ambulatory Care

Inpatient Utilization - Non-Acute Care

Mental Health Utilization - Inpatient Discharges and Average Length of Stay

Mental Health Utilization - Percentage of Members Receiving Inpatient, Day/Night and Ambulatory Services

Chemical Dependency Utilization - Inpatient Discharges and Average Length of Stay

Chemical Dependency Utilization - Percentage of Members Receiving Inpatient, Day/Night and Ambulatory Services

Outpatient Drug Utilization (for those with a drug benefit)

Health Plan Descriptive Information

Board Certification/Residency Completion

Total Enrollment by Percentage

Enrollment by Product Line (Member Years/Months)

Reporting Clarifications

The following HEDIS measures will not be required to be submitted:

Health Plan Descriptive Information:

Practitioner Compensation

Arrangements with Public Health, etc.

Exhibit IA - Continuing Cost Contracts: Required HEDIS Measures For Medicare Reporting For Summary Data

Effectiveness of Care

Anti-depressant Medication Management

Cholesterol Management After Acute Cardiovascular Events

Breast Cancer Screening

Beta Blocker Treatment After A Heart Attack

Comprehensive Diabetes Care

Follow-up After Hospitalization for Mental Illness

Controlling High Blood Pressure

Medicare Health Outcomes Survey

Access to/Availability of Care

Adults' Access to Preventive/Ambulatory Health Services

Availability of Language Interpretation Services, Parts I & II

Health Plan Stability

Years in Business/Total Membership

Practitioner Turnover

Use of Services

Ambulatory Care

Outpatient Drug Utilization (for those with a drug benefit)

Health Plan Descriptive Information

Board Certification/Residency Completion

Total Enrollment by Percentage

Enrollment by Product Line (Member Years/Months)

Exhibit II - Submitting Patient-Level Data

Required Measures

MCOs must provide the patient identifier, or HIC number, for all beneficiaries included in the summary data. MCOs must submit patient-level data by reporting unit. The HIC number is assigned by CMS to the beneficiary when s/he signs up for Medicare, and MCOs use this number for accretions and deletions. In addition to the patient identifier, MCOs also must provide the member month contribution for each beneficiary and indicate how each beneficiary contributed to the calculation of the following summary measures.

NOTE: Section 1876 cost contracts (whether or not they convert to become an M+C MCO in the reporting year) should only report patient-level data for the summary measures that are listed in Attachment I.A for the following three domains.

1 - Effectiveness of Care

Breast Cancer Screening

Beta Blocker Treatment After A Heart Attack

Comprehensive Diabetes Care

Follow-up After Hospitalization for Mental Illness

Anti-depressant Medication Management

Cholesterol Management After Acute Cardiovascular Events

Controlling High Blood Pressure

2 - Access/Availability of Care

Adults' Access to Preventive/Ambulatory Health Services

3 - Use of Services

Frequency of Selected Procedures

Inpatient Utilization - General Hospital/Acute Care

Ambulatory Care

Inpatient Utilization - Nonacute Care

Mental Health Utilization- Inpatient Discharges and Average Length of Stay

Mental Health Utilization - Percentage of Members Receiving Inpatient, Day/Night and Ambulatory Services

Chemical Dependency Utilization- Inpatient Discharges and Average Length of Stay

Chemical Dependency Utilization - Percentage of Members Receiving Inpatient, Day/Night and Ambulatory Services

To be useful, patient-level data must match the summary data for the measures discussed here, i.e., the patient file should contain all beneficiaries enrolled in the contract at the time that the summary measures are calculated. To ensure an exact match, the MCO should make a copy, or "freeze," its database when the summary measures are calculated. If the measure was calculated using the hybrid methodology, the patient-level data should be reported on the minimum required sample size (411) or the total denominator population if less than 411. NCQA will provide MCOs with exact file specifications and explicit instructions by the Spring of the reporting year, which is sufficient time to allow MCOs to identify the best way to fulfill this requirement. These instructions and file specifications will be posted on NCQA's web site at www.ncqa.org. MCOs are advised to frequently review the NCQA web site for updates on the data submission process.

Exhibit III - Additional Information On The Medicare Health Outcomes Survey

Data Feedback

Please remember that individual member level data will not be provided to plans after baseline data collection. However, you will receive the following from CMS:

HOS Plan Performance Profile

This profile will be mailed to all plans participating in the last year's baseline cohort. This quality improvement tool, which presents an aggregate overview of the baseline health status of your MCO's Medicare enrollees, was developed and extensively tested to ensure that MCOs would find the data useful and actionable. Your State Peer Review Organization/Quality Improvement Organization will also receive copies of the performance profiles and stands ready to collaborate with you on interpreting the data, identifying opportunities to improve care, assisting you in planning effective, measurable interventions, and evaluating and monitoring the results of your interventions. Using data from the Health Outcomes Survey to plan and conduct a quality improvement project may fulfill one of the Quality Assessment and Performance Improvement requirements (QAPI) under QISMC. If you do not receive your performance profile by June 30 of each year, please contact Health Services Advisory Group (HSAG) at 1-(888) 880-0077 or e-mail to azpro.hos@sdps.org. Each MCO receives one performance profile free of charge. Additional and replacement copies are available at cost from HSAG.

Vendor Reports

The vendors administering the survey may provide you with reports on the progress of mail and telephone survey administration. Each report may consist of data on the number of surveys issued during the first and second survey mailings, the number of surveys returned completed or partially completed, the number of sampled members for whom a survey could not be obtained (e.g., due to death, disenrollment, language barrier), and mail and telephone response rate calculations.

Please DO NOT ask your vendor for additional analyses or member specific data. They are prohibited from providing this type of information.

Requests for interpretation of the data or more detailed analyses of the data should be directed to your State PRO/QI.

Appendix A - National QAPI Project Operational Policy Letters

1999 - Diabetes

Diabetes is a major health problem which is becoming more prevalent in all age groups. The increasing prevalence is attributed both to higher detection and to poorer health habits.

Adult onset diabetes is highly prevalent in the Medicare population and over 150,000 Americans die each year from diabetes and its complications. Complications of the disease include blindness, kidney failure, nerve damage, and cardiovascular disease. For most persons with diabetes, many of these complications can be prevented or delayed with appropriate monitoring and treatment. However, studies in both fee-for-service and managed care settings indicate that care is suboptimal. The Diabetes National Project focuses on improving monitoring in the outpatient setting.

Overview of Diabetes Project

The CMS-sponsored national project for 1999 focused on diabetes mellitus, using a standardized measurement set for diabetic processes of care and suggested interventions. M+C organizations with existing diabetes mellitus projects were allowed to substitute their own studies in place of CMS's project. However, those who participated in CMS's study had the benefit of participation in a national standardized measurement system. CMS did not require pre-approval of such projects.

One of the main objectives of this project is to reduce rates of blindness, amputations, kidney failure and the rate of diabetes-associated cardiovascular disease that is the major cause of death for the elderly population with diabetes. Diabetes and the complications of the disease can be prevented or delayed by management of blood glucose through diet, exercise and medication, by management of other risk factors such as lipids, blood pressure, smoking and by appropriate and timely examinations and treatment (e.g., eyes and feet).

The performance measures that were used for this project were the Diabetes Quality Improvement Project (DQIP) Measures. The finalized set of DQIP measures were released in August, 1998. Adoption of the DQIP measures was the result of a collaborative effort among several organizations, including CMS, the American Diabetes Association (ADA) and the National Committee for Quality Assurance (NCQA) Council on Performance Measures, which adopted six of the eight DQIP measures for its Health Employer Data Information Set (HEDIS) for the year 2000.

2000 - Pneumonia

According to the Centers for Disease Control and Prevention, pneumonia and influenza are the sixth leading causes of death in the United States. The incidence of pneumonia increases with age and approximately 90 percent of deaths attributed to this condition are in the population age 65 and older. Medicare patients with pneumonia are being hospitalized at the rate of approximately 600,000 per year, utilize over 4.2 million inpatient days, and account for more than 500,000 emergency department visits each year.

Overview of Pneumonia Project

The main objective of this project is to decrease the morbidity and mortality associated with community-acquired pneumonia in Medicare beneficiaries enrolled in M+C Organizations. In order to accomplish this goal, a series of process objectives have been developed which include:

- Increase immunization rates for pneumococcal and influenza vaccines;
- Increase the number of inpatients receiving timely antibiotic administration;
- Increase the use of initial antibiotic therapy consistent with current guidelines;
- For inpatients, increase the collection of blood cultures prior to the initial antibiotic dose; and
- Increase the number of hospitalized patients screened for or given pneumococcal or influenza vaccines.

National Pneumonia Project Quality Indicators

The Centers for Medicare & Medicaid Services (CMS) worked with a Pneumonia technical expert panel whose members included representatives from the American Thoracic Society, the Infectious Disease Society of America, the Pneumonia Patient Outcomes Research Team, the American Pharmacy Association, the Institute of HealthCare Improvement, and other influenza/pneumococcal experts. This panel guided the writing of the final pneumonia indicators based upon a combination of both ambulatory and hospital-based data.

Medicare+Choice organizations could choose one or more of the national pneumonia indicator(s) from the list below. In addition to the seven defined quality indicators, CMS was also interested in exploring alternative options with M+C Organizations (as described below). The seven national pneumonia indicators were:

- Influenza vaccination rates;
- Pneumococcal vaccination rates;
- Proportion of patients given an initial antibiotic consistent with current recommendations;
- Proportion of inpatients who have blood cultures collected before antibiotics administered;
- Proportion of inpatients with pneumonia screened for or given influenza vaccination;
- Proportion of inpatients with pneumonia screened for or given pneumococcal vaccination; and
- Proportion of patients who receive the initial antibiotic dose within eight hours of hospital arrival.

Alternative M+C Organization 8th Indicator

CMS was aware of M+C Organization expertise and creativity in the development of ambulatory quality indicators, as well as their participation in collaborative, community-based projects working to reduce the development of antibiotic resistant bacteria. If a QAPI project based on these activities required a quality indicator different from the above seven, M+C Organizations were allowed to submit those indicators for CMS comment. This alternative quality indicator had to meet the following requirements:

- Indicator should affect the M+C Organization's Medicare enrollees;
- Indicator should be measurable; and
- Indicator should reflect the national pneumonia project goal of reducing morbidity and mortality associated with pneumonia.

Organizations interested in pursuing this eighth option were required to work through their CMS RO representative.

Support/Communication for Projects

CMS encourages M+C Organizations to work in collaboration with their local Peer Review Organization (PRO), as they proceed with the conduct of the pneumonia project. Under the PRO Sixth Scope of Work, PROs are required to conduct a pneumonia project using the indicators described above. It is to the mutual advantage of the PRO and the M+C Organization to work collaboratively on their respective projects to promote efficiency, administrative simplification and reduction of resource burden. The Oklahoma Foundation for Medical Quality has been identified as the Pneumonia Clinical Area Support PRO, or "CASPRO", and will serve as a resource to other PROs in maintaining project staff lists, pneumonia literature and pneumonia intervention data on their web page (www.nationalpneumonia.org). Pneumonia data entry and analysis provider software were available on the web site in March of 2000. In addition to PRO support, CMS and the Centers for Disease Control and Prevention (CDC) have collaborated on an immunization intervention project using standing orders programs to increase adult immunization rates. An evidence-based standing orders program and intervention materials have been developed and CMS and CDC are available to representatives from M+C Organizations to discuss implementing this program in M+C Organization settings. If an M+C Organization chooses not to utilize PRO support, questions regarding design and implementation should be directed to their CMS RO representative.

2001 - Congestive Heart Failure

Year 2001 National Project on Congestive Heart Failure (CHF) for Medicare + Choice Organizations (M+C Organization).

Note that a related project, the Year 2001 Project on Extra Payment in Recognition of the Costs of Successful outpatient CHF Care is included in Chapter 7 of this Manual.

For the year 2001, the national project must address congestive heart failure (CHF). According to the American Heart Association, approximately 3,000,000 Americans are currently diagnosed with CHF. Of these, over 80 percent (2,400,000) are over the age of 65, most being Medicare enrollees. The one-year mortality rate for CHF is between 20 - 30 percent in the elderly. CHF

patients also experience significant functional limitations. Recent studies suggest effective clinical treatments and disease management strategies which may be effective in improving patient function, reducing mortality rates, decreasing hospital admissions and improving overall patient quality of life.

The National CHF QAPI project is similar in many ways to the previous diabetes and pneumonia national efforts. M+C Organizations will identify the relevant patient population, perform baseline data collection and calculate the baseline values for the selected quality indicators. They will then design and implement improvement strategies, and perform follow-up indicator data collection and measurement.

However, there are aspects to this National CHF QAPI project which differ from previous projects. This project requires M+C Organizations to measure and report performance on two specified quality indicators instead of one, and CMS will review the outcome on each indicator. M+C Organizations will be expected to achieve significant and sustained improvement on the second indicator (QAPI #2).

As with the 1999 and 2000 national quality projects, some organizations may have existing projects that could be modified to meet the requirements of the national CHF project. Those organizations wishing to utilize projects currently underway may do so if:

- They follow the requirements of this Manual chapter;
- Utilize the CHF quality indicators as described herein, and
- Conduct a re-measurement in 2001 to establish a new baseline against which to assess their improvement.

National CHF QAPI Quality Indicators

CMS has developed the quality indicators based on evaluation and treatment recommendations contained in the Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline Number 11, Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction (AHCPR Publication No. 94-0612, June 1994), the American College of Cardiology/American Heart Association Task Force Report Guidelines for the Evaluation and Management of Heart Failure ("JACC' 1995;26:1376-98), and the Heart Failure Society of America Guidelines for Management of Patients with Heart Failure Caused by Left Ventricular Systolic Dysfunction-Pharmacological Approaches ("J Cardiac Failure" 1999;5:357-82).

The indicators are also based on experience gained from the design and implementation of quality indicators for CMS's Inpatient National Heart Failure Project and the pilot outpatient Heart Failure Performance Improvement Effort, which utilized expert input from an American Heart Association Work Group. Additionally, CMS utilized the principles and recommendations contained in the report of an American Heart Association/American College of Cardiology work group "Evaluating quality of care for patients with heart failure. A summary from the First Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke." "Circulation" 2000;101: e122-e140. The indicators have been previously tested by CMS for feasibility of data collection in the outpatient setting, reliability, and acceptability of the

measure to providers. M+C Organizations, physicians and trade associations provided input throughout this process to help refine the design and selection of the quality indicators.

The two National project CHF QAPI quality indicators are:

- QAPI #1 = Proportion of CHF patients with assessment of left ventricular function;
- QAPI #2 = Proportion of CHF patients with left ventricular systolic dysfunction (LVSD) who
    - Have been prescribed an angiotensin-converting enzyme inhibitor (ACEI); *or*
    - Have documentation of a reason why ACEI was not prescribed.

Appendix I contains more detailed measurement specifications for the CHF indicators.

Use of Alternative CHF Indicators

At their option, if a M+C Organization has a baseline level above 75 percent for QAPI indicator #1 and 80 percent for QAPI indicator #2, it may design and use an alternative quality indicator. Prior to proceeding to use an alternative indicator, however, M+C Organizations must provide information to CMS RO (RO) managed care staff demonstrating that they have met the required baseline levels. RO staff will in turn work with the CMS Office of Clinical Standards and Quality in assisting the M+C Organization in the design of the alternative indicator. M+C Organizations are encouraged, although not required, to also work with their State PRO.

Regardless of the choice of alternative indicator, the selected measure must meet the following requirements:

- Indicator should affect the M+C Organizations Medicare enrollees;
- Indicator should be measurable; and
- Indicator should reflect the National CHF QAPI goal of reducing morbidity and mortality associated with congestive heart failure.

Technical Support for the National CHF QAPI Project

CMS encourages M+C Organizations to work in collaboration with their State PRO in the design and implementation of their QAPI CHF projects. In the event that the M+C Organization chooses not to utilize the PRO, questions regarding design and implementation should be directed to the CMS RO managed care staff.

If the M+C Organization works cooperatively with the PRO on quality improvement projects, CMS will pay the PRO and/or Clinical Data Abstraction Centers (CDACs) the costs of abstracting information from the M+C Organization medical records, as in prior years. In addition, if the medical records need to be photocopied prior to abstraction by the PRO/CDAC, the M+C Organization’s cost of such photocopying will be reimbursed by CMS through the PRO.

CMS is developing an optional data collection instrument for use in data abstraction. This will include data specifications, e.g., words and phrases that indicate LVEF assessment and LV systolic dysfunction. It will also include lists of ICD-9-CM and CPT codes likely to indicate that LVF was assessed. These optional tools will be available to all M+C Organizations regardless of who performs data abstraction. They will be posted to our web page at www.cms.hhs.gov.

QAPI Quality Indicators for Heart Failure

NB: Both quality indicators must be measured and reported to CMS.

Quality Indicator QAPI 1:

Proportion of heart failure patients with assessment of left ventricular function:

Population:	M+C Organization enrollees with a continuous enrollment of at least 180 days prior to the date of data collection, who have encounter/billing diagnoses of heart failure in the inpatient or outpatient settings, including: (a) Those enrollees discharged alive from an acute care hospital with a principal discharge diagnosis of heart failure[2] in the one year prior to the date of data collection; as well as: (b) Those enrollees without a hospital principal discharge diagnosis of CHF, but with three or more physician encounters with a diagnosis of CHF[3], in the one year prior to the date of data collection.
Denominator:	A census or random sample of M+C Organization enrollees from the 'Population' as (LVF) have been evaluated. Documentation of LVF evaluation consists of a billing record indicating that LVF evaluation has been performed, defined above.
Numerator:	Those in denominator with documentation that left ventricular function quantitative or qualitative lab report of LVF evaluation results, clinician notation that LVF evaluation has been performed, clinician notation of LVF results, or any other chart or administrative evidence that LVF evaluation has been performed.
Data Sources:	Enrollees with heart failure: Enrollment data, billing data, encounter data, hospital discharge data, any other reviewable source.
LVF evaluation:	Billing data, radiology or laboratory data, medical records, physician summary, any other reviewable source.

[2] ICD-9-CM codes: 402.01, 402.11, 402.91, 404.01, 404.11, 404.91, 428.x

[3] See footnote 1.

Quality Indicator QAPI 2:

Proportion of heart failure patients with left ventricular systolic dysfunction (LVSD) who:

- Are prescribed angiotensin converting enzyme inhibitors (ACEI); OR
- Have documented reason for not being on ACEI

Population: Those in numerator of QAPI Quality Indicator 1 with left ventricular systolic dysfunction (LVSD). LVSD is defined as an ejection fraction less than 40 percent or equivalent narrative description[4]

Denominator: A census or random sample of M+C Organization members from the 'Population' defined above.

Numerator: Those in denominator who have:

1. Been prescribed ACEI; OR
2. Chart documentation of one or more of the following contraindications to ACEI use:
    - Moderate or severe aortic stenosis, OR
    - History of angioedema, hives, or severe rash with ACEI use; OR
    - Bilateral renal artery stenosis; OR
3. Chart documentation of any specific reason why ACEI is not used (e.g., cough, hyperkalemia, hypotension, renal insufficiency/failure, other physician-noted reason); OR
4. Chart documentation of participation in a clinical trial testing alternatives to ACEIs as first-line heart failure therapy.

Data Sources: LVF evaluation results (quantitative or qualitative): Radiology or laboratory test results, medical record, physician summary, any other reviewable source.

Prescription of ACEI: Pharmacy data, medical records, physician summary, any other reviewable source.

Reason for not prescribing ACEI: Inpatient or outpatient diagnosis codes, medical record, any other reviewable source.

Participation in a clinical trial testing ACEI alternatives: any reviewable source

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[4] A list of qualitative descriptions from laboratory reports or clinician notes considered consistent with LVSD will be provided.

2002 - Breast Cancer Screening

Overview of the Breast Cancer Screening (BCS) Project

The main objective of this project is to decrease the morbidity and mortality associated with breast cancer in female Medicare beneficiaries enrolled in M+C Organizations. In order to accomplish this goal, it is important to increase the level of early detection of the disease by encouraging optimal use of mammography.

National BCS QAPI Project Specifications

This project will involve the use of the HEDIS® breast cancer screening measure as described by the NCQA in Volume 2 of its HEDIS 2002 Technical Specifications. Briefly, this measure considers the percentage of women age 52 through 69 years who were continuously enrolled during the measurement year and the preceding year, and who had a mammogram during the measurement year or the preceding year.

Baseline data for the project will use the Medicare HEDIS 2002 (measurement year 2001) reported rate filed through NCQA by June 28, 2002. M+C Organizations that do not report HEDIS 2002 because they do not meet minimum enrollment or contract effective date requirements will not have to participate in the 2002 BCS project since it is not likely they will have sufficient incidence to develop a baseline due to low enrollment.

Re-measurement, after interventions, will use the HEDIS specifications in effect at that time. If the BCS measure has been rotated or if HEDIS is no longer being used at the point of re-measurement then HEDIS 2002 specifications will be used.

Rewarding High Performance

We recognize that some organizations have already achieved a high rate on screening by mammography and that opportunity for additional improvement would be difficult and costly to achieve. Therefore, CMS has decided that MCOs that have a reported rate at or above 80 percent for HEDIS 2001 (measurement year 2000) will be excused from performing the national BCS project and will have to perform only the M+C Organization selected project for this year. For HEDIS 2000 there were 61 HEDIS submissions which met or exceeded the 80 percent rate. Additionally, organizations that report a rate below 80 percent for HEDIS 2001, but report a rate at or above 80 percent for HEDIS 2002 (measurement year 2001) will be exempt from the 2002 national project. Organizations that did not report HEDIS 2001, but report a rate at or above 80 percent for HEDIS 2002, will also be exempt from the 2002 national project.

Although CMS does not receive the annual HEDIS report from NCQA until approximately August 1, organizations are aware of their own rates several months earlier. Additionally, most M+C Organizations are aware of their previous BCS rates and are in a position to judge the effectiveness of previous interventions so they can determine the level of effort that will be required to achieve demonstrable improvement in the future. Therefore, using HEDIS 2002 for the baseline should not cause a problem for initiating the 2002 national project. Also, it will permit the use of data from the previous year, consistent with QAPI project provisions.

Organizations that do not have to perform the national project will be notified by CMS, about October 1st of 2001 and 2002, that they are exempt based on data from HEDIS 2001 (measurement year 2000) or HEDIS 2002 (measurement year 2001) reporting years, respectively. CMS will input the exemption into the M+C Quality Review Organization QAPI database.

Project Initiation and Implementation

CMS requires that the organization achieve demonstrable and sustained improvement in clinical care as a result of performing this project. Therefore, interventions must achieve improvement that is significant and sustained over time.

Organizations that are currently engaged in a similar BCS project as their internally selected project will need to follow guidance in section 1.3.3.3 of the QISMC document. This requires drawing a new baseline based on HEDIS 2002 (measurement year 2001) from which a re-measurement will be made while completing the previously initiated M+C Organization selected project. The national QAPI project will not affect the cycle of internal optional projects.

Support/Communication for Projects

We encourage M+C Organizations to work in collaboration with their local PRO as they seek appropriate interventions to improve mammography rates and reduce burden on providers of services. In addition to PRO support, we would like to alert MCOs about the Centers for Disease Control and Prevention's information resources on the web at http://www.cdc.gov/cancer/nbccedp/. Another helpful site is located at http://cis.nci.nih.gov.

Please send any questions regarding this OPL/BCS project to your RO managed care staff, or to: Richard Malsbary, (410) 786-1132 in the Center for Beneficiary Choices.

∗Kerlikowske, et al. JAMA 1993; 270(20): 2444-2450

∗∗http://www.cancer.org/NBCAM_fastfacts.html (cited 2001 January 4)

2003 - Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services

Reducing clinical health care disparities (CHCD) is one of the major challenges facing the entire health care industry. Compelling evidence exists that race and ethnicity correlate with persistent, and often increasing, health disparities. Since 1993, key indicators have shown that our nation's health has greatly improved. However, this good news does not apply to all Americans, a fact that has been recognized by leading organizations and health care researchers across the United States.[5, 6, 7, 8, 9, 10] Achieving new health care goals will require a national commitment to identify

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5 Mandelblatt JS, Gold K, O'Malley AS, et al: Breast and Cervix Cancer Screening Among Multiethnic Women: Role of Age, Health and Source of Care: *Preventive Medicine* 418-425. 1999.

6 Gornick ME, Eggers PW, Reilly TW, et al. Effects of Race and Income on Mortality and Use of Services Among Medicare Beneficiaries; *New England Journal of Medicine* 335:791-799, September 12, 1996.

and address the causes underlying higher levels of disease and disability in certain racial and ethnic groups. The urgent need for this commitment is further emphasized by the fact that the overall population is expected to grow dramatically, especially in the number of Hispanics, Asians and the minority elderly over age 85.

An increasing body of health services research also indicates that the provision of culturally and linguistically appropriate services (CLAS) leads to improved health outcomes, increased patient or beneficiary satisfaction, and organizational efficiencies that result in decreased expenditures. Many of the critical interventions that support the provision of culturally and linguistically appropriate services occur at the clinical encounter between health care providers and patients, but it is not the only locus of concern. A health care organization must also think about how it provides support for its customers in terms of customer service relations and communications, compliance with plan operating procedures, addressing grievances and appeals, etc.

Overview of 2003 National QAPI Projects

For the year 2003 national QAPI project, an M+C Organization will have a choice between initiating a project that addresses clinical health care disparities (CHCD) or culturally and linguistically appropriate services (CLAS). M+C Organizations that select a project that addresses CHCD must focus on one of four clinical areas - diabetes, pneumonia, congestive heart failure, or mammography. They must also use previous guidelines issued by CMS in the form of OPLs to determine appropriate quality indicators and implementation strategies.[11] [12] [13] M+C Organizations that select a project that addresses CLAS must focus on language access or organizational support for CLAS. M+C Organizations that wish to initiate a CHCD or CLAS project in 2002 (begin baseline data collection in 2001), may do so and receive credit for the year 2003 national QAPI project.

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7 Tortolero-Luna G, Glober GA, Villarreal R, Palos G, Linares A Screening Practices and Knowledge, Attitudes, and Beliefs about Cancer among Hispanic and Non-Hispanic White Women 35 Years Old or Older in Nueces County, Texas: *Journal of the National Cancer Institute Monograph* 49-56, 1995.

8 Center for Health Quality, Outcomes, and Economic Research: *Quarterly 2*, Spring 1999.

9 Racial and Ethnic Disparities in Access to Health Insurance and Health Care: UCLA Center for Health Policy Research and The Henry J. Kaiser Family Foundation 1, October 1999.

10 Influenza and Pneumococcal Vaccination Levels Among Adults Aged Greater Than or Equal to 65 Years: United States 47(38): 797-802, October 2, 1998.

11 http://www.cms.hhs.gov/medicare/mgdqual.htm. OPL #129 (1) The Year 2001 National Project on Congestive Heart Failure (CHF) for Medicare+Choice Organizations (M+C Organization); and (2) Extra Payment in Recognition of the Costs of Successful Outpatient CHF Care. OPL #116 Quality Improvement System for Managed Care (QISMC) Year 2000 National Project on Community-Acquired Pneumonia.

12 http://www.cms.hhs.gov/quality/3l.htm. Diabetes Quality Improvement Project (DQIP).

13 Breast Cancer Screening OPL.

Clinical Health Care Disparities

CHCD projects must measure and improve care for individuals enrolled in the M+C Organization from any, all, or a subset of the following populations:

- American Indian/Alaskan Native;
- Asian;
- Black/African American;
- Native Hawaiian/Pacific Islander, and
- Hispanic/Latino.

CHCD projects should demonstrate improvement for the selected population(s) in the quality indicators set forth in the OPL for the chosen clinical area. M+C Organizations may measure the disparity between the rate for the selected population(s) and the overall enrolled population, but a reduction in the amount of disparity is not required.

The M+C Organization should identify enrollees in the selected population(s) using an appropriate data source, such as plan data collected at the time of, or subsequent to, enrollment, or the data supplied by CMS that is collected by SSA at the time of original enrollment in Medicare. Other data sources, such as zip-code/census data, may be used to target interventions to appropriate individuals. For M+C Organizations selecting pneumonia as a clinical topic, CAHPS data, which includes the race/ethnicity of respondents, may be used to determine rates. Plans wishing to use CAHPS for this purpose must notify CMS by July 1st of the year of the CAHPS survey; an additional sample of enrollees from the selected population(s), or a subset of the selected population, will be drawn to increase the sample size used in determining the rate.

Examples of two CHCD projects follow. M+C Organizations may find these examples useful in developing their own project plans.

Culturally and Linguistically Appropriate Services (CLSA)

M+C Organizations that select CLAS must conduct a project that addresses one of two broad categories - language access and organizational support. Projects that address language access should focus on limited English proficiency (LEP) managed care enrollees.[14] Projects that focus on organizational support should be built on the understanding of, and in response to specific, cultural and linguistic needs of beneficiaries enrolled in a managed care plan. Examples of CLAS projects that address language access and organizational support are provided in Appendix A, "2003 - Clinical Health Care Disparities or Culturally and Linguistically

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14 LEP individuals are those who "…cannot speak, read, write, or understand the English language at a level that permits them to interact effectively with health care providers and social service agencies." DHHS Office for Civil Rights. *Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency*. 65 FR 52763. August 30, 2000 at www.hhs.gov/ocr/lep.

Appropriate Services" of this chapter. M+C Organizations may find these examples useful in developing their own project plans. M+C Organizations that decide to use one of the example projects provided in this appendix may decide, however, to implement an intervention that is not addressed by the example. This is acceptable, as long as the intervention can be linked to the topic and outcome of the project.

CLAS projects should use the following framework:

- Identify an opportunity for improvement;
- Develop and/or conduct meaningful intervention(s);
- Determine if the opportunity for improvement or goal has been achieved; and
- Review one year later to ensure improvement has been sustained.

Project Support and Evaluation

We encourage M+C Organizations to collaborate on or develop a community-wide approach for conducting QAPI projects that focus on CHCD or CLAS. Interventions, for example, may be implemented on a community-wide or regional basis. Each M+C Organization, however, will be assessed individually on the success of their project. M+C Organizations may have their QAPI projects evaluated at a level less than the contract (H-number), but may not have their QAPI projects evaluated at a level greater than the contract (H-number). For example, an M+C Organization may not request an evaluation of QAPI projects for a multi-State area, unless CMS has a contract (H-number) for the multi-State unit.[15]

We also encourage M+C Organizations to work with their local Peer Review Organization (PRO) to identify interventions that will decrease health care disparities and/or provide culturally and linguistically appropriate services. In addition, to assist M+C Organizations that focus on CLAS for their project, CMS is working with the Agency for Healthcare Quality and Research (AHRQ) and one of their contractors to develop detailed specifications and interventions for two of the example projects.

M+C Organizations that meet the following conditions may receive an automatic pass for the 2003 national project by providing CMS the report (analysis) from the State Medicaid agency or accrediting organizations that verifies the satisfactory completion of the QAPI project and results.

- M+C Organizations that have conducted a CLAS project for a State Medicaid program and have met the State's requirement for demonstrable improvement during the project period (projects must be completed or reviewed between 2001 through 2003).

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15 HCFA has a contract with Kaiser Mid-Atlantic that serves several states and the District of Columbia.

- M+C Organizations that have conducted a CLAS project for private accreditation that meets the accreditation organization's requirement for improvement during the project period (projects must be completed or reviewed between 2001 through 2003).

For M+C Organizations that complete a project after 2003 that is determined to meet an accrediting organization's or State Medicaid agency's requirements, CMS will also accept that determination, as long as the determination is made prior to the measurement reporting year, which is 2005. If the project does not meet the accrediting organizations or State Medicaid agency's requirements, however, it must be reported to and reviewed by CMS.

For QAPI projects, CMS requires demonstrable improvement. For non-clinical CLAS projects, CMS will allow an M+C Organization to demonstrate improvement by using structural measures that show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Additional Resources

M+C Organizations seeking guidance on developing QAPI projects that address CHCD or CLAS may use the following sources:

- U.S. Department of Health and Human Services Office for Civil Rights. Title VI of the Civil Rights Act of 1964: Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency. "Federal Register", August 30, 2000. 2000;65(169):52762-74; and

- U.S. Department of Health and Human Services Office of the Secretary. National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Health Care. "Federal Register" , December 22, 2000. 2000;65(247):80865-80879.

Please send any questions regarding this OPL or CHCD/CLAS projects to your RO managed care staff, or to: Trisha Kurtz, (410) 786-4670 in the Medicare Managed Care Group.

Clinical Health Care Disparities Sample QAPI Projects

These sample projects are not required. M+C Organizations may, however, find these sample projects useful in developing their own QAPI project plans

Example 1 - Mammography

This project seeks to increase the use of mammography screening with a focus on clinical health care disparities. The M+C Organization with a Medicare enrollment of 10,000 decides to aggregate all of the potential categories to create a selected population. The M+C Organization uses race and ethnicity that is collected at the time an individual enrolls in the plan to identify the population, and determines that in 2001 about 10 percent of its enrollment were in a population that the M+C Organization selected for their QAPI project, about 200 of whom were women of appropriate age. Beginning in 2003, the M+C Organization uses claims alone to determine the rate. For the baseline year (2002), the rate for the selected population is 50 percent (performance gap of 50 percent), and for the overall enrolled population the rate is 55 percent (performance gap of 45 percent), so - although the existence of a disparity in this example, it is not necessary

to conduct the project. For this M+C Organization the apparent disparity is 5 percent. The M+C Organization uses this same methodology to determine the rates for the years 2003, 2004, and 2005.

In 2003, the M+C Organization does a mailing to a sample of the selected and the overall enrolled populations to determine if there are any special barriers to mammographic screening among the selected population. It finds that there are two notable barriers - availability of screening centers on evenings and weekends, and the disbelief among the selected population that screening is of benefit. It does a special mailing to enrollees identifying screening centers with extended hours, and making the case for benefits of screening, and makes this mailing available to it PCPs.

For the 2003 reporting period there is no improvement in rates, but in 2004 the rate for the selected population is 56 percent. Compared to baseline this means that the performance gap has been reduced from 50 percent to 44 percent, which is a 12 percent improvement in gap. In 2005 the rate for the selected population is 55 percent, which demonstrates that improvement has been sustained.

Example 2 - Pneumonia

This project seeks to increase flu/pneumonia vaccine rates for a selected population(s). The M+C Organization with Medicare enrollment of 5000 decides to aggregate all of the potential categories to create a selected population. In June of 2002 it informs CMS of its need for CAHPS results for the selected population. During the Fall of 2002, CMS augments the usual CAHPS sample with an additional sample of 100 enrollees from the selected population. In the spring of 2003, the M+C Organization receives CAHPS results for 2002 by racial/ethnic category. For this year, for the 500 respondents, the rates of flu and pneumococcal vaccination were 30 percent and 20 percent. For the selected population, there were a total of 125 respondents, and the rates were 30 percent and 25 percent.

Although there is no disparity between the selected and the overall enrolled population, the MCO proceeds with the project, focusing on interventions specific to the selected population. The M+C Organization requests similar breakdowns of CAHPS results for the reporting years 2003, 2004, and 2005.

In 2003, the M+C Organization does a mailing to a sample of the selected and the enrolled populations to determine if there are any special barriers to flu and pneumococcal vaccination among the selected population. It finds that there are no special barriers. It does a mailing to all enrollees in the Fall reminding them of the benefits of screening. Using census data to identify zip codes with higher proportions of residents from the selected population, the M+C Organization works with the State health department to publicize the importance of immunization, and available sources of it, in those areas.

Using CAHPS data, in the 2003 reporting year there is improvement in rates for the selected population, to 35 percent (flu) and 30 percent (pneumococcal). Compared to baseline this means that the initial gap of 70 percent has been reduced to 65 percent, which represents a 7 percent improvement in gap. For the 2004 reporting period, the rates for the selected population are 40 percent and 35 percent. This represents a 14 percent improvement in the gap. For the 2005

reporting period the rates for the selected population are unchanged from those of the prior year, which demonstrates that improvement has been sustained.

Culturally and Linguistically Appropriate Services Sample QAPI Projects

These sample projects are not required. M+C Organizations may, however, find these sample projects useful in developing their own QAPI projects plans.

Language Access

Language access is critical for minority individuals who have "limited English proficiency" (LEP). Research shows that language barriers have a negative impact on utilization, satisfaction, and possibly adherence to treatment regimens[16]. LEP has been linked to fewer physician visits, reduced receipt of preventive services, and higher rates of missed appointments and medication noncompliance among LEP patients[17]. Included among the negative effects of language barriers are higher rates of diagnostic testing, omission of vital information, misdiagnoses, inappropriate treatment and misunderstanding[18.]

Incentives for M+C Organizations to undertake efforts directed at ensuring access to services for LEP enrollees through the provision of required language access services include:

- More accurate medical histories and clearer descriptions of symptoms leading to fewer diagnostic errors;
- More appropriate testing and screening yielding fewer missed opportunities for early detection and treatment;
- More successful patient education resulting in reduced behaviors constituting risk factors for disease and exposure to risk;
- Clearer communication between physicians and patients concerning treatment options leading to more appropriate treatment and improved compliance with treatment regimens; and

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[16] Brach, C., and Fraser, I. 2000. Can Cultural Competency Reduce Racial and Ethnic Health Disparites? A Review and Conceptual Model. "Medical Care Research and Review" 57(1): 181-217

[17] Derose, K.P., and Baker, W.D. 2000. Limited English Proficiency and Latinos' Use of Physician Services. "medical Care Research and Review" 57(1): 76-91

Commonwealth Fund. 1995. "National Comparative Survey of Minority Health Care". NewYork: Commonwealth Fund.

Eraker, S.A., Kirscht, J.P., and Becker M.H. 1984. Understanding and Improving Patient Compliance. Annals of Internal Medicine 100(2): 258-268

[18] David, R.A., and Rhee, M. 1998. The Impact of Language as a Barrier to Effective Health Care in an Underserved Urgan Hispanic Community. "Mount Sinai Journal of Medicine 65". (5,6): 393-397

- Better protection for the M+C Organization against tort liability, malpractice lawsuits, and charges of negligence.

M+C Organizations are also required, as are all recipients of Federal financial assistance, to take steps to ensure LEP persons have meaningful access to the health services they provide.

Example 1 - Compile or Enhance and Make Available a Practitioner Directory Identifying Bilingual/Multi-Lingual Practitioners

Identify an Opportunity for Improvement

- Identify the languages likely to be encountered by appropriate M+C Organization practitioners;
- Use these data to assess the need to identify plan practitioners who are bilingual/multi-lingual;

Intervention

- Survey M+C Organization practitioners to request the voluntary identification of those who are bilingual/multilingual;
- Compile or enhance and publish a directory identifying the bilingual/multi-lingual practitioners and the language(s) in which they are competent;
- Make the directory available to all enrollees through normal channels;
- Include notice of the availability of the directory in outreach materials to M+C Organization LEP populations.

Benchmark/Goal

- Make the directory that identifies bilingual/multilingual practitioners, and/or notice of that directory, available to M+C Organization enrollees by completion of the project.

Outcome

For improvement, M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 2 - Establish a System to Identify M+C Organization LEP Beneficiaries and Access and Use This Information

Identify an Opportunity for Improvement

Assess the adequacy of any existing system(s) for identifying M+C Organization LEP enrollees and for accessing and using this information.

Intervention

Identify enrollees written/oral language needs for a medical encounter. (Identification methods include survey, enrollment application, etc.) Incorporate and record this information in the plan data (e.g., plan enrollment database) so that it is accessible to staff and/or providers.

Benchmark/Goal

The M+C Organization identifies its LEP enrollees and provides for the access and use of this information by providers and staff. A new or significantly improved system exists to identify M+C Organization LEP enrollees and to access and use this information.

Outcome

For improvement, M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 3 - Acquainting M+C Organization LEP Enrollees of Their Right to Language Services

Identify an Opportunity for Improvement

Evaluate the plan's current process for acquainting M+C Organization LEP enrollees of their right to language access services.

Intervention

Develop or enhance the process for acquainting M+C Organization LEP enrollees of their right to language access services.

Benchmark/Goal

New or enhanced procedures exist and are operational to acquaint M+C Organization LEP enrollees of their right to receive language assistance services. Procedures include processes for both verbal offers and written notices in the enrollee's preferred language.

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 4 - Provide Oral Language Interpretation Assistance to M+C Organization LEP Enrollees

Identify an Opportunity for Improvement

Identify the languages likely to be encountered in the M+C Organization service area and enrollee population by reviewing census data, CMS-provided race and ethnicity data for M+C Organization's enrollees and/or data from school systems and community agencies and organizations.

- Select one or more of the most dominant LEP groups in the service area.
- Evaluate the adequacy of any existing process (es) to provide oral language interpretation services to enrollees in the selected LEP groups.
- Identify the points of contact in the M+C Organization where language assistance is likely to be needed (e.g., beneficiary services).
- Define the resources that will be needed to provide effective language assistance to M+C Organization enrollees in the selected LEP groups, and identify the location and availability of these resources.

Intervention

Expand existing capacity as necessary to address unmet need by hiring bilingual staff or paid interpreters, contracting with interpreters, engaging community volunteers, and/or arranging for telephone interpreter services.

Benchmark/Goal

The M+C Organization offers and provides oral language assistance including bilingual staff and interpreter services to M+C Organization LEP beneficiaries in the selected groups at points of contact in a timely manner during hours of operation. A new or significantly improved system for providing oral language services to individuals with limited English proficiency in the selected groups who seek services from the M+C Organization is implemented and fully operational.

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 5 - Provide Written and Oral (Sight) Translations of Vital Documents and Information to M+C Organization LEP Enrollees

Identify an Opportunity for Improvement

Identify the non-English languages that are likely to be encountered in the M+C Organization's service area by reviewing census data, CMS-provided race and ethnicity data for M+C Organization enrollees and/or data from school systems and community agencies and organizations.

Identify one or more of the most dominant LEP language groups in the service area.

Evaluate the adequacy of available translated materials to meet the needs of language group(s).

Intervention(s)

One or more of the following:

- Secure written translations into the selected LEP language(s) of vital documents and information. Translated materials should be responsive to the culture as well as the levels of literacy of M+C Organization LEP enrollees in these language groups;

- Provide/post signs in public areas (e.g., waiting rooms) in the selected LEP language(s) notifying LEP enrollees of a variety of patient rights, availability of conflict and grievance resolution, and directions to service locations;

- Provide/post way-finding signs to identify or label the location of specific services (e.g., registration, examining rooms);

- Make available translated written documents to LEP enrollees in the selected language group(s).

Benchmark/Goal

A new or significantly improved system for improving access for LEP beneficiaries to easily understood patient-related materials and/or posted signage is implemented and fully operational. The M+C Organization makes available translations of, at a minimum, vital documents and information for the selected one or more most dominant LEP language groups in the service area. For other language groups, the M+C Organization provides written notice in the primary language of the LEP beneficiary of the right to receive oral translation of written materials.

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Potential Organizational Support Class QAPI Projects

For purposes of the QAPI project, the premise for the organizational support for CLAS is built on understanding and responding to specific cultural and language needs of Medicare and Medicaid beneficiaries enrolled in the managed care plan. Health journal literature indicates that the provision of culturally and linguistically appropriate services leads to better health outcomes, increased customer satisfaction, and organizational efficiencies that result in decreased expenditures.

Many of the critical interventions that support the provision of culturally and linguistically appropriate services occur at the clinical encounter between health care providers and patients. But that is not the only locus of concern. A health care organization must carefully think about how it provides support for its customers in terms of customer service relations and communications, compliance with plan operating procedures, negotiating complaints and grievance and appeals processes, etc.

Example 1 - Establish and Implement a Plan to Recruit and Retain Bi/Multi-Cultural and Bi/Multi-Lingual Minority Employees Who Reflect the Dominant Racial, Ethnic and Linguistic Minorities Served

Rationale

There are distinct communication and service advantages to recruiting and retaining employees within the M+C Organization who reflect the demographics of the enrolled population. This is especially true at key points of beneficiary encounters, such as customer service, including navigating the complaints and appeals processes. Also, the customer service representative provides a wide array of information across all aspects of plan services and refers beneficiaries to other parts of the organization to obtain information, assistance and services.

Initial Assessment

Identify dominant cultural and linguistic minority groups enrolled in the M+C Organization; assess whether M+C Organization employees at key points of beneficiary encounters have the capacity to understand and meet cultural and language needs of enrollees.

Interventions (Steps in Completing the Project)

- Assess the diversity of populations served with regard to culture and language.
- Review employee recruitment and retention practices; do these practices reflect sensitivity to the linguistic and cultural needs of communities served?
- Develop a written plan with regard to recruiting and retaining employees who reflect sensitivity to the linguistic and cultural needs of communities served.
- Acquire board sign-off to implement the plan with an effective date within the next year and has a budget to support the plan.

Benchmark/Goal

The M+C Organization has a written plan for recruiting and retaining employees who reflect sensitivity to the linguistic and cultural needs of the communities served. The organization is better able to meet the needs of linguistic and cultural minorities by systematically attempting to recruit and retain employees who reflect the cultural and linguistic minority communities served.

NOTE**:** This does not require a particular ratio be met with regard to so many employees per so many beneficiaries

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 2 - Establish and Implement a Plan to Recruit and Retain Bi/Multi-Cultural and Bi/Multi-Lingual Minority Practitioners Who Reflect the Dominant Racial, Ethnic And Linguistic Minorities Served

Rationale

There are distinct communication and service advantages to recruiting and retaining practitioners who reflect the demographics of the enrolled population. This is especially true at key points of

beneficiary encounters, such as the clinical setting, where the practitioner provides a wide array of direct services.

Initial Assessment

Identify dominant cultural and linguistic minority groups enrolled in the M+C Organization; assess whether M+C organization practitioners have the capacity to understand and meet cultural and language needs of enrollees.

Interventions - (Steps in Completing the Project)

- Assess the diversity of populations served with regard to culture and language.
- Review practitioner recruitment and retention practices to ensure that these practices reflect sensitivity to the linguistic and cultural needs of communities served.
- Develop a written plan with regard to recruiting and retaining practitioners that reflect sensitivity to the linguistic and cultural needs of communities served.
- Acquire board sign-off to implement the plan with an effective date within the next year and has a budget to support the plan.

Benchmark/Goal

The M+C Organization has a written plan for recruiting and retaining practitioners who reflect sensitivity to the linguistic and cultural needs of the communities served. The organization is better able to meet the needs of linguistic and cultural minorities by systematically attempting to recruit and retain practitioners who reflect the cultural and linguistic minority communities served.

NOTE: This does not require a particular ratio be met with regard to so many practitioners per so many beneficiaries.

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 3 - Develop or Provide Access to CLAS Training Programs for Employees and Practitioners

Rationale

CLAS training programs increase cultural awareness, knowledge, and skills, leading to changes in clinical and administrative understanding of patients. CLAS training provides a way to introduce staff to interaction issues that have previously gone unnoticed or misinterpreted. Therefore, a critical part of organizational support for CLAS is ensuring that employees and practitioners receive ongoing generalized training and education in delivery of CLAS. Further, at the clinical level in particular, continuing medical education related to specific disease incidence and prevalence and treatment efficacy and outcomes is critical.

Initial Assessment

Review current capabilities for developing or providing CLAS training either through internal or external sources.

Interventions - (Steps in Completing the Project)

- Assess the diversity of populations served with regard to culture and language.
- Establish and/or identify CLAS training that addresses the needs of the enrolled population. (CMS will provide technical assistance regarding CLAS training sources for optional use by M+C Organizations.)
- Assist employees and practitioners in attending CLAS training.
- Establish a mechanism to record that employees and practitioners have attended CLAS training.

Benchmark/Goal

Employees and/or practitioners have received CLAS training. If CLAS training is already underway, then the M+C Organization shall increase the number attending the training. If the program is new, then the M+C Organization shall demonstrate that the program is initiated and that there is participation with significant attendance by employees and practitioners.

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 4 - Conduct an Organizational Assessment to Identify Opportunities for Improvement and Develop a Multi-Year Plan for Improving Provision of CLAS

Rationale

An organizational assessment to identify opportunities for improvement is essential for creating an incremental, coherent effort in the provision of CLAS. An assessment provides a status check on where the M+C Organization is in the provision of CLAS, and a gap analysis between where the organization is now and where it wants to be at a future point in time.

Initial Assessment

Review current activities relating to conducting an organizational assessment of the provision of CLAS.

Interventions

- Assess the diversity of populations served with regard to culture and language.
- Assess organizational capacity for providing CLAS.

- Use the organizational assessment to build a multi-year plan for providing CLAS.
- Put into place the necessary organizational structure needed to execute the multi-year plan.

Benchmark/Goal

M+C Organization conducts an organizational assessment to identify opportunities for improvement in the provision of CLAS. Based on the assessment, M+C Organization puts into place the necessary organizational structure needed to execute the multi-year plan.

Outcome

For improvement M+C Organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Appendix B - M+C Quality Glossary

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

Accreditation Cycle for M+C Deeming

The duration of CMS's recognition of the validity of an accrediting organization's determination that a Medicare+Choice organization (M+CO) is “fully accredited.”

Baseline Data

Initial data gathered before improvements or interventions are made that will be compared with data collected later to determine whether changes have been effective.

Benchmarking

The process of measuring products, services, strategies, processes, and practices against known leaders/best-in-class companies.

Consumer Assessment of Health Plans Study (CAHPS)

An annual satisfaction survey, administered by CMS, in which a sample of members from each Medicare managed care organization are asked for their opinions relating to clinical and administrative services provided by the Managed Care Organization (MCO.)

Continuous Quality Improvement (CQI)

An integrated, comprehensive approach to continuously examine, refine, and revise organizational processes to meet and exceed customers’ expectations. Integrates fundamental management approaches, improvement efforts, tools, and training.

Coordinated Care Plan

A plan that includes a CMS-approved network of providers that are under contract or arrangement with the M+C organization to deliver the benefit package approved by CMS. Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs), as well as other types of network plans (except network MSA plans. See 42 CFR. § 422.4(a)(1.)

Cost Benefit Analysis

Weighing known costs against probable benefits; objective is to have potential benefits to exceed (additional) costs.

Customer

Anyone who receives a service or product; can be internal and/or external to the organization.

Deemed Status

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

Deeming Authority

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

Equivalency Review

The process CMS employs to compare an accreditation organization's standards, processes and enforcement activities to the comparable CMS requirements, processes and enforcement activities.

Expected variation

A change or measurement observed in a step of the process which one could predict would occur because of natural causes; data points are within the upper and lower control limits

Goal

The measurable outcome of the process under study, as defined by the improvement team.

Health Outcomes Survey (HOS)

The first outcomes measure used in the Medicare program. It is a longitudinal, self-administered survey that uses a health status measure, the SF 36, to assess both physical and mental functioning. A sample of members from each Medicare+Choice health plan is surveyed. Two years later these same members are surveyed again in order to evaluate changes in health status.

Health Plan Employer Data and Information Set (HEDIS â)

A widely used set of health plan performance measures utilized by both private and public health care purchasers to promote accountability and assess the quality of care provided by managed care organizations. HEDIS® is developed and maintained by the National Committee on Quality Assurance (NCQA) in collaboration with CMS and other entities. HEDIS® 2002 contains over 50 measures across 8 domains of care. Annual HEDIS reporting has been required of Medicare managed care organizations since January 1997.

Improvement

Planned, fundamental changes which result in unprecedented levels of performance. It is not the "removal of an irritant," solving a particular problem, or "fire fighting."

Licensed by the State as a Risk-Bearing Entity

An entity that is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage. The entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an M+C contract.

Measures of Performance

Characteristics of what is done and how well it is done.

M+C Organization

A public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider sponsored organization receiving waivers) that is certified by CMS as meeting the M+C contract requirements. See 42 CFR. §422.2.

M+C Plan

Health benefits coverage offered under a policy or contract offered by a Medicare+Choice Organization under which a specific set of health benefits are offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan. See 42 CFR. §422.2. An M+C plan may be a coordinated care plan (with or without point of service options), a combination of an M+C medical savings account (MSA) plan and a contribution into an M+C MSA established in accordance with 42 CFR §422.262, or an M+C private fee-for-service plan. See 42 CFR. §422.4(a).

Operational Definition

A description in quantifiable terms of what to measure and the steps to follow to measure it consistently (e.g., the operational definition of a report handed in on time is one that is put in the correct mailbox within 10 minutes of the stated deadline).

Physician Incentive Plan (PIP)

Any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to a plan's enrollees. See 42 C.F.R. § 422.208(a).

Population

The total number of individual units for a defined area.

Preferred Provider Organization (PPO)

An M+C Organization coordinated care plan that: (a) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization

offering the plan; (b) provides for reimbursement for all covered benefits regardless of whether the benefits are provided with the network of providers; and (c) is offered by an organization that is not licensed or organized under State law as an HMO. See Social Security Act Section 1852(e)(2)(D), 42 U.S.C. §139w-22(e)(2)(D).

Quality

Meeting and exceeding customer expectations, doing the right things right, and making continuous improvements. Is defined by the customer.

Sample

A subgroup of units chosen from a diffuse group of units or population.

Standard deviation

A measure of variability exhibited by the distance from the mean that a typical data point is expected to fall.

Subgroup

A sample selected from a large population

Variation

The inevitable differences in measurements observed in a given step of a process.