Medicare Managed Care Manual

Chapter 5 - Quality Assessment

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10 - Introduction

(Rev. 29, 08-01-03)

Title 42 CFR Part 422, Subpart D, "Quality Assurance," establishes the quality assessment and performance improvement (QAPI) requirements that Medicare+Choice Organizations (M+C organizations) must meet under the Social Security Act (the Act). These requirements do not apply to §1876 cost plans or §1833 Health Care Prepayment Plans. This chapter is divided into four main areas:

- Section 20 - Quality Assessment and Performance Improvement Program
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20 - Quality Assessment and Performance Improvement (QAPI) Program

(Rev. 29, 08-01-03)

All M+C organizations must give priority to quality assurance and engage in activities and efforts that demonstrably improve their performance. The 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, CMS is committed to working with M+C organizations toward a common goal of ensuring high-quality and cost-effective care.

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

The organization's Quality Assessment and Performance Improvement (QAPI) program is administered through clear and appropriate administrative arrangements.

There must be evidence that the M+C organization has an on-going quality assessment improvement program. Most organizations will have a QAPI program that is administered by a multi-disciplinary committee that includes clinical and administrative personnel. Other arrangements are permissible, as 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 ensure communication and coordination. The organization's QAPI program description must show the role, structure, staffing, and function of each participating component and the interrelations among components.

The organization must conduct an annual evaluation of their QAPI program's effectiveness and make any necessary changes. 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.

The policy making body is required to oversee and is accountable for the QAPI program. 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 work plan. It must receive and review periodic reports on QAPI activities.

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.

There is formal and ongoing communication and collaboration among the policy making body that oversee the QAPI program and the other functional areas of the organization, e.g., health services management and member services.

The M+C organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the M+C plan provided by the organization, which includes the QAPI program (42 CFR 422.202(4)(b). This rule applies to subcontracted physician groups as well (422.202(4)(b)(3)(c)). Key activities that physicians should be involved in may include: 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.

The organization should 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.

20.1.1 - M+C Organizations Using Physician Incentive Plans

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

20.2 - Health Information System

The organization maintains a health information system that collects, integrates, analyzes, and reports data necessary to implement its QAPI program. 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 CMS is to improve patient care. For this reason, the health information system requirements focus 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 as specified by CMS.

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 and to meet the data collection requirements for performance improvement projects.

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.

This 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.

The QAPI program should routinely collect and interpret information from all parts of the organization to identify issues in the areas of clinical services, access to care, and member services. Type 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 organization ensures that information and data received from providers are accurate, timely, and complete. 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. 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 re-credentialing or re-contracting with practitioners and providers 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. 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's formats should be included in the validation.

The Health Insurance Portability and Accountability Act of 1996 includes privacy and data utilization provisions that apply to managed care organizations and providers. The CMS is working with M + C organizations on how to implement this Act. 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 - Quality Assessment and Performance Improvement (QAPI) Projects

(Rev. 29, 08-01-03)

20.3.1 - Basic Requirements

(Rev. 29, 08-01-03)

The M+C organization must:

- As of 2002, M+C organizations are only required to initiate one QAPI project per year. Beginning in 2004, M+C organizations will have the option of conducting either the national CMS QAPI project or a local marketplace initiative;

- Achieve required minimum performance levels on standardized quality measures. These required levels of performance may be established by CMS. 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:** CMS has yet to establish or require minimum performance levels.

- 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 .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.

- 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.

20.3.2 - Project Initiation Requirements

(Rev. 29, 08-01-03)

Effective as of 2002, each newly contracting M+C organization is expected to initiate the yearly CMS QAPI project before the end of the second contract year and in each subsequent year. For example, organization A signs a contract with CMS on January 1, 2002, and organization B signs a contract August 1, 2002. For both organizations, the second contract year will be 2003. Initiation of a QAPI project is not required in year 2002, the first year of the contract.

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

QAPI project years are independent of the CMS on-site review cycle.

20.3.3 - Types of QAPI Projects

(Rev. 29, 08-01-03)

20.3.3.1 - National QAPI Projects

(Rev. 29, 08-01-03)

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

CMS will seek to select QAPI national project topics based on the following factors to the degree possible:

- Align managed care quality efforts with fee-for-service quality activities in order to improve health care outcomes for beneficiaries and reduce provider burden;
- Select QAPI national projects based on Health Plan Employer Data and Information Set (HEDIS®) measures for consistency with private purchasing efforts;
- Seek relevance to both the Medicare and Medicaid populations;

Maximize resources by selecting a QAPI national project that is consistent with current QIO clinical priority areas

See Appendix A for listing of CMS National QAPI Projects.

20.3.3.2 - M+C Organization Selected QAPI Projects

(Rev. 29, 08-01-03)

This project type was required for years 1999 and 2000. The M+C organization was required to initiate a project on a topic of their own choosing, based on the needs of their own population. The requirement for an M+C organization to initiate and conduct a M+CO selected QAPI project was eliminated effective in 2002.

20.3.3.3 - CMS-Directed Special Projects

(Rev. 29, 08-01-03)

The CMS may require an organization to conduct particular QAPI projects that are specific to the organization and that relate to topics and involve quality indicators of CMS' choosing.

There may be instances in which CMS 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 may require the organization to conduct a particular project. In addition, CMS may specify project topics and quality indicators to be used by a particular plan, if CMS 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.

This type of project may be required in response to a corrective action request or a previous QAPI project that did not meet CMS' expectations. An M+C organization will be informed by CMS if it will be required to conduct this type of project.

20.3.3.4 - Local Marketplace Initiative QAPI Projects

(Rev. 29, 08-01-03)

The CMS has encouraged local marketplace initiatives, under which several contracting organizations undertake a joint quality improvement project addressing a common topic. This project type will become an option beginning in 2004.

Parameters for an acceptable local marketplace initiative require that:

- It must be a community-wide initiative in which most or all M+C organizations participate and be initiated, facilitated, approved or required by a private purchaser group, QIO, State Medicaid Agency or other state government agency. This does not preclude M+C organizations from the role of facilitator, initiator or requestor so long as one or more of the other organizations function in these roles;
- The topic must be relevant to the Medicare population;
- Medicare enrollees must be in the population sample for the project; and
- The M+C organization must report on M+C organization specific data although Medicare data does not need to be separated from the other purchasers

(Medicaid/commercial) unless separation of data is necessary for other reporting purposes such as Medicare HEDIS requirements.

- M+C organizations must follow QAPI requirements such as the use of baseline measurement, interventions, and re-measurement as established under §20.7.

20.3.3.5 - Pre-Existing Projects

(Rev. 29, 08-01-03)

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

- Follows the requirements in this manual chapter;
- Utilizes the appropriate quality indicators; and
- Conducts a re-measurement in the applicable QAPI initiation year to establish a new baseline against which to assess its improvement.

M+C organizations which have satisfactorily completed a state Medicaid project and met the State's requirement for improvement or have conducted a project that meets the requirements for improvement of a private accreditation organization granted deeming authority by CMS, may use those projects as the CMS QAPI project if the following requirements are met:

1. Medicare enrollees are included in the sample;
2. The project is relevant to the Medicare population;
3. The project was completed or reviewed during the project period;
4. The M+C organization provides CMS with a report (analysis) from the State Medicaid agency or accrediting organization that verifies the satisfactory completion of the QAPI project;
5. For a CMS national project, the M+C organization must use CMS specified indicators.

A M+C organization should contact its CMS RO representative regarding the process for reporting a project so credit may be afforded for monitoring purposes.

20.3.3.6 - Multi-Year QAPI Projects

(Rev. 29, 08-01-03)

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 of 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 of outcomes can come only after process improvements that are not closely enough related to outcomes to meet the requirement
- Improvement will require multiple system interventions that cannot be implemented over a short period.

All other project types listed previously (national, CMS-directed special, local market place initiative, or pre-existing) are not considered multi-year projects, in this context, even though they are conducted over several years. A "regular" QAPI project cannot be converted into a multi-year project without prior approval.

The M+C organization should identify its intention to do a multi-year project significantly in advance of the proposed implementation date. To attain consideration of a multi-year project, the M+C organization should notify CMS via an e-mail request to QAPI@cms.hhs.gov.

20.4 - Attributes of Quality Assessment and Performance Improvement (QAPI) Projects

(Rev. 29, 08-01-03)

These attributes are applicable to all QAPI projects. CMS also applies these attributes in the development of CMS National projects. An individual QAPI project involves:

Selection and prioritization of topics

- 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;
- Significant improvement sustained over time.

Because the key QAPI project components are interdependent, failure on any one of them affects the overall project. The organization's documentation of a completed project must provide evidence of compliance with each component. Please refer to Appendix C for specific guidance in the development of a QAPI project.

20.5 - Significant Improvement

(Rev. 29, 08-01-03)

The M+C organization's interventions in its QAPI project result in significant improvement in its performance as evidenced in repeat measurements of the quality indicators specified for each performance improvement project undertaken by the organization. It is not expected that a QAPI project initiated in a given year will achieve improvement in that same year. The CMS assumes a 3-year cycle for most M+C organizations to reach demonstrable improvement.

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 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.

Significant 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.

It is essential that the measures of performance before and after the M+C organization's interventions be comparable in order to measure improvement accurately. The same methods for identifying the target population and for selecting individual cases for review must be used for both measurements. For example, in a project to improve care of diabetes patients, 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 repeat measurement should use the same methodology and time frames 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.

20.5.1- Benchmarks

(Rev. 29, 08-01-03)

Benchmarks may be established by CMS for national QAPI projects. When the project is one determined by the managed care organization or as a local marketplace initiative, the

benchmarks must reflect performance in other organizations, local, State or national norms as established through comparative data, or reasonable expectations of optimum performance. The organization must be able to document the basis on which its benchmark was determined.

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

NOTE: The CMS has not determined benchmarks for national QAPI projects. However, exemptions have been allowed from some QAPI projects based on predetermined performance levels.

20.5.2 - Performance Target

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

20.6 - Sustained Improvement

(Rev. 29, 08-01-03)

The M+C organization sustains the improvement in performance relative to the baseline rate, through the continued measurement of quality indicators, for at least one year after the significant improvement in performance is first achieved. After an M+C organization has achieved sustained improvement for a project, CMS does not require any further documentation on that project. A M+C organization may then continue or discontinue that project.

20.7 - Evaluation of QAPI Projects

(Rev. 29, 08-01-03)

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

(Rev. 29, 08-01-03)

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

20.7.2 - CMS Regional Office Representatives

(Rev. 29, 08-01-03)

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

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

20.7.3 - M+CQRO Reviewers

(Rev. 29, 08-01-03)

Three Quality Improvement Organizations (QIOs) have a contract to evaluate QAPI projects. Known as Medicare+Choice Quality Review Organizations (M+CQRO), the three contractors are California Medical Review, Inc., Delmarva Foundation for Medical Care and Island Peer Review Organization. They have developed the training and implementation materials and manuals that are used to provide technical assistance to M+C organizations and CMS in the design, development, implementation and evaluation of their quality assessment and performance improvement programs.

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

20.7.4 - Project Completion Report

(Rev. 29, 08-01-03)

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

M+C organizations which have consolidated contract H numbers over the course of the project will report on the current H-number as recognized by CMS. M+C organizations

will report significant improvement on the end of the project contract H numbers, but make note of any change in service areas that might have affected the study outcomes. In some instances units for baseline measurement may not be exactly the same as units used in re-measurement. If unsure of how to proceed, please contact your RO representative.

The Project Completion Report is in a password protected web-based format. The report information will be directly submitted into the CMS Health Plan Management System (HPMS) database where the web-based project completion report is housed. Each M+C organization has limited access to the HPMS database.

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

Please submit the original completed forms to:

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

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

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

The M+CQROs will evaluate the QAPI projects. This review will include (but not be limited to) analysis of the choice of focus area, patient population and eligibility criteria, selection of intervention and methodological integrity as required by CMS. The review will be done solely from the data contained in the QAPI Project Completion Report without on-site review.

20.7.5 - Reporting Time Frames

(Rev. 29, 08-01-03)

The M+C organization will have 90 days from the completion of their project to submit its Project Completion Report electronically, via the HPMS system, to the M+CQRO. The completion date of a project is usually close to the end of the 3-year project cycle,

and is the date on which the last data run of the project was completed. This data run demonstrates the required significant and sustained improvement.

The M+C organization determines the actual date of project completion. However, depending on the year of the project (1999 National, 2001 national, etc) and which data year the M+C organization uses, a deadline date of October 1 has been established. These October deadline dates are effective beginning 2004. If a M+C organization knows that there will be a significant delay in the reporting of their project beyond the deadline date, they should notify their CMS Regional Office representative.

The following chart illustrates *CMS' expectations regarding* the QAPI *project implementation and* reporting cycles for the years 1999 through 2004. The elements include the year of the required QAPI project, the years in which a baseline may be collected for that project, and then based on the baseline data period selected, the dates that the project report is due to CMS for both significant and sustained improvements. Projects may be completed and submitted to CMS for evaluation at any time prior to the due date.

Required Reporting Time Frames for All QAPI Projects Based on Data Period

Project	Baseline Data Year	Demonstrable Improvement Due Date	Sustained Improvement Due Date
1999 Project	1998	Oct 1, 2001	Oct 1, 2002
	1999	Oct 1, 2002	Oct 1, 2003
2000 Project	1999	Oct 1, 2002	Oct 1, 2003
	2000	Oct 1, 2003	Oct 1, 2004
2001 Project	2000	Oct 1, 2003	Oct 1, 2004
	2001	Oct 1, 2004	Oct 1, 2005
2002 project	2001	Oct 1, 2004	Oct 1, 2005
	2002	Oct 1, 2005	Oct 1, 2006
2003 project	2002	Oct 1, 2005	Oct 1, 2006
	2003	Oct 1, 2006	Oct 1, 2007
2004 project	2003	Oct 1, 2006	Oct 1, 2007
	2004	Oct 1, 2007	Oct 1, 2008

20.7.6 - Project Review Report

(Rev. 29, 08-01-03)

The Project Review Report will be sent to CMS via the HPMS system from the M+CQRO reviewers. This report will highlight the strengths and weaknesses of each project. The 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. For significant improvement, if a project scores 50 or higher, a corrective action will not be required. If the project scores a 49 or less, CMS will require a corrective action plan.

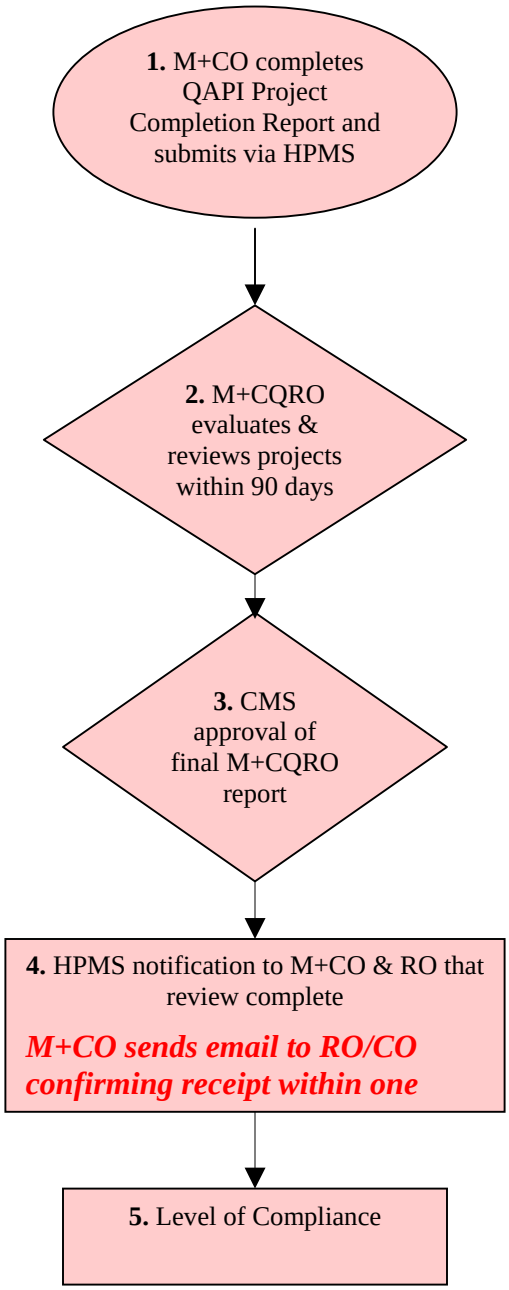
All aspects of the QAPI projects are important, however, some areas such as significant (demonstrable) and sustained improvement were determined to be the most significant. The scoring is weighted based on the significance placed on particular elements. Scoring is divided into a section for significant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

20.7.7 - Communication Process

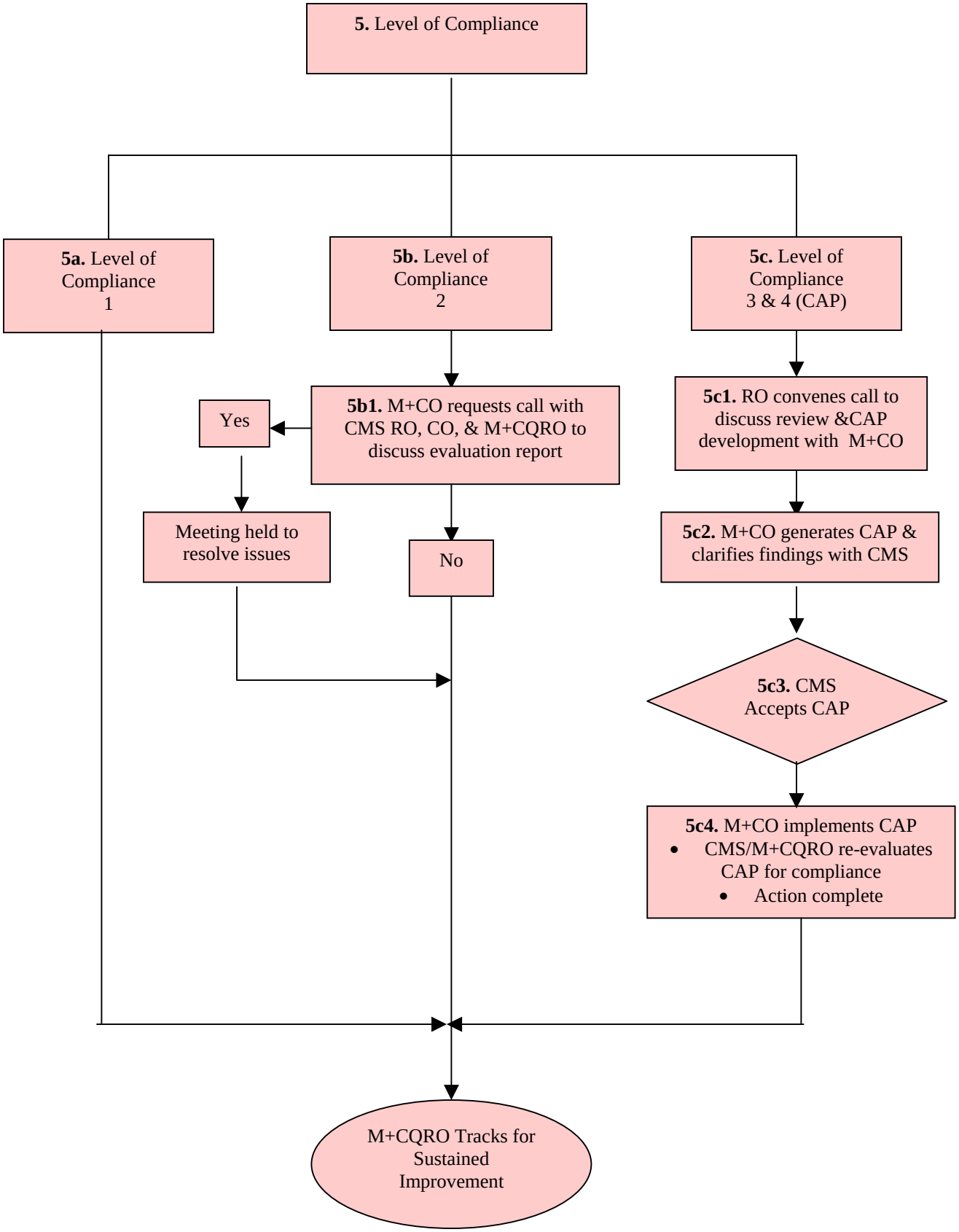
(Rev. 29, 08-01-03)

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

QAPI Project Communication Process



QAPI Project Communication Process



1. M+CO completes QAPI Project Report and submits via HPMS

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

3. *CMS approval of final M+CQRO report.*

4. After CMS has approved a project evaluation, the HPMS system will generate an e-mail to the M+CO to notify of the final evaluation. Within one week of receipt of the final evaluation, the M+C organization will confirm to CMS staff that it has received their evaluation via HPMS.

5. Level of Compliance

5a. Level of compliance 1: (Compliant) M+C organization continues with its project and goal of attaining sustained improvement.

5b. Level of compliance 2: (Compliant with minor deficiencies)

5b1. M+C organization may request a conference call with CMS RO, CO, and M+CQRO to clarify and discuss project results or any issues with the evaluation. The M+C organization should contact their CMS RO representative to facilitate this call. This session is informational and serves as a learning discussion for future projects. The M+C organization then continues with its project and goal of attaining sustained improvement.

5c. Compliance levels 3 and 4: M+C organizations at these compliance levels must prepare a corrective action plan

5c1 - After the M+C organization has confirmed receipt of it's evaluation, it must then contact it's CMS RO representative to convene a conference call with CMS CO and M+CQRO staffs to discuss the completed project review. Typically, dates and times are based upon when the M+C organization will be ready to discuss its project. The CMS expects that this call will occur within a few weeks of the M+C organizations' receipt of the project review.

5c2 - The goal of the above stated conference call is to (1) generate a CAP that is both beneficial to Medicare member and to the M+C organization, and (2) allow CMS to provide technical assistance and clarify findings. Typically, the CAP suggested in the final report should be adequate, but this discussion between CMS and the M+CO allows for the opportunity to generate a mutually agreed upon plan. The M+C organization has 45-days from initial receipt of the project review to submit a CAP for CMS approval.

5c3 - After receipt of a CAP from the M+C organization, CMS will either accept the CAP or reject it. If the CAP was agreed upon by the plan and CMS, it will be accepted.

5c4 - Once the CAP has been accepted, the M+C organization implements the CAP in the specified time frames. The CMS and the M+CQRO will re-evaluate the CAP for compliance. Once the CAP has been resolved, the M+C organization will then continue with the project for sustained improvement.

20.8 - Other Tools

(Rev. 29, 08-01-03)

In addition to the Project Completion Report and Project Review Report, other tools have been developed to assist M+C organizations in the implementation of the QAPI projects. An instructional guide and a reviewer guide provide 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.

All tools are available on http://www.cms.hhs.gov/healthplans/quality.

20.9 - Corrective Action Plans

(Rev. 29, 08-01-03)

In the event that an M+C organization does not meet the set requirements in the standards and guidelines determined by CMS, a Corrective Action Plan (CAP) will be required. Please review the previous communication flow chart (5C) on the CAP process. The CAP is meant to bring the M+C organization into compliance with the QAPI requirements. Once all CAP's have been resolved, CMS will automatically increase the M+C organization's significant improvement score to a total value of 50 points out of a possible 80 points. This increase brings the M+C organization into a compliance level of 2, which does not require corrective action. This increase will positively affect the total project score after sustained improvement is evaluated in the following year.

Possible Examples of CAP Elements

- Sampling methodology is inappropriate - The M+C organization may be required to re-sample and re-calculate final figures for the project under review. The M+C organization may also be required to collaborate with the QIO for future sampling efforts.

- Methodology is appropriate and study is sound, but did not achieve significant and sustained improvement - The M+C organization may be required to add or strengthen interventions. If appropriate, it may also be allowed to have a specific extension of time if the reviewers believe that more time would show the improvement.

- Interventions do not support indicators - The M+C organization may be required to implement new interventions or collaborate with its QIO on future projects.

- Conducts a project, but has poor planning, methodology, indicators, interventions, etc - The M+C organization may be instructed to collaborate with its QIO in future projects.

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

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

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.

25 - Summary of Preferred Provider Organization and Private Fee-For-Service (PPO/PFFS) Quality Improvement Requirements

(Rev. 16, 09-27-02)

The following provides a summary of quality improvement requirements relating to M+C preferred provider organizations and private fee for service plans. These requirements closely follow the provisions of 42 CFR 422.152(e) and 422.154. The requirements for these organizations have been extracted from the overall M+C provisions and are listed separately so that PPO/PFFS plans may quickly identify applicable requirements.

PPO Definition: A PPO plan has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; and provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under State law as an HMO. 42 CFR 422.4(a)(1)(iv)

PFFS Definition: An M+C PFFS plan is health benefits coverage offered by an organization to Medicare beneficiaries in a defined service area. The plan includes a specific set of benefits offered at a uniform premium and uniform level of cost sharing. The plan pays providers at a pre-determined level on a fee-for-service basis and the payment rate does not vary based on frequency of a rendered service. The plan does not restrict an enrollee's choice of providers who are authorized to provide services if the provider agrees to the plan's payment terms. 42 CFR 422.2 and 422.4(a)(3)

A. Medicare+Choice PPOs and PFFS plans must have an ongoing quality assessment and performance improvement (QAPI) program per 422.152(a). The program should include the following elements:

    a. The policymaking body oversees and is accountable for the QAPI program;
    b. A designated senior official is responsible for QAPI program administration;

c. Employed or affiliated providers and consumers actively participate in the QAPI program; and

d. There is formal and ongoing communication and collaboration among the policymaking body that oversees the program and the other functional areas of the organization, e.g., health services management and member services.

Additional requirements of the QAPI program stipulate that it:

1. Measures and reports performance using standard measures required by CMS including the following areas:

    1. Clinical areas - effectiveness of care, perception of care, use of services; and

    2. Non-clinical areas - access and availability to care, appeals and grievances, and organizational characteristics. 422.152(e)(1)

Currently, CMS has adopted the National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS)™ as an acceptable standardized performance reporting system. See Exhibit 1B for the PPO/PFFS reporting matrix;

2. Maintains a health information system that collects, integrates, analyzes and reports data that is necessary to implement and support the activities of the QAPI program; 422.152(f)(1)(i);

3. Ensures that information and data received from health care providers is reliable and complete. Service data should be collected in standardized formats to the extent feasible and appropriate. The PPO/PFFS plan should routinely review reported data for accuracy, completeness, logic, and consistency; 422.152(f)(1)(ii);

4. Makes all collected information available to CMS for review purposes; 422.152(f)(1)(iii);

5. Evaluates the continuity and coordination of care to the extent possible. For example, if the plan offers a drug benefit there should be a system to monitor contra-indicated prescriptions; 422.152(e)(2);

6. Evaluates the impact and effectiveness of the QAPI program at least annually. This would include an evaluation of the effectiveness of the PPO's or PFFS plan's communications with enrollees. The evaluation should also determine whether the organization has met any performance goals that may be established for that particular organization; 422.152(f)(2); and

7. Achieves remedial action for problems that come to the attention of the plan from various sources. This would include correction of systemic problems that come to its attention through internal surveillance, complaints or other mechanisms. Additionally, the organization should routinely monitor the issue resolution

process and maintain, aggregate and analyze information on the nature of issues raised by enrollees and on their resolution. This information should be used to develop activities under the QAPI program, both to improve the issue resolution process itself, and to make improvements that address other system issues that have been identified. 422.152(f)(3);

8. M+C PPO plans must maintain a written agreement with an independent quality review and improvement organization approved by CMS. These entities are commonly referred to as quality improvement organizations (QIO). If a PFFS plan performs utilization management it must also have an agreement with a QIO; 422.154(a);

9. If the M+C organization uses written protocols for utilization review, the protocols must (1) be based on current standards of medical practice and (2) should incorporate mechanisms to evaluate appropriate use of services and to inform enrollees and providers of the evaluation results. The mechanisms should have the capacity to detect both under-utilization and over-utilization of services. 422.152(e)(3)(i) & 422.152(e)(3)(ii);

10. The organization oversees and is accountable for any functions or responsibilities that are delegated to other entities, such as claims processing, health services network management, etc. The following requirements apply to all delegated functions: 42 CFR 422.502(i)

    1. A written agreement specifies the delegated activities and reporting responsibilities of the entity and provides for revocation of the delegation or other remedies for inadequate performance.

    2. The organization evaluates the entity's ability to perform the delegated activities prior to delegation.

    3. The performance of the entity is monitored on an ongoing basis and formally reviewed by the organization at least annually.

If the organization delegates selection of providers to another entity, the organization retains the right to approve, suspend, or terminate any provider selected by that entity.

35 - The Medicare + Choice Deeming Program

(Rev. 29, 08-01-03)

This section discusses the Medicare + Choice Deeming Program. Regulations that govern the program are set forth in *Title* 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

(Rev. 58, 08-13-04)

Deeming Authority

The authority granted by CMS to private, national accrediting organizations to determine, on CMS' 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. Each AO defines fully accredited differently. Currently CMS has entered an agreement with NCQA, JCAHO, and AAAHC to be deeming accrediting organizations. Below describes each AO's fully accredited status levels.

NCQA

Health plans may earn the following NCQA Accreditation status levels based on their compliance with NCQA's rigorous requirements and their performance on HEDIS® and CAHPS®:

- ***Excellent:*** *NCQA's highest accreditation status is granted only to those plans that demonstrate levels of service and clinical quality that meet or exceed NCQA's rigorous requirements for consumer protection and quality improvement. Plans earning this accreditation level must also achieve HEDIS results that are in the highest range of national or regional performance.*
- ***Commendable:*** *This accreditation level is awarded to plans that demonstrate levels of service and clinical quality that meet or exceed NCQA's rigorous requirements for consumer protection and quality improvement. The 'Commendable' designation is equivalent to NCQA's former 'Full Accreditation' designation.*

- ***Accredited:*** *Health plans that earn the "Accredited" designation must meet most of NCQA's basic requirements for consumer protection and quality improvement. "Accredited" is equivalent to the former "One-Year" designation.*

Joint Commission Accreditation Health Organization

Accreditation with Requirements for Improvement (previously Accreditation with Type I Recommendations) *is awarded to a health care organization that demonstrates satisfactory compliance with applicable JCAHO standards in most performance areas, but has deficiencies in one or more performance areas or in meeting accreditation policy requirements which require resolution within a specified time period.*

Provisional Accreditation *is awarded to a previously unaccredited health care organization that demonstrates satisfactory compliance with a subset of standards during a preliminary on-site evaluation. This decision remains in effect until one of the other official accreditation decision categories is assigned, based on a complete survey against all applicable standards approximately 6 months later.*

AAAHC

AAAHC has five types of accreditation decisions resulting from an initial accreditation survey, re-accreditation survey (survey following 3-year term) or a re-survey (survey following one-year or 6-month provisional term of accreditation or a 6-month deferral).

Three Years *– The Accreditation Committee awards an organization accreditation for 3 years when it concludes that the organization is in substantial compliance with the standards, and the committee supports the accuracy of the findings and the organization's commitment to continue providing high-quality medical care and services as reflected in the standards.*

One Year *– The Accreditation Committee awards an organization accreditation for 1-year when a limited portion of the organization's operations require action to meet some standards and the organization requires sufficient time to achieve compliance.*

Six Month Provisional *– The Accreditation Committee awards an organization a provisional 6-month term of accreditation when it concludes that the organization is in substantial compliance with the standards but it is not eligible for a 3-year term of accreditation because the organization does not meet specific requirements , e.g., the organization has not been operational for 6 months. The Accreditation Committee also awards provisional accreditation to organizations that are in compliance with the standards but the organization's demonstration of continued compliance with the standards is not sufficiently established to grant a longer term of accreditation.*

Private, National Accrediting Organization

Organizations that seek deeming authority must be private, national accrediting organizations. To meet CMS' 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 the AO specific 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' recognition of the validity of an accrediting organization's determination that an M+C organization is "fully accredited." CMS will continue to perform the biennial monitoring audit. 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, CMS will recognize the deemed status of M+C organizations if they are accredited at the same jurisdictional level (whether contract, state, or multi-state) that CMS would have used if it, rather than the accrediting organization, had conducted the survey.

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

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

35.2 - Deeming Requirements

(Rev. 10, 08-14-02)

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

1. Quality assessment and improvement (§1852(e) of the Social Security Act);
2. Confidentiality and accuracy of enrollee records (§1852 (h) of the Social Security Act);
3. Anti-discrimination (§1852(b) of the Social Security Act);
4. Access to services (§1852(d) of the Social Security Act);
5. Information on advance directives (§1852(i)of the Social Security Act); and

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

35.3 - General Rule

(Rev. 29, 08-01-03)

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 a 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 5 by an organization that is approved by CMS on March 1 of the same year, on January 5 the accrediting organization must have used the same standards and review processes that CMS determined on March 1 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 1.

35.4 - Obligations of Deemed M+C Organizations

(Rev. 29, 08-01-03)

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, a M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accrediting organization's accreditation process. There are two types of validation surveys:

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

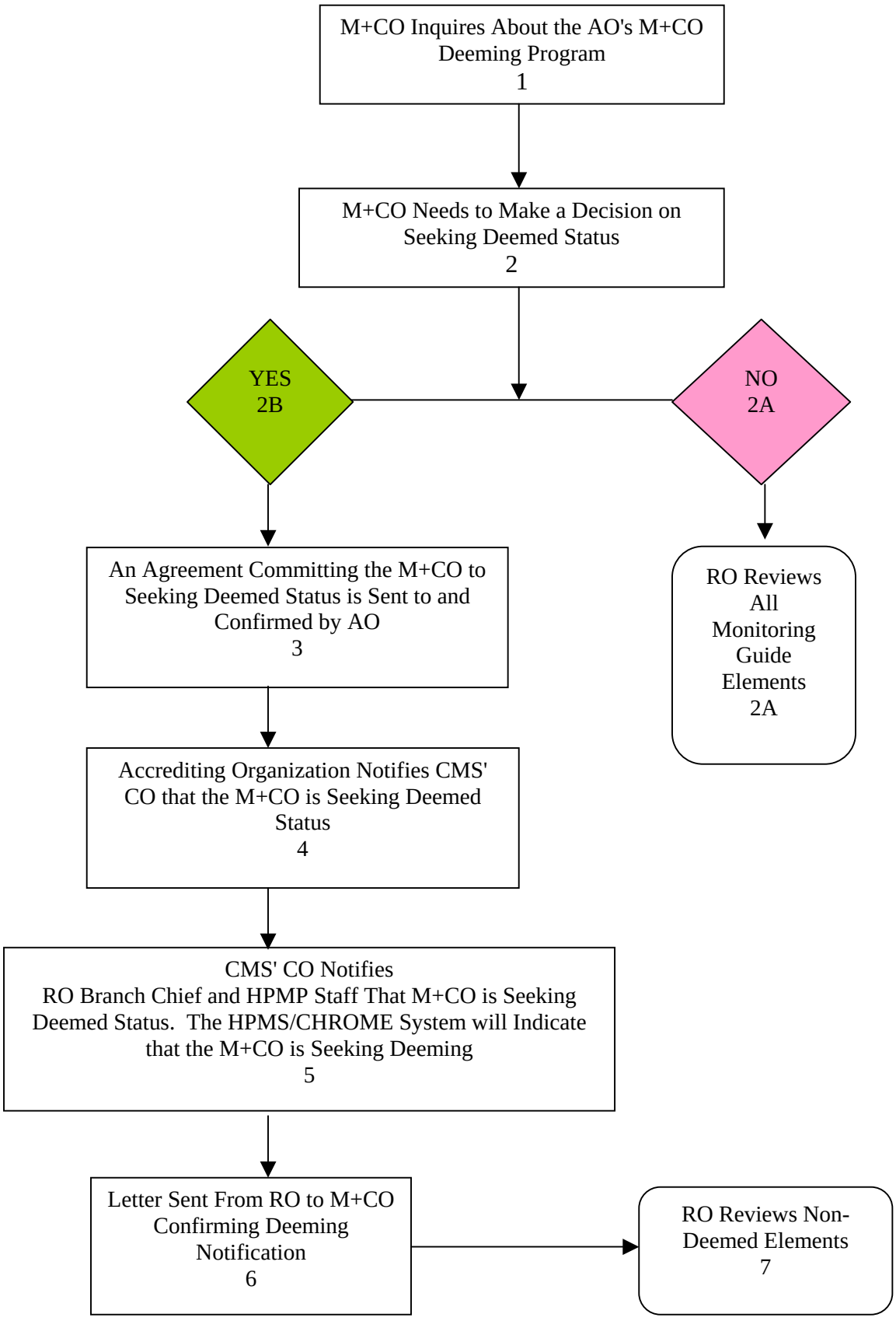
2. Retrospective (or look behind) surveys.

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

M+C organizations *that* seek deemed status via accreditation by a CMS-approved accrediting organization can submit the cost of accreditation as an administrative cost in their Adjusted Community Rate (ACR) submission. Administrative costs that bear a

significant relationship to the M+C plan being priced are allowed to be included in the ACR. However, the cost for the accreditation should be equally allocated between the M+C organizations Medicare and non-Medicare line of business.

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


M+CO Inquires About the AO's M+CO Deeming Program
1
M+CO Needs to Make a Decision on Seeking Deemed Status
2
YES
2B
NO
2A
An Agreement Committing the M+CO to Seeking Deemed Status is Sent to and Confirmed by AO
3
RO Reviews All Monitoring Guide Elements
2A
Accrediting Organization Notifies CMS' CO that the M+CO is Seeking Deemed Status
4
CMS' CO Notifies
RO Branch Chief and HPMP Staff That M+CO is Seeking Deemed Status. The HPMS/CHROME System will Indicate that the M+CO is Seeking Deeming
5
Letter Sent From RO to M+CO Confirming Deeming Notification
6
RO Reviews Non-Deemed Elements
7

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

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

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

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

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

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

2A. The Decision is No: The RO Reviews All Monitoring Guide Elements. The M+C organization decides not to seek deemed status, the RO will schedule and conduct a performance assessment visit using the *most* current version of the monitoring *guide*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   After receiving notification from the central office that the M+C organization is seeking deemed status, the RO will then send the M+C organization a letter that notifies the M+C organization that the AO has informed CMS that it (the M+C

organization) is seeking deemed status. This letter will also be a vehicle to confirm that the M+C organization does indeed intend to seek deemed status via accreditation from the AO.

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

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

35.4.1 - Deemed Status and CMS Surveys

(Rev. 10, 08-14-02)

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

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

Thus, CMS' 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. The CMS will also retain the authority to investigate "serious" complaints about an M+C organization.

35.4.2 - Removal of an M+C Organization's Deemed Status

(Rev. 10, 08-14-02)

The 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.

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

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

35.5 - CMS' Role

(Rev. 10, 08-14-02)

The 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. The CMS may approve an organization for deeming authority, if it can demonstrate, through the application process, that its accreditation program is at least as stringent as CMS', and it meets 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' RO staff identifies that an M+C organization is not in compliance with a deemable requirement, RO staff must notify CMS CO deeming staff who will ensure that the accrediting organization initiates a corrective action process, when and if appropriate. Although beneficiary-specific complaints will continue to be handled by RO staff, the RO will not issue the corrective action requirement for deficiencies found in deemed areas.

35.5.1 - Oversight of Accrediting Organizations

(Rev. 29, 08-01-03)

After approving an accrediting organization for deeming authority, CMS has a critical role in providing oversight of accrediting organizations' performance. The 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; and

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

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

Equivalency Review

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

1. The 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

The CMS or its agent may *monitor and evaluate AO functioning on a regular basis utilizing a mix of the following methods:*

1. *Desk Review: CMS will review the AO's survey reports on a random selection of deemed MCOs.*

2. *Observational (concurrent) Survey: CMS will accompany the AO on a deemed Accreditation survey to validate the organization's accreditation process.*

3. *Retrospective/Look Behind Survey: CMS will conduct a survey of the M+CO within 30 days of the AOs survey and compare results.* 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.

Initially, CMS will conduct only concurrent/observational reviews of accrediting organization performance. Then, CMS will phase-in a combination of *desk reviews, concurrent/observational, and look behind surveys*.

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

(Rev. 10, 08-14-02)

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

(Rev. 10, 08-14-02)

If an equivalency review, validation review, onsite observation, or CMS' 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 §35.6.1 of 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

(Rev. 10, 08-14-02)

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

Accrediting organizations must also ensure the following:

- Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;
- The majority of the membership of its governing body is not comprised of managed care organizations or their representatives; and
- Its governing body has a broad and balanced representation of interests and acts without bias.
- In addition, if CMS takes an adverse action based on accreditation findings, approved accrediting organizations must permit their surveyors to serve as witnesses.

35.6.1 - Application Requirements

(Rev. 29, 08-01-03)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10. A list of all the M+C organizations that the organization has currently accredited, by 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 each was accredited (if denied, the date it was denied), and the level (category) of accreditation it received.

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

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

14. A written presentation that demonstrates that it will be able to furnish data electronically, *in a CMS compatible format.*

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

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

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

As part of the application process, CMS may visit the accreditation organization's offices to verify representations made by the organization in its application, including, but not limited to, *reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision-making process, and interviewing* the organization's staff.

35.6.2 - Application Notices

(Rev. 10, 08-14-02)

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. The 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

The 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.

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

35.6.3 - Withdrawing an Application

(Rev. 10, 08-14-02)

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

(Rev. 29, 08-01-03)

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

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

    b. Notice of all accreditation decisions;

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

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

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

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

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

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

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

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

    b. Submit a new crosswalk reflecting the new requirement; and

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

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

7. Accrediting organizations must report its assessment of accredited M+C organization QAPI projects*, and results of deemed surveys and any corrective actions, if required,* to CMS via HPMS

Disclosure of Accreditation Survey Reports:

Accreditation surveys of Medicare+Choice organizations performed by private accreditation organizations under §1852(e)(4) of the Act may not be released to the public by CMS, except to the extent that such surveys relate to an enforcement action taken by the Secretary. Accrediting organizations (AO) must, however, have methods to disclose the accreditation status of deemed M+COs.

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

(Rev. 10, 08-14-02)

An accreditation organization that has received notice of denial of its request for deeming authority (or specific deeming categories) may request reconsideration. The CMS will reconsider any determination to deny, remove, or not renew the approval of deeming authority to private accreditation organizations, if the accreditation organization files a written request for reconsideration. The request must be filed within 60 days of the receipt of notice of an adverse determination. The request for reconsideration must specify the findings or issues with which the accreditation organization disagrees, and the reasons for the disagreement.

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

35.7.1 - Informal Hearing Procedures

(Rev. 29, 08-01-03)

The 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 conducts the *hearing, receives testimony, and reviews* 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 does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

35.7.2 - Informal Hearing Findings

(Rev. 10, 08-14-02)

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

- Separately numbered findings of fact; and

- The legal conclusions of the hearing officer.

35.7.3 - Final Reconsideration Determinations

(Rev. 10, 08-14-02)

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

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. 32, 10-03-03)

40.1 - Background

(Rev. 32, 10-03-03)

This section provides information regarding the annual Medicare HEDIS submission and provides clarification for Medicare contracting organizations under applicable law, regulations and contract requirements governing Medicare+Choice (M+C) organizations, the §1876 of the Act cost contracting organizations, and demonstration projects. This section also explains reporting requirements for HOS and CAHPS and addresses specific CMS implementation requirements. Throughout this section of Chapter 5, the general term, Managed Care Organization (MCO), will be used to refer to all contracting organizations, unless otherwise specified. Effective January 1, 1997, CMS began requiring MCOs to report on performance measures from the HEDIS® reporting set relevant to the Medicare managed care population, and to participate both in CAHPS® and the Health Outcomes Survey (HOS). These requirements are consistent with the law and with the requirements of other large purchasers. It is critical to CMS' 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).

The CMS makes summary, plan-level performance measures available to the public through media that are beneficiary-oriented, such as the Medicare Personal Plan Finder and Medicare Health Plan Compare tools on (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 and reasons also are available in printed form through the same toll free line. HEDIS summary-level data files are available through CMS' Internet Web site as a Public Use File (http://www.hcfa.gov/hedisdwn.htm). Complete HEDIS and CAHPS (including the annual M+C CAHPS survey and the 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' 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' Office of Information Services. For more information about Medicare data for research purposes, go to http://www.cms.hhs.gov and then select the area for Researchers.

The following is a chart describing HEDIS, HOS, and CAHPS program requirements.

Table - Program Requirements

Contract Year	Sampling Frame/ Period	Dates for Participation Eligibility	Minimum Sample Size	Financial Responsibility	Demon-strations	Mergers and Acquisitions	Cost Contract Report-ing	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)	MCO pays for external HEDIS Audit	Required in some cases as specified in this manual	Reporting by surviving MCO only	Report Cost Contract Measures Only	MCO must submit Audited Summary and Patient-Level Data by the last business day in June.
Health Outcomes Survey	Members continuously enrolled 6 months prior to survey sampling	Medicare contract in place no later than Jan. 1 of previous year	1000 (If less than 1000 enrollees, all members must be surveyed.)	MCO pays for NCQA certified vendor to administer survey	Yes (See section on demon-strations)	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 and Disenrollees)	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 enrollees (If less than 600, all members will be surveyed.) Disenrollee sampling proportionate to disenrollment rate	CMS pays for survey administration	Yes (See section on demon-strations)	Reporting of surviving MCO's membership only only	Yes	CMS will conduct survey in the Fall.
Quarterly CAHPS Disenrollment Reasons Survey	Members who have disenrolled during previous quarter	Medicare contract in place no later than Jan. 1 of previous year	Approximately 388, (If less than 388, all disenrolled members will be surveyed except those for CAHPS Assessment)	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. 32, 10-03-03)

A - Effects of the Balanced Budget Act of 1997

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

B - Requirements for MCOs

1. Reporting Requirements

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

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

        The HEDIS technical specifications are updated annually. For example, MCOs preparing HEDIS 2003 data submissions must follow instructions in HEDIS 2003, Volume 2, and the HEDIS 2003, Volume 2 Update (to be released in October 2002). 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 2003 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+COs must report are listed in Exhibit I, and the Medicare relevant measures that continuing cost

contractors must report are listed in Exhibit IA. M+C PPO and PFFS plan reporting requirements are shown in Exhibit IB. Note that two measures in the Health Plan Descriptive Information Domain (that are listed in NCQA's Technical Specifications as appropriate for 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 section C below for specific requirements for demonstration projects.

c. Medicare+Choice CAHPS Survey - All Organizations that had a Medicare contract in effect on or before July 1, of the previous year, must comply with the M+C CAHPS survey of current enrollees and disenrollees.

d. Medicare CAHPS Disenrollment Reasons Survey - All organizations that had a Medicare contract in effect on or before January 1 of the previous year must comply with the Medicare CAHPS disenrollment Reasons Survey (hereinafter "The Reasons" Survey. The Reasons Survey does not apply to organizations that began a contract effective after January 1 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 (Volume 61, "Federal Register," 13430, March 27, 1996). The Medicare CAHPs can be used 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 "HEDIS Volume 5, HEDIS Compliance Audit™: Standards, Policies and Procedures."

   Sampling and Reporting Unit - *In 2004* MCOs will have one reporting unit for HEDIS, HOS, *and Disenrollment Reasons and Rates,* for each contract. This aligns HEDIS and HOS reporting with the level at which MCO performance is monitored and quality assessment and performance improvement projects are performed, i.e. at the contract level. *Note that HEDIS 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.

Medicare CAHPS instituted a local sampling and reporting unit for the traditional CAHPS survey of enrollees and disenrollees that accommodates comparison with Medicare CAHPS fee-for-service (FFS) *and Private Fee-For-Service (PFFS) plans and* retains the collection of beneficiary satisfaction and experience data at a local level. 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. Currently, the CAHPS data on Medicare managed care plans is compared to CAHPS data on Original Medicare at the State level in the Medicare Personal Plan Finder and Medicare Health Plan Compare on www.medicare.gov and in the annual CAHPS health plan reports. The comparisons between managed care, private fee-for-service, and Original Medicare are displayed. Please send questions to CAHPS@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.

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" (see *Members who switch product lines*) 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 expanded or reduced 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 that did not have enrollment on January 1st of the measurement year or later will not report HEDIS performance measures for the corresponding reporting 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 list of 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. M+C preferred provider organizations and private fee for service plans due to the structure of their organizations are not able to report all measures of M+C coordinated care plans. Consequently, a separate reporting matrix for these organizations is included as Exhibit I.B.

12. 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. The 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.

***NOTE**: An entity that acquires and novates an existing Medicare contract must file a HEDIS report since the membership, benefits and medical delivery system are essentially unchanged. Therefore, during negotiations for the acquisition it is essential that parties agree on a method of data exchange that will permit the acquiring organization to file a HEDIS report covering the measurement year in which the transaction occurred.*

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 for similar type plans. However, specific waivers contained in the demonstration contracts that have been or will be negotiated with CMS take precedence over any requirements specified in this manual section. The chart below summarizes reporting requirements by type of demonstration. For further information on the requirements for specific demonstrations, contact the CMS project officer in the Division of Demonstration Programs.

Demonstration	**HEDIS**	**HEDIS Audit**	**M+C CAHPS**	**Disenrollee Reasons Survey**	**HOS**
Social HMOs	YES	YES	YES	YES	YES
Minnesota Senior Health Options	NO	NO	NO	NO	NO
Wisconsin Partnership Program	NO	NO	NO	NO	NO
Evercare	NO	NO	NO	NO	NO
Medicare Alternative Payment Demo I	*	*	*YES*	*YES*	*
PPO	*	*	*YES*	*NO*	*

***Contact the CMS project officer in the Division of Demonstration Programs with additional questions and for advice on whether a report should be filed.**

D - Implications for Failure to Comply

The 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' contractor performance oversight process using the M+C Monitoring Review Guide, Version I.

E - Use of Data

Data reported to CMS under this requirement will be used in a variety of ways. The HEDIS, CAHPS, and Disenrollment summary data *is available to assist the Medicare beneficiary to make informed choices. This data will provide comparative information on contracts to beneficiaries to assist them in choosing among MMC plans and FFS*. In addition, CMS expects MCOs to use the data*, including HOS 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. Additionally, *all four* data *sets* may be used for research purposes by public or private entities. 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. *For example, CMS has developed a Performance Assessment System that will array information from the HEDIS, HOS, CAHPS, and disenrollment data sets in a manner that will permit performance evaluation by CMS. The MCOs can also view their own PAS information online via secured access to the Health Plan Management System.*

40.3 - HEDIS Submission Requirements

(Rev. 32, 10-03-03)

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 making 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, including M+C PPOs and PFFS plans, must submit HEDIS patient-level data at the same time. The CMS requires 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 Questionnaires (HOQ) on the NCQA Web site in late February. MCOs must accurately complete the HOQ in order to have an appropriate HEDIS Data Submission Tool(c) (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. NCQA can provide more information to MCOs regarding the tool and the submission process. MCOs will not be allowed to change data after submission to NCQA.

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 Effectiveness of Care 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 will 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, and in accordance with the Health Insurance Portability and Accountability Act. 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' 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. The CMS requires each MCO to contract with an NCQA Licensed Organization for an 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 http://www.ncqa.org/. The CMS will require that the Licensed Organizations follow the established standards, policies and procedures in NCQA's HEDIS, Volume 5. The MCO must ensure that the site visit audit team is led by a NCQA Certified HEDIS Compliance Auditor. In addition, the plan's chief executive officer, president, or other authorized person, such as the medical director, will be required to provide written attestation to the validity of the plan-generated data.

C - Final Audit Reports, Use and Release

Following the receipt by the MCO of the Final Audit Report from the NCQA-licensed audit firm, the MCO must make available a copy of the complete final report to the CMS ROs as needed. CMS ROs may request the report upon completion or as part of the pre-site monitoring visit package. In addition, the reports should be available for review onsite during monitoring visits. 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. 32, 10-03-03)

A - Survey Process

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 managed care 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 survey is designed to achieve a 70 percent response rate. If the contract-market has fewer than 1,000 eligible members, all will be surveyed.

Additionally, each year a cohort drawn two years previously will be resurveyed. The results of this re-measurement will be used to calculate a change score for the physical health and emotional well being of each respondent. Depending on the amount of expected change the respondent*'s physical and mental health status* will be categorized as *better, the same or worse than expected* over the two-year period. *Members who are deceased at follow-up are included in the "worse" physical outcome category.*

All M+C organizations and continuing cost contracts that held §1876 risk and cost contracts, as well as Social HMOs (SHMOs), with Medicare contracts in effect on or before January 1 of the *previous* year must comply with this survey requirement. 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, at their expense, are expected to contract with any of the NCQA certified vendors for administration of the survey to do 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' contractor, regarding administration of the survey.

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.

B - 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 *Baseline* Profile *Report*

This profile will be mailed to all plans participating in the previous 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 *baseline* 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 (QAPI) program requirements. *Baseline profile reports should be available by late June or early July. Effective Fall 2003, plan report distribution will no longer occur in hard copy format. Instead all report distribution will occur electronically through HPMS. Please contact your plan's CMS Quality Point of Contact to gain access to your HOS reports.*

HOS Performance Measurement Report and Data

After the administration of each follow up cohort, a cohort specific performance measurement report is produced. Survey responses from baseline and follow up are merged to create a performance measurement data set. The HOS performance measurement results are computed using a rigorous case mix/risk adjustment model. The resulting aggregation of these scores across beneficiaries within a plan yields the HOS plan level performance measurement results. The performance measurement reports and corresponding data results are designed to support MCO quality improvement activities.

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/QIO.

40.5 - Medicare CAHPS Requirements for Enrollees and Disenrollees

(Rev. 32, 10-03-03)

A. Information Regarding the CAHPS *Satisfaction* Survey

In the fall of each year, CMS administers the Medicare Managed Care CAHPS survey, which consists of the core CAHPS questions plus additional questions specific to Medicare. In fall 2003, this survey effort will begin to include private fee-for-service contracts, and CMS will call its CAHPS survey effort, the Medicare+Choice CAHPS Survey. Coordinated care contracts, continuing cost contracts and private fee-for-service contracts in effect on or before July 1st of the previous year are included. Organizations that 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 contract ends.

The CMS selects the sample for each local reporting unit within a contract. More information on the local sampling and reporting unit for the M+C CAHPS Survey is described in greater detail under §40.2 above.

This survey process includes both enrollees and disenrollees. For most plans, *within* the enrollee component of the MMC CAHPS Survey, the *reporting unit consists of* a random sample of 600 members who were continuously enrolled in the contract for 6 months and were not institutionalized. *For plans with large enrollment numbers, counties with more than 20,000 enrollees become an additional sampling and reporting unit.* For MCOs with fewer than 600 eligible members, all eligible members are surveyed.

For the disenrollee portion of MMC- CAHPS the sample rate fluctuates. The sample size will be determined by the application of the sampling rate for the CAHPS survey to the population of disenrollees and will not exceed 600. 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 pays 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' administration will be publicly released. These data will be disseminated to the public via Medicare Health Plan Compare and Medicare Personal Plan Finder on (www.medicare.gov) and 1-800-MEDICARE. In the summer of each year CMS will provide the MCOs participating in the CMS administration of the CAHPS survey with detailed reports for internal quality improvement efforts, consistent with the Privacy Act (Title 5, USC, §552a).

B. Information Regarding CAHPS Disenrollment Survey

The Medicare CAHPS Disenrollment Reasons Survey asks beneficiaries about their reasons for leaving their Medicare managed care plan. CMS combines reasons for disenrolling with the annual disenrollment rates for reporting to beneficiaries through the Medicare Personal Plan Finder and Medicare Health Plan Compare on http://www.medicare.gov/ and at 1-800 MEDICARE.

The CMS administers the Reasons Survey on a quarterly basis. Beginning in July 2003, CMS began including private fee-for-service plans in its administration of the Reasons Survey.

The sampling size for the Disenrollment Reasons Survey is approximately 388, or if less than 388, all disenrolled members will be surveyed after accommodating the disenrollee stratum of the M+C CAHPS *Satisfaction* 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.

Information from the Reasons Survey is provided to the participating contractors in an interim report after the first two quarters of the survey and in a final annual report following survey completion. *In Fall of 2003, an interactive version of the annual disenrollment report also will be available online through HPMS.*

40.6 - Minimum Performance Levels and Performance Goals

(Rev. 32, 10-03-03)

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 through its new Policy Clarification Support (PCS) Web page. The PCS page is accessible from the main NCQA Web site (http://www.ncqa.org). To access PCS, click on Support on the bottom of the gray bar along the left side of the NCQA home page and then click on Policy Clarification Support. The direct link for the PCS Web page is: http://www.ncqa.org/programs/faq/PCS.asp. From here, users can view Frequently Asked Questions (FAQ) and Policy Updates or submit a question to PCS staff. You can also reach NCQA through its Customer Support Line at (888) 275-7585. Questions about Medicare HEDIS not resolved through NCQA can be directed to Richard Malsbary at (410) 786-1132 in CMS' 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 *program*, please contact Chris Haffer in CMS' 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. *For technical questions regarding the use of technical data or reports, please contact the HOS Information and Technical Support Telephone Line at HSAG at 1-888-880-0077 or via email at hos@azqio.sdps.org.*
3	*CAHPS*	*For technical questions regarding the* MMC *CAHPS Survey, please contact Amy Heller at (410) 786-9234 of CMS' Center for Beneficiary Choices or email CAHPS@cms.hhs.gov. For the Disenrollment Reasons Survey, 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.

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

(Rev. 32, 10-03-03)

Effectiveness of Care

**Colorectal Cancer Screening*

Anti-depressant Medication Management

Cholesterol Management After Acute Cardiovascular Events

Breast Cancer Screening

**Osteoporosis Management in Women Who Had a Fracture*

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

**Management of Urinary Incontinence in Older Adults (collected through HOS)*

Access to/Availability of Care

Adults' Access to Preventive/Ambulatory Health Services

**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment*

**Claims Timeliness*

**Call Answer Timeliness*

**Call Abandonment*

Health Plan Stability

Practitioner Turnover

Years in Business/Total Membership

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

Identification of Alcohol and Other Drug Services

Outpatient Drug Utilization (for those with a drug benefit)

Health Plan Descriptive Information

Board Certification

Total Enrollment by Percentage

Enrollment by Product Line (Member Years/Months)

** New measure for HEDIS® 2004. Reporting of a new measure in the first year is optional.*

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

(Rev. 32, 10-03-03)

Effectiveness of Care

**Colorectal Cancer Screening*

Anti-depressant Medication Management

Cholesterol Management After Acute Cardiovascular Events

Breast Cancer Screening

**Osteoporosis Management in Women Who Had a Fracture*

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

**Management of Urinary Incontinence in Older Adults (collected through HOS)*

Access to/Availability of Care

Adults' Access to Preventive/Ambulatory Health Services

**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment*

**Claims Timeliness*

**Call Answer Timeliness*

**Call Abandonment*

Health Plan Stability

Practitioner Turnover

Years in Business

Total Membership

Use of Services

Ambulatory Care

Outpatient Drug Utilization (for those with a drug benefit)

Health Plan Descriptive Information

Board Certification

Total Enrollment by Percentage

Enrollment by Product Line (Member Years/Months)

** New measure for HEDIS®2004. Reporting of a new measure in the first year is optional.*

Exhibit IB - HEDIS Reporting Matrix for M+C Private Fee For Service Plans and Preferred Provider Organizations

(Rev. 32, 10-03-03)

HEDIS 2004 Measure	*Applicable to PFFS/PPO*	*Not Applicable to PFFS/PPO*	*Comments*
Effectiveness of Care			
**Colorectal Cancer Screening*		**X**	*Requires medical record review*
Breast Cancer Screening	*X*		
**Osteoporosis Management in Women Who Had a Fracture*	*X*		*Must be reported only by plans with a pharmacy benefit*
Controlling High Blood Pressure		*X*	*Requires medical record review*
Beta Blocker Treatment After a Heart Attack		**X**	*Requires medical record review and prescription information*
Cholesterol Management After Acute Cardiovascular Events	*X*		*LDL-C Screening rate is required. LDL-C Level is not required due to need for medical record review.*
Comprehensive Diabetes Care	*X*		*Rates are required for HbA1c Testing, Eye Exams and LDL-C Screening but not for HbA1c control, LDL-C control or Monitoring for Diabetic Nephropathy which requires medical record review.*
Follow-up After Hospitalization for Mental Illness	*X*		

HEDIS 2004 Measure	*Applicable to PFFS/PPO*	*Not Applicable to PFFS/PPO*	*Comments*
Antidepressant Medication Management	*X*		*Must be reported only, by plans with pharmacy and mental health benefit*
Medicare Health Outcomes Survey	*X*		*Requires contract with NCQA certified vendor to administer survey*
Management of Urinary incontinence in Older Adults	*X*		*Measure will be collected through Health Outcomes Survey*
Access /Availability of Care			
Adults' Access to Preventive/Ambulatory Health Services	*X*		
**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment*	*X*		
**Claims Timeliness*	*X*		
**Call Answer Timeliness*	*X*		
**Call Abandonment*	*X*		
Satisfaction with the Experience of Care			
HEDIS/CAHPS ™ 3.0H , Adult (enrollee and disenrollee components)	*X*		*Must provide information that CMS needs to administer survey*

HEDIS 2004 Measure	*Applicable to PFFS/PPO*	*Not Applicable to PFFS/PPO*	*Comments*
Health Plan Stability			
Practitioner Turnover	*X*		*Measure must be reported only by PPOs with a contracted physician network.*
Years in Business/Total Membership	*X*		
Use of Services			
Frequency of Selected Procedures	*X*		
Inpatient Utilization --- General Hospital/Acute Care	*X*		
Ambulatory Care	*X*		
Inpatient Utilization-Non-Acute Care	*X*		
Mental Health Utilization --- Inpatient Discharges and Average Length of Stay	*X*		
Mental Health Utilization-Percentage of Members Receiving Services	*X*		
Chemical Dependency Utilization---Percentage of Members Receiving Services	*X*		
Identification of Alcohol and Other Drug Services	*X*		

HEDIS 2004 Measure	*Applicable to PFFS/PPO*	*Not Applicable to PFFS/PPO*	*Comments*
Outpatient Drug Utilization	*X*		*Reporting is limited only to plans with a pharmacy benefit*
Health Plan Descriptive Information			
Board Certification	*X*		*Measure must be reported only by PPOs with a contracted physician network*
Total Enrollment by Percentage	*X*		
Enrollment by Product Line (Member Years/Member Months)	*X*		

** New measure for HEDIS 2004. Reporting of a new measure in the first year is optional.*

Exhibit II - Submitting Patient-Level Data

(Rev. 39, 11-07-03)

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

Colorectal Cancer Screening

Breast Cancer Screening

Osteoporosis Management in Women Who Had a Fracture

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

Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

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

Identification of Alcohol and Other Drug 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. National Committee for Quality Assurance (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 http://www.ncqa.org. MCOs are advised to frequently review the NCQA Web site for updates on the data submission process.

Appendix A - National QAPI Project Operational Policy Letters

(Rev. 29, 08-01-03)

1999 - Diabetes

Diabetes is a major health problem that 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' project. However, those who participated in CMS' study had the benefit of participation in a national standardized measurement system. The 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, and 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 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 *must* affect the M+C Organization's Medicare enrollees;
- Indicator *must* be measurable; and
- Indicator *must* 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 Quality Improvement Organization (QIO) formerly known as Peer Review Organization (PRO), as they proceed with the conduct of the pneumonia project. Under the PRO Sixth Scope of Work, PROs were required to conduct a pneumonia project using the indicators described above. It is to the mutual advantage of the QIO/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 QIO/PRO, or "CASPRO", and will serve as a resource to other QIO/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 QIO/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 activity, Extra Payment in Recognition of the Costs of Successful Outpatient CHF Care in 2002 and 2003 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’ 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, the M+C Organization should notify their RO representative that it has attained a baseline level greater than 75 percent and intends to use an alternative indicator. If the M+CO desires assistance with the development of its alternative indicator, the M+CO should work with their state QIO. M+C Organizations are encouraged, although not required, to also work with their state QIO.

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

- Indicator affects the M+C Organizations Medicare enrollees;
- Indicator *is* measurable; and
- Indicator reflect*s* 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 QIO in the design and implementation of their QAPI CHF projects. In the event that the M+C Organization chooses not to utilize the QIO, questions regarding design and implementation should be directed to the CMS RO managed care staff.

If the M+C organization works cooperatively with the QIO on quality improvement projects, CMS will pay the QIO 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 QIO.

CMS has developed an optional data collection instrument for use in data abstraction. This includes 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 *are* be available to all M+C Organizations regardless of who performs data abstraction. They will be posted to our Web page at http://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[1] 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[2], 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.

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[3]

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

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. *T*his 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.

A list of organizations that do not have to perform the national project will be posted as an addendum to OPL 2001.133 at the CMS Web site about October 1st of 2002. This

posting will inform the exempt M+COs that they are exempt based on data from HEDIS 2002 (measurement year 2001). A similar posting was made in 2001 for M+COs exempt based on data from HEDIS 2001 (measurement year 2000). The 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 QIO as they seek appropriate interventions to improve mammography rates and reduce burden on providers of services. In addition to QIO 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.[4], [5], [6], [7], [8], [9] Achieving new health care goals will require a national commitment to identify 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 focus 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.[10] [11] [12] 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.

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 that will be supplied by CMS starting in January of 2003 on the Monthly Membership Report. The race and ethnicity data supplied by CMS is collected by SSA at the time of original enrollment in Medicare. Prior to January 2003 M+COs that would like to receive an aggregated report of race and ethnicity data for their Medicare-enrolled population must send a request to Trisha Kurtz at pkurtz@cms.hhs.gov.

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 (CLAS)

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.[13] 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 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.[14]

We also encourage M+C Organizations to work with their local Quality Improvement Organization (QIO) formerly known as 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).
- 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 Center for Beneficiary Choices.

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 its 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 [15]. 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 [16]. Included among the negative effects of language barriers are higher rates of diagnostic testing, omission of vital information, misdiagnoses, inappropriate treatment and misunderstanding [17].

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
- 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; and
- 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; and
- 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); and
- 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 **must** 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 focus 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 of Directors 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 **must** 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 *of Directors* 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 **must** 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 Culturally Linguistic Appropriate Services (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 **must** 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 must show what was in place prior to the quality improvement effort and what is operational at the end of the project.

2004 - Diabetes

Background

Diabetes is a major health problem that 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.

Goal

Improve the health status of Medicare enrollees with diabetes within the Medicare+Choice population through improved monitoring and treatment.

Objectives

1. *Maximize CMS' opportunity to improve the health status of Medicare managed care enrollees.*
2. *Seek consistency with the Quality Improvement Organization's (QIO) quality improvement efforts in diabetes for the Medicare fee-for-service population.*
3. *Reduce the level of burden in terms of cost and effort on M+C organizations and their health care providers.*
4. *Coordinate the project with existing initiatives and programs of public and private organizations.*
5. *Recognize and reward performance of M+COs.*

Overview of Diabetes Project

The CMS-sponsored national project for 1999 focused on diabetes mellitus, using the Diabetes Quality Improvement Project (DQIP) Measures. The CMS-sponsored national project for 2004 will also focus on diabetes mellitus and use the DQIP Measures because further review of the data indicates additional opportunity for improvement. One of the 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).

Selection of diabetes as a topic was based on:

1. *Aligning managed care quality efforts with fee-for-service quality activities in order to improve health care outcomes for beneficiaries;*
2. *Reducing provider burden as it is a "performance expectation" for the National Business Coalition on Health/V-8 for 2002;*

3. *Existence of HEDIS measures;*
4. *Relevance to both Medicare and Medicaid populations; and*
5. *Maximizing Quality Improvement Organization (QIO)/Peer Review Organization (PRO) resources by selecting a M+CO project consistent with current QIO clinical priority areas.*

Performance Indicators for 2004 Diabetes National QAPI Project

The performance measures for the 2004 Diabetes National QAPI Project are based on the Diabetes Quality Improvement Project (DQIP) Measures. The data for the project can be easily obtained and should not place additional burden on health care providers in the accumulation of the information. M+COs will have multiple indicators to choose from for the project while being obligated to report on only one indicator. M+COs may perform the 2004 national QAPI project using HEDIS 2004 (measurement year 2003) for the baseline and by selecting and reporting on one of the DQIP indicators. This gives organizations the opportunity to select from screening measures permitting data collection by the administrative method or from outcome measures requiring medical record review.

M+COs that submitted one, two or three indicators for their 1999 Diabetes National Project may not repeat any of the same indicators for their 2004 Diabetes National Project. However, an exception will be permitted for those M+COs that reported four or more indicators for their 1999 Diabetes National Project. The CMS is permitting this exception because M+COs had the option to submit multiple indicators through HPMS and accreditation organizations may require M+COs to submit multiple indicators for their 1999 Diabetes National QAPI Project. M+COs who submitted four, five or all six HEDIS DQIP indicators for their 1999 Diabetes National QAPI Project will have the flexibility to repeat any/or all of the six indicators for their 2004 Diabetes National QAPI Project. The CMS will not restrict a M+CO from repeating indicators when that M+CO's 1999 National QAPI Project resulted in the M+CO reporting on four, five or all six DQIP indicators.

The Comprehensive Diabetes Care Measures in HEDIS consists of six indicators for which rates must be filed annually by Medicare managed care organizations. Based on HEDIS 2001 (measurement year 2000) mean rates for two of the six indicators exceeded 80 percent. Hemoglobin tested was 83.4 and LDL-C screening was 80.9. With mean rates this high it may be difficult for M+COs to achieve much further improvement and projects pertaining to the other indicators might be more productive. In fact, the National Business Coalition on Health (V8) has eliminated these two indicators from its performance expectation criteria .

For M+COs that prefer to collect data administratively through claims systems rather than through medical record review in order to reduce the need to have contact with provider offices, it is possible to collect information administratively for the process or screening indicators, Eye Exams and Kidney Disease Monitored. The outcome indicators, HbA1C Poorly Controlled and LDL-C Controlled, require medical record review to obtain accurate rates. However, most M+COs use the hybrid methodology, a combination of administrative and medical record review, to collect the data since this generally

improves the rate. By selecting a QAPI project that uses HEDIS reported information, an M+CO would not necessarily have to do additional medical record review. It will be up to the M+CO to determine whether to use the administrative or hybrid method, however, the methodology used for the baseline must be the same methodology used to measure initial and sustained improvement.

Alternative Option

1. M+COs have the option to complete the National Diabetes QAPI Project for 2004 or a local/collaborative marketplace initiative. Parameters for an acceptable collaborative effort require that:
    1. It must be a community-wide initiative in which most or all MCOs participate and be initiated, facilitated, approved or required by a private purchaser group, QIO, state Medicaid Agency or other state government agency;
    2. The topic must be relevant to the Medicare population;
    3. Medicare enrollees must be in the population sample for the project;
    4. The M+CO must report out M+CO specific data, although, Medicare data does not need to be separated from the other purchasers (Medicaid/commercial) unless separation of data is necessary for other reporting purposes such as Medicare HEDIS requirements, and
    5. M+COs must follow QAPI requirements as established earlier in Chapter 5 of the M+C manual (use of baseline, measurement, re-measurement and interventions).
2. The M+CO may also address clinical health care disparities (CHCD) in their diabetic population. Following the CHCD guidance given in the 2003 National project, the M+CO may opt to study any one of the previously listed minority groups as a subset of their general population. The HEDIS DQIP measures must be used as defined by this 2004 Diabetes project. 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.

Rewarding Performance

Similar to the approach used for the National M+CO Breast Cancer Screening QAPI in 2002, high performing M+COs will be exempt from the National QAPI Project. The mechanism for accomplishing this is different since multiple indicators are involved.

M+COs will be exempted from the 2004 National Diabetes QAPI Project based on rates filed for HEDIS 2003 (measurement year 2002) or HEDIS 2004 (measurement year 2003). The exemption would apply for those M+COs that meet or exceed the 75th percentile average of all four rates. The four rates are: HbA1C Poorly Controlled, LDL-C Controlled, Eye Exam, and Kidney Disease Monitored. It should be noted that the rate for HbA1C Poorly Controlled would be reversed scored so that the 75th percentile will reflect the rate of proper HbA1C control and will be comparable in the same direction as the other three rates.

Appendix B - M+C Quality Glossary

(Rev. 13, 09-11-02)

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' 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 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' 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 organization 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®)

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)(3).

MCO

Managed care organization. The organization may or may not be a Medicare + Choice organization.

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 M+C organization's enrollees. See 42 CFR 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 42 CFR 422.4 (a)(1)(iv).

Quality

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

Quality Improvement Organization (QIO)

CMS contracts with a QIO, formerly known as Peer Review Organization, in each state to fulfill provisions in Title XI of the Social Security Act as amended by the Peer Review Improvement Act of 1982. These provisions relate to improving the quality of care for Medicare beneficiaries, protecting the integrity of the Medicare Trust Fund by ensuring that payments for services are reasonable and medically necessary and protecting beneficiaries by addressing care related complaints and other beneficiary issues.

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.

Endnotes - Click on the number to return to the originating text:

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

[2] See footnote 1.

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

[4] 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.

[5] 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.

[6] 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.

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

[8] 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.

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

[10] 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.

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

[12] Breast Cancer Screening OPL.

[13] 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 http://www.hhs.gov/ocr/lep.

[14] CMS has a contract with Kaiser Mid-Atlantic that serves several states and the District of Columbia.

[15] 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

[16] 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

[17] 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

[18] 1818 David, R.A., and Rhee, M. 1998. The Impact of Language as a Barrier to Effective Health Care in an Underserved Urban Hispanic Community. “Mount Sinai Journal of Medicine 65”. (5,6): 393-397

Appendix C - Attributes of Projects

This section, "Attributes of Projects," applies to all QAPI projects. The CMS considers these attributes in the development of the CMS National projects. However, this section is especially relevant to any project, such as the local marketplace initiative and pre-existing project that is developed by the M+C organization to fulfill the QAPI project requirements for CMS.

1. Selection of Topics

Topics are identified through continuous data collection and analysis of comprehensive aspects of patient care and member services by the organization. Topics are systematically selected and prioritized to achieve the greatest practical benefit for enrollees. 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.

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. The organization's affiliated providers and enrollees must have opportunities to participate in the selection and prioritization of QAPI projects.

2. Prioritization of 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.

3. Focus Areas

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

Clinical Focus Areas:

- Primary, secondary, and/or tertiary prevention of acute conditions;
- Primary, secondary, and/or tertiary prevention of chronic conditions;
- Care of acute conditions;
- Care of chronic conditions;
- High-volume services;
- High-risk services; and
- Continuity and coordination of care.

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, and 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.

Non-Clinical Focus Areas:

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

QAPI projects 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, 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 by the organization.

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

For detailed guidance regarding definition and implementation of cultural competency requirements, see Appendix A, "National QAPI Project Operational Letters."

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

NOTE: In early 2001, the focus area, "interpersonal aspects of care," was eliminated.

4. Quality Indicators

Assessment of the M+C organization's performance for each selected topic is measured using one or more quality indicators. 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. 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.

All clinical indicators measure changes in health status, functional status, or enrollee satisfaction, or are 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. 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 must 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. While organizations are encouraged to consider enrollee satisfaction as an important aspect of care in any of the clinical areas, 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.

5. Interventions

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

6. Data Collection and Methodology

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

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. Please refer to the Health Information section (20.2) of this chapter.

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 multiple subcontractors collect data. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

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 .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.

7. Sampling

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

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

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:

- The performance of all practitioners and providers who serve Medicare enrollees and whose activities are the subject of the indicator: 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.

- 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.

- 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.

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.